ADDITIONAL OHCA CRITERIA FOR ALL OVERRIDE REQUESTS

Additional OHCA criteria for all override requests

Override Reason	Edit/Override Code	MMIS Edit Description	Form	Additional notes/criteria/restrictions
Brand	3004	BRAND NAME NDC REQUIRES PA	Pharm-11	Reviewed for clinical appropriateness based on information submitted & claims history
Compound	4349	PRICE LIMIT EXCEEDED FOR COMPOUND CLAIMS	Pharm-4	No specific form; reviewed for clinical appropriateness based on information submitted & claims history
Dosage Change	5109/5113	PRESCRIPTION REFILLED TOO SOON/CONTROLLED RX REFILLED TOO SOON	Pharm-12	Reviewed for clinical appropriateness based on information submitted & claims history
High Dose	7000	CLAIM FAILED A PRODUR ALERT	Pharm-13	Pharm-13 is generated by the help desk and is not currently available online; reviewed for clinical appropriateness based on information submitted & claims history
Ingredient Duplication	7000	CLAIM FAILED A PRODUR ALERT	Pharm-25	Form is typically generated by the help desk; APAP ingredient duplication; reviewed for clinical appropriateness based on information submitted & claims history
Lost/Broken Rx	5109/5113	PRESCRIPTION REFILLED TOO SOON/CONTROLLED RX REFILLED TOO SOON	Pharm-12	Form is typically generated by the help desk; approval is granted once every 12 months for lost/broken/stolen meds and is not considered for controlled meds without a police/fire report; reviewed for clinical appropriateness based on information submitted, claims history, & approval history for same override reason
MAT Override	5114/4023/7027	RECENT OPIOID RX, CONCURRENT USE NOT ALLOWED/NDC VS SEX RESTRICTION/DRUG QUANTITY PER DAY LIMIT HAS BEEN EXCEEDED	Pharm-4 or Pharm-13	MAT Override is selcted for any MAT med needing an override; no specific form; Pharm-13 is generated by the help desk and is not currently available online; reviewed for clinical appropriateness based on information submitted & claims history

NDC vs Age	4025	NDC VS AGE RESTRICTION	Pharm-4	No specific form; reviewed for clinical appropriateness based on information submitted & claims history
NDC vs Sex	4023	NDC VS SEX RESTRICTION	Pharm-4	No specific form; reviewed for clinical appropriateness based on information submitted & claims history
Nursing Home Issue	5109	PRESCRIPTION REFILLED TOO SOON	Pharm-12	Form is typically generated by the help desk; most "nursing home issues" are for 5109 (early refill) when the member is being admitted to a LTC facility.
Opioid MME Limit	5112	CUMULATIVE MME PER DAY LIMIT EXCEEDED	Pharm-111	Reviewed for clinical appropriateness based on information submitted & claims history
Opioid Quantity	4334/7027	ACUTE VS CHRONIC NARCOTIC QUANTITY LIMIT/DRUG QUANTITY PER DAY LIMIT HAS BEEN EXCEEDED	Pharm-32 or Pharm-13	Pharm-32 and Pharm-13 are generated by the help desk and are not currently available online; only approved for >4/day for oncology, hemophilia, or sickle cell dx or due to shortage of other strengths; reviewed for clinical appropriateness based on information submitted & claims history
Other	various	various	Pharm-4, various	"Other" is only selected as the reason if nothing else applies; an example is 5109 (early refill) when the member needs a 2nd albuterol inhaler to leave at school.
Quantity vs Days Supply	4026/7027	NDC VS DAYS SUPPLY/DRUG QUANTITY PER DAY LIMIT HAS BEEN EXCEEDED	Pharm-13	Pharm-13 is generated by the help desk and is not currently available online; reviewed for clinical appropriateness based on information submitted & claims history

STBS/STBSM	2048/4002	ALIEN RECIPIENT ON REVIEW/NDC INDICATES A NON-COVERED DRUG ON DOS	Pharm-4, various	No specific form; reviewed for clinical appropriateness based on information submitted & claims history
Step Therapy Exception	N/A	N/A	Pharm-136	No specific edits associated but has different approval/denial codes (780/781) for tracking; reviewed for clinical appropriateness based on information submitted & claims history; samples are not considered
Stolen	5109/5113	PRESCRIPTION REFILLED TOO SOON/CONTROLLED RX REFILLED TOO SOON	Pharm-12	Form is typically generated by the help desk; Approval is granted once every 12 months for lost/broken/stolen meds and is not considered for controlled meds without a police/fire report
Third Brand Request	6601	TWO BRAND NAME DRUG LIMIT REACHED	Pharm-48	Pharm-48 is generated by the help desk and is not currently available online; approval may be granted for one additional brand per month; reviewed for clinical appropriateness based on information submitted & claims history

Brand Required Drug List:

- In general, OK requires PA for any brand name drug for which there is a US FDA A-rater generic equivalent. There are some products however, for which OK has determined greater cost-effectiveness in the use of the brand name product
- In scenarios where a POS rejection is occurring for the generic of a Brand Required Product, the expectation is that the claim be re-processed for the brand name.
    - These rejections will trigger a R75/PA Required
- If providers submit a PA request for the generic of a Brand Required product and:
    - *Does NOT* indicate brand substitution to be inappropriate, the provider/pharmacy should be redirected to the covered brand name.
    - *Does* indicate brand substation to be inappropriate,
        - If specific criteria *is* available for that product, the UM review should be based on that.
        - If specific criteria *is not* available for that product, the UM review should be based on a patient-specific, clinically significant reason why the member cannot use brand name.

EPSDT Review Clarification:

- NDCs flagged as requiring EPSDT review can *only* be reviewed with the EPSDT criteria.
    - And only for members <20 years.
- If these NDCs are not approvable under EPSDT, they are not approvable at all.
- There are no exceptions for coverage for members >20 years.

3rd Brand Name Request Overrides:

- *Pending creation of new OK policy*
- *Principles of step-therapy should be applied. Approval requires evidence of trial/failure of all appropriate generic (or brand-required) alternatives listed in the appropriate therapeutic class per the OHCA PA Criteria website.*
- *Requests for more than 3 brand name products will not be approved.*

Duplicate Therapy Overrides: *Refer to **OK.CP.PMN.04** Duplicate Therapy posted 01/2025*

Split Fill Policy Overrides: *Refer to **CC.PHAR.24** located in Archer*

UM REVIEW GUIDE: INTERIM CRITERIA & ADDITIONAL INTERNAL NOTES

Posted criteria on the OHCA website is always considered the primary source of information. This document contains language authored by OHCA for **a)** interim criteria not yet posted to their website (*italicized*) and **b)** additional comments for consideration toward PA approval in what might otherwise have been denied. All **blue** headers are linked to corresponding OHCA sub-page. Requests for edits/updates should be submitted via Operations Excellence.

ANTI-INFECTIVES

- **SYSTEMATIC ANTIBIOTICS**
  - **ZEVTERA**
    - **Interim Criteria (*if applicable*):**
    - *Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:*

1. *An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and*
2. *Member must be 18 years of age or older; and*
3. *A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and*
4. *Approval quantity will be based on package labeling and FDA approved dosing regimen(s).*

    - *Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:*

1. *An FDA approved diagnosis of CABP caused by designated susceptible microorganisms (culture/ sensitivity results must be submitted); and*
2. *Member must be 3 months of age or older; and*
3. *A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and*
4. *For members who require weight-based dosing, the member's recent weight, taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling; and*
5. *Approval quantity will be based on package labeling and FDA approved dosing regimen(s).*

    - *Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Staphylococcus aureus Bloodstream Infection (Bacteremia) (SAB) Diagnosis]:*

1. *An FDA approved diagnosis of SAB caused by designated susceptible microorganisms (culture/ sensitivity results must be submitted); and*
2. *Member must be 18 years of age or older; and*

3. *For methicillin-resistant Staphylococcus aureus (MRSA), a patient-specific, clinically significant reason why the member cannot use vancomycin or other cost-effective therapeutic equivalent alternative(s) must be provided; and*
4. *For methicillin-susceptible Staphylococcus aureus (MSSA), a patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., nafcillin, oxacillin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and*
5. *Approval quantity will be based on package labeling and FDA approved dosing regimen(s).*

- **BLUJEPA**
  - **Interim Criteria (*if applicable*):**
  - *Blujepa (Gepotidacin) Approval Criteria:*

1. *An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated microorganisms (culture/sensitivity results must be submitted); and*
2. *Member must be a female 12 years of age or older and weigh ≥40kg; and*
3. *Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m2) and must not be on dialysis; and*
4. *Member must not have severe hepatic impairment (Child Pugh C); and*
5. *Prior to and during treatment, the potential for drug interactions should be evaluated, including:*
    - *Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and*
    - *Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and*
    - *Monitor digoxin serum concentrations as clinically indicated; and*
    - *Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and*
6. *Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and*
7. *If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and duration treatment, as clinically indicated; and*
8. *A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and*
9. *A quantity limit of 20 tablets per 5 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- **EMBLAVEO**
  - **Interim Criteria (*if applicable*):**
  - *Emblaveo™ (Aztreonam/Avibactam) Approval Criteria:*

1. *An FDA approved diagnosis of complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms (e.g., Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex, Serratia marcescens) in adults who have limited or no alternative treatment options (culture/sensitivity results must be submitted); and*
2. *Member must 18 years of age or older; and*
3. *Must be used in combination with metronidazole; and*
4. *A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, a fluoroquinolone (e.g., ciprofloxacin, levofloxacin) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s); and*
5. *A quantity limit of 57 vials per 14 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **CEDAX, SUPRAX**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Cefixime for Otitis Media: OHCA and PMC have received calls from prescribers regarding cefixime for otitis media. The prescribers are following guidelines and described their current treatment regimen as 1st line Amoxicillin, then, if necessary, Augmentin, and then, if necessary, ceftriaxone or cefdinir. However, ceftriaxone may not be feasible as it is IM daily x 3 days and cefdinir has high failure rates. Cefixime is a reasonable next step if a patient has tried multiple GDMT, Cefixime may be the more cost-effective step in lieu of referrals to ENTs. Culture and sensitivity results should be requested if available (ear infections are typically treated empirically and not always cultured).
  - Irinotecan-induced diarrhea: Cefixime should be approved for prevention/treatment of diarrhea due to irinotecan. It should be approved for the duration of irinotecan treatment.
  - Gonococcal infections:
    - First line: ceftriaxone 500mg IM x1 plus doxycycline 100mg PO BID x 7 days (if chlamydia cannot be ruled out). Ceftriaxone dose should be increased to 1 gram if weight is ≥150kg.
    - Second line: cefixime 800mg (400mg CAP x 2) PO x 1 dose. Should only be used if ceftriaxone unavailable. This regimen has limited efficacy for pharyngeal gonorrhea.
  - Azithromycin 2 grams PO X 1 plus gentamicin 240mg IM x 1 is another alt. regimen for patients with cephalosporin allergy.

- Recent sex partners (i.e., persons having sexual contact with the infected patient <60 days preceding onset of symptoms or gonorrhea diagnosis) should be referred for evaluation, testing, and presumptive treatment. If the patient's last potential sexual exposure was >60 days before onset of symptoms or diagnosis, the most recent sex partner should be treated. If an obstetrician–gynecologist or other health care provider cannot ensure that an infected patient's partner will be promptly linked to care, and where legally accepted, expedited partner therapy with cefixime 800mg PO X 1 and doxycycline 100mg PO BID x 7 days should be delivered to the partner by the patient, a disease investigation specialist, or through a collaborating pharmacy.

- **ORLYNVAH**
  - **Interim Criteria (*if applicable*):**
  - *Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Approval Criteria:*

1. *An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, and Proteus mirabilis in adults who have limited or no alternative treatment options (culture/sensitivity results must be submitted); and*
    - *Must not be used for the treatment of complicated urinary tract infections (cUTI) or complicated intraabdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cUTI or cIAI; and*
2. *Member must be a female 18 years of age or older; and*
3. *Member must not have any contraindications to use of Orlynvah™, including:*
    - *Serious hypersensitivity reactions (e.g., anaphylaxis, Stevens-Johnson syndrome) to Orlynvah™ or to other beta-lactam antibacterial drugs (e.g., penicillins, cephalosporins, carbapenems); and*
    - *Known blood dyscrasias; and*
    - *Known uric acid kidney stones; and*
    - *Concurrent treatment with ketorolac tromethamine; and*
4. *Provider must verify the member does not have a creatinine clearance (CrCL) <15mL/min and is not on hemodialysis; and*
5. *A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and*
6. *A quantity limit of 10 tablets per 5 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Orlynvah™ (sulopenem etzadroxil/probenecid) is a combination of sulopenem etzadroxil, a penem antibacterial, and probenecid, a renal tubular transport inhibitor, indicated for the treatment of uncomplicated urinary tract infections (uUTIs) caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, and Proteus mirabilis, in adult female patients who have limited or no alternative oral antibacterial treatment options.
  - Limitations of Use: Orlynvah is not indicated for the treatment of:

- Complicated urinary tract infections (cUTI) or as a step-down treatment after intravenous (IV) antibacterial treatment of cUTI
- Complicated intra-abdominal infections (cIAI) or as a step-down treatment after IV antibacterial treatment of cIAI
- How Supplied: Tablet containing 500mg sulopenem etzadroxil and 500mg probenecid
- Dosing: 1 tablet orally with food twice daily for 5 days
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213972s000lbl.pdf
- Coverage: Orlynvah™ will be covered with a hard PA with the criteria listed below.
- Quantity Limit: 10 tablets per 5 days

- **PIVYA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Although recommended as a first-line option empirically, fosfomycin may not be a reasonable alternative choice in all uUTIs. The 2024 IDSA Guidance on the Treatment of Antimicrobial Resistant Gram-negative Infections states that Fosfomycin is not suggested to treat uUTI caused by Klebsiella pneumoniae and other gram-negative organisms as clinical failure is possible; however, fosfomycin is efficacious against E. coli, including ESBL-producing strains. The last guideline update for uUTI was 2010; updates to the IDSA guidelines are in progress so it is uncertain if empiric recommendations will be changing soon. Fosfomycin only has FDA breakpoints for E. coli and E. faecalis, so susceptibilities for every organism considered a designated susceptible organism will not be available.
- **TETRACYCLINE**
  - **Interim Criteria (if applicable):**

Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria:

~~*1. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).*~~

2. *For the capsule formulation, a quantity of 56 capsules for 14 days is available without a prior authorization for a diagnosis of Helicobacter pylori (H. pylori) infection; or*
3. *For the tablet formulation, approval also requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation, which is available without prior authorization; and*
4. *A quantity limit of 56 capsules or tablets per 14 days will apply; and*
    - *A quantity limit override for longer durations of therapy for indications other than for the eradication of H. pylori infection will require a patient specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).*

- **Additional Internal Notes (*for consideration toward approval*):**
- Please consider approving tetracycline caps for H. pylori if the member requires a tetracycline regimen vs. other regimens (is more cost effective to approve tetracycline separately than approving an H. pylori convenience pack).
- Tetracycline 250mg and 500mg Capsules and Tablets are a component of bismuth quadruple therapy (BQT) for the eradication of Helicobacter pylori (H. pylori), along with a bismuth salt (e.g., bismuth subcitrate or subsalicylate), a nitroimidazole (e.g., metronidazole), and a proton pump inhibitor (PPI). Due to increasing antibiotic resistance to clarithromycin in North America, the American College of Gastroenterology (ACG) now recommends BQT as first-line. Regimens containing clarithromycin or levofloxacin are not recommended for use without evidence of macrolide and quinolone susceptibility, according to the 2024 updated ACG recommendations. Based on the new guideline recommendations and a re-evaluation of net costs, the PA for the tetracycline capsules will be removed and a quantity limit will be imposed on both the capsules and the tablets to reduce alternative uses over longer durations (i.e., acne) for which other therapies such as doxycycline or minocycline would be more cost-effective. Due to higher net costs, tetracycline tablets will continue to require prior authorization.
- The #56 per 14 days quantity limit will also apply to the capsule formulation, even though it is available without prior authorization in order to limit its use for indications other than eradiation of H. pylori infection. Overrides of the quantity limit will require a reason why more cost-effective therapeutic alternatives cannot be used (e.g., doxycycline, minocycline capsules).

- **VABOMERE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - If patient started therapy inpatient, please consider these requests for approval if appropriate diagnosis as may not be appropriate for patient to change therapy.
  - Max 14 days of total treatment (Internal Comments: According to prescribing information, total duration of treatment is up to 14 days. Patients may have received doses in hospital, therefore may need to verify total length of treatment remaining.)
  - 84 vials per 14 days [Dose is dependent on renal function, please refer to prescribing information to verify dose (and appropriate number of vials to approve) if member has renal impairment.]
- **XACDURO**
  - **Interim Criteria (*if applicable*):**
  - *Xacduro® (Sulbactam/Durlobactam) Approval Criteria:*

1. *An FDA approved diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex (culture/sensitivity results must be submitted); and*
2. *Member must be 18 years of age or older; and*

3. *A patient-specific, clinically significant reason why the member cannot use a carbapenem, ampicillin/sulbactam, polymyxin B, or other cost effective therapeutic equivalent alternative(s) must be provided; or*
    - *A clinical exception will apply for infections caused by carbapenem-resistant Acinetobacter baumannii (CRAB), in which case Xacduro® will be approved; and*
4. *The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and*
5. *Approval quantity will be based on Xacduro® package labeling and FDA approved dosing regimen(s).*

- **ARIKAYCE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Recommended treatment for MAC consists of a 3-drug regimen of a macrolide (e.g., azithromycin), a rifamycin (e.g., rifampin), and ethambutol for a minimum of 12 months; the addition of an injectable aminoglycoside may also be considered. Initial: 6 months 580mg/8.4mL vial per day

- **<u>ANTIVIRAL AGENTS</u>**
    - **LIVTENCITY**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Please consider subsequent approvals after the 8-week approval depending on the provided information. Similar to Prevymis, there may be situations when the member may need to continue CMV prophylaxis (see Prevymis internal comment for examples). Consider subsequent approvals of 4 weeks at a time if appropriate.
    - **PREVYMIS**
        - **Interim Criteria (*if applicable*):**
        - ***Prevymis® (Letermovir Tablets, Oral Pellets, and Injection) Approval Criteria [Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:***

1. *An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogenic HSCT; and*
2. *Member must be 6 months of age or older and weigh at least 6kg; and*
3. *Member must be CMV R+; and*
4. *Member must have received a HSCT within the last 28 days; and*
    - *If the member was previously started on Prevymis®, the date of the first dose must be provided; and*
5. *Members taking concomitant cyclosporine will only be approved for the 240mg dose; and*
6. *Members must not be taking the following medications:*
    - *Pimozide; or*
    - *Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or*
    - *Rifampin; or*

- *Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and*

7. *For Prevymis® oral pellets, an age restriction will apply. The oral pellet formulation may be approvable for members 6 years of age and younger. Members 7 years and older must have a patient-specific, clinically significant reason why the member cannot use the Prevymis® tablet formulation; and*
8. *Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist; and*
9. *Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and*
10. *Approvals will be for the duration of 100 days post-transplant.*
    - *For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and*
    - *Approval length for vial formulation will be based on duration of need; and*
    - *Approvals may be extended to 200 days post-transplant if the member is at risk for developing a late CMV infection (the member's risk factors must be provided); and*

- *The following quantity limits will apply:*
    - *Tablets and vials for IV injection: 1 tablet or vial per day; or*
    - *Oral pellets:*
        - *20mg: 4 packets per day; or*
        - *120mg: 2 packets per day; and*
        - *For requests exceeding the quantity limit, additional information about why the member cannot use the oral tablet must be provided.*
- ***Prevymis® (Letermovir Tablets, Oral Pellets, and Injection) Approval Criteria [Kidney Transplant Diagnosis]:***

1. *An FDA approved indication of prophylaxis of cytomegalovirus (CMV) disease in kidney transplant recipients; and*
2. *Member must be 12 years of age or older and weigh at least 40kg; and*
3. *Member must be at high risk [i.e., donor CMV seropositive/recipient CMV seronegative (D+/R-)]; and*
4. *Member must have received a kidney transplant within the last 7 days; and*
    - *If the member was previously started on Prevymis®, the date of the first dose must be provided; and*
5. *Members taking concomitant cyclosporine will only be approved for the 240mg dose; and*
6. *Members must not be taking the following medications:*
    - *Pimozide; or*
    - *Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or*

- *Rifampin; or*
- *Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and*

7. *For Prevymis® oral pellets, the member must have a patient-specific, clinically significant reason why the member cannot use the Prevymis® tablet formulation; and*
8. *Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and*
9. *Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and*
10. *Approvals will be for the duration of 200 days post-transplant*.
    - *For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and*
    - *Approval length for vial formulation will be based on duration of need*.

- *The following quantity limits will apply:*
    - *Tablets and vials for IV injection: 1 tablet or vial per day; or*
    - *Oral pellets:*
        - *20mg: 4 packets per day; or*
        - *120mg: 2 packets per day; and*
        - *For requests exceeding the quantity limit, additional information about why the member cannot use the oral tablet must be provided*.
- **Additional Internal Notes (*for consideration toward approval*):**
- Some clinical situations where extended primary prophylaxis (through 200 days post-transplant) is likely appropriate:
    - Diagnosis of graft versus host disease (GVHD) that is not quiescent (e.g., active GVHD that is requiring treatment). Acute GVHD is riskier than chronic GVHD.
    - Treatment of acute GVHD with 1mg/kg of systemic prednisone (or equivalent) per day.
    - Treatment of acute GVHD with ≥2 immunosuppressants (e.g., tacrolimus, high-dose corticosteroids, ibrutinib, ruxolitinib, belumosudil).
    - Previous use of post-transplant cyclophosphamide as part of GVHD prophylaxis in the allogeneic stem cell transplant preparative regimen.
    - Member has a related donor with at least 1 mismatch at 1 of the specified 3 human leukocyte antigen (HLA) gene loci (HLA-A, B, or DR)
    - Member has an unrelated donor with at least 1 mismatch at 1 of the specified 4 HLA gene loci (HLA-A, B, C, and DRB1)
    - Member has a haploidentical donor
    - Umbilical cord blood as the stem-cell source was used

        - Member had ex-vivo T-cell-depleted grafts
    - Prevymis is now FDA approved for prophylaxis of CMV disease in kidney transplant recipients (approval criteria was added at DUR in February 2024). Prevymis may be appropriate for other solid-organ transplant recipients, so please use your clinical judgment and approve if clinically appropriate (use criteria/approval length for the kidney indication). We have received recent requests for use post-liver transplant in patients who have started on Valcyte but have not been able to tolerate it due to persistent/progressive leukopenia. In general, post-liver transplant patients should use Valcyte, unless they are unable to tolerate or have a reason why it is not appropriate. Please note, these requests may be appropriate even though the member is not starting Prevymis within 7 days of transplant (since they were first started on Valcyte).
    - Prevymis® (letermovir) criteria is being updated to address if the member was started on Prevymis® prior to the first request received and ensure it was started within the appropriate timeframe.

- **<u>ANTIPARASITIC AGENTS</u>**
    - **ALBENZA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Please note: There are several off-label indications for Albenza. Please refer to compendia for appropriate dosing and acceptable off label uses and approval length should be based on diagnosis.
    - **BENZIDAZOLE**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - May consider approval for members over 12 years of age with supporting clinical information and the following:
        - All cases of acute infection (including congenital) or reactivated infection
        - Children 18 years or younger with chronic Trypanosoma cruzi infection
        - Adults 19 to 50 years of age without advanced Chagas cardiomyopathy
        - Previously untreated T. cruzi–infected patients awaiting organ transplantation
        - Patients coinfected with human immunodeficiency virus (HIV)
        - Women of reproductive age to reduce the probability of congenital transmission (not currently pregnant or breastfeeding)
        - Approval Length: 60 days
    - **DARAPRIM**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Daraprim® is recommended for use in preventing Toxoplasmosis (or PCP) if the member is Toxoplasma IgG positive and has a CD4 <100 cells/mm3. The preferred treatment is TMP-SMX 1 DS tablet PO daily. Daraprim is recommended as an alternative regimen (Dapsone + Pyrimethamine 50mg weekly + leucovorin weekly) if the member cannot take the TMP-SMX (allergic to medication).

Members must take the regimen until their CD4 count is >200 cells/mm3 for >3months.

- **EMVERM**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Treatment with Albenza (albendazole) is not recommended during pregnancy. Mebendazole is also not recommended during pregnancy. The risks of therapy to pregnant women must be weighed against the risks of delaying treatment (dependent on type of infection). CDC.gov and uptodate.com have useful resources for recommended treatment options for each of the worms, including treatment options during pregnancy. Please refer to these resources to verify appropriate anthelmintic therapy depending on type of worm.
  - Please note: the CDC no longer lists pyrantel pamoate as recommended treatment option for roundworm. This can be removed from message if member has this specific worm.
  - Approval length based on indication.
  - Quantity Limit based on indication:
    - Enterobius vermicularis (pinworm): 2 tablets per approval
    - Trichuris trichiura (whipworm): 6 tablets per approval
    - Ascaris lumbricoides (common roundworm): 6 tablets per approval
    - Ancylostoma duodenale (common hookworm): 6 tablets per approval
    - Necator americanus (American hookworm): 6 tablets per approval
- **IMPAVIDO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Impavido is FDA approved for cutaneous, mucosal, and visceral leishmaniasis; however, it is not currently covered by SoonerCare due to no current federal drug rebate agreement (FDRA). The manufacturer ended their FDRA in 2018. Members needing Impavido will need to go through the manufacturer's patient assistance program (PAP) and fill out the online form at: https://www.impavido.com/order-page or call 908-635-2326 for immediate assistance.

- **COVID-19 RELATED PRODUCTS**
  - **COVID-19 TESTS**
    - SoonerCare covers at home COVID tests. The tests that do not need to be sent in to a lab are covered without a PA and have a cost of around $10 per test. The link to the fax blast we sent out in December: https://oklahoma.gov/content/dam/ok/en/okhca/docs/providers/types/pharmacy/policy/COVID%20Test%20Fax%20Bla st-final.pdf
    - The expensive OTC tests (Ellum and Lucira) are covered with a PA as well as the tests that require point of care collection or lab/not in home patient ran/read tests.
    - PA criteria for OTC COVID-19 tests other than PCR tests:

        - Proof (screenshots) all non-PA'd NDCs are not available through 2 wholesalers
    - PA criteria for OTC COVID-19 PCR tests:
        - A clinical reason a PCR test is needed over antigen tests which includes but is not limited to required for travel, required confirmatory test after positive antigen test, etc.
- **IVERMECTIN**
    - Approval criteria = an FDA approved indication. Ivermectin has not been approved by the FDA for the prevention or treatment of Covid-19, and both the FDA and CDC have recently released health advisories discouraging the use of ivermectin for Covid-19.
- **LAGEVRIO**
    - Lagevrio was authorized for use under an Emergency Use Authorization (EUA) for the treatment of adults with mild-to-moderate Covid-19 who are at high risk for progression to severe Covid-19 including hospitalization or death or for whom alternative Covid-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. Lagevrio is not covered by SoonerCare, so all NDCs are inactive. Members needing Lagevrio will need to go through Merck's patient assistance program (PAP).
    - PAP hotline number: 800-727-5400 (providers can call to ask questions/have the enrollment forms/attestation form faxed)
    - The PAP is available to all people (whether they have Medicaid/other insurance or not). There is an application and an attestation the provider will have to fill out and fax to Merck for them to approve/deny. The application (filled out/signed by the provider) is considered the prescription so a separate prescription is not needed. The attestation is for those to fill out who have insurance (so our members will need to fill it out). Additionally, approval/denial is based on income limits:
        - 1 person household: $58,320 or less
        - Each additional person: add $20,560
        - Ex: 2 person household: $78,880 or less
    - Per Merck, the provider will fill out the form for Lagevrio in office, fax to the number on the form (915- 849-1037), and in about 20-30 minutes after the form is received, the provider will know if the patient is approved. If the patient is approved, Merck will "donate" the product and ship it directly to the patient.

BIOLOGICS

- **SYLVANT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Sylvant may increase hemoglobin levels in MCD patients
    - We are not suggesting the patient be forced to try other therapies. It appears all other treatments are based on anecdotal evidence and one patient case studies. Even these are few and far between.

- **<u>THROMBOCYTOPENIA AGENTS</u>**
  - **WAYRILZ**
    - **Interim Criteria (*if applicable*):**
    - *Wayrilz™ (Rilzabrutinib) Approval Criteria:*

1. *An FDA approved diagnosis of persistent or chronic immune thrombocytopenia (ITP); and*
2. *Member must be 18 years of age or older; and*
3. *Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and*
4. *Previous insufficient response to at least 2 of the following treatments:*
    - *Corticosteroids; or*
    - *Immunoglobulins; or*
    - *Splenectomy; or*
    - *Thrombopoietin receptor agonists; or*
    - *Fostamatinib; or*
    - *Rituximab; and*
5. *Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and*
6. *Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Wayrilz™ and during treatment as clinically indicated; and*
7. *Prescriber must verify that the member will be monitored for signs and symptoms of infection while on Wayrilz™; and*
8. *Member must not be taking any of the following medications concomitantly with Wayrilz™:*
    - *Moderate to strong CYP3A inhibitors (e.g., itraconazole, clarithromycin); and*
    - *Moderate to strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin); and*
    - *Proton pump inhibitors; and*
9. *Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 1 week after the last dose; and*
10. *Female members must not be breastfeeding during treatment and for at least 1 week after discontinuation of treatment; and*
11. *A quantity limit of 60 tablets per 30 days will apply.*

    - **Additional Internal Notes (*for consideration toward approval*):**
  - **ADZYNMA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - iTTP and cTTP can present very similarly as both will show a potential ADAMTS13 activity level <10% but the main difference is that iTTP is caused by autoantibodies inhibiting the ADAMTS13 activity and cTTP is caused by biallelic pathogenic variants in the ADAMTS13 gene. Treatment is recommended to be initiated as soon as possible if TTP is suspected due to the life-threatening nature of the diagnosis.

Genetic testing for cTTP can take anywhere from weeks to months to be returned and providers may start treatment inpatient prior to genetic testing results being available just based on the ADAMTS13 activity levels and the absence of autoantibodies. Please consider a short-term approval even if they do not have the genetic testing available if they state the member has an ADAMTS13 activity level <10% and absence of autoantibodies and they were already started on treatment with Adzynma. We will need to ask them to submit the genetic testing when they have it so that we know cTTP has been confirmed as Adzynma is not FDA approved for iTTP at this time, and we are only covering it for the FDA approved indication of cTTP.

- **CABLIVI**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - They will likely start this inpatient and then we can approve for those who need to continue it outpatient. Please be careful if they say they are going to follow up with a hematologist in the future that should count as being prescribed in consultation with a hematologist
- **DOPTELET**
  - **Interim Criteria (*if applicable*):**
  - *Doptelet® (Avatrombopag) and Doptelet® Sprinkle (Avatrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:*

1. *An FDA approved indication for the treatment of 1 of the following:*
   - *Thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; or*
   - *Thrombocytopenia in pediatric patients 1 year of age and older with persistent or chronic ITP who have had an insufficient response to a previous treatment; and*
2. *Member must be 1 years of age or older; and*
3. *Previous insufficient response with at least 1 of the following treatments:*
   - *Corticosteroids; or*
   - *Immunoglobulins; or*
   - *Splenectomy; and*
4. *A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and*
5. *Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and*
6. *Prescriber must verify platelet counts will be assessed as per package labeling:*
   - *Initiation of treatment: Weekly until a stable platelet count ≥50 x 10^9/L has been achieved, and then obtained monthly thereafter; and*
   - *Change in formulation: Weekly until a stable platelet count and dose will be adjusted as needed before resuming monthly monitoring; and*
   - *Discontinuation: Weekly for 4 weeks following discontinuation; and*
7. *Must be prescribed by, or in consultation with, a hematologist or oncologist; and*

8. *Doptelet® must not be used in an attempt to normalize platelet counts; and*
9. *Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and*
10. *Prescriber must verify member is not breastfeeding; and*
11. *An age restriction will apply for Doptelet® Sprinkle. The sprinkle capsule formulation may be approvable for members 1 to 5 years of age. Members 6 years of age and older must use the tablet formulation; and*
12. *For Doptelet® Sprinkle, prescriber must verify that the member and/or caregiver has been counseled on the proper preparation and administration of Doptelet® Sprinkle; and*
13. *A quantity limit of 60 tablets or sprinkle capsules per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- If platelet count <40mg X 10^9/L: 60mg (3 tablets) once daily for 5 days If platelet count 40 to <50mg X 10^9/L: 40mg (2 tablets) once daily for 5 days
- Thrombopoietin receptor agonists (TPO-RAs) available without a PA:
    - Romiplostim (Nplate) is administered as a once-weekly subcutaneous injection
    - Eltrombopag (Promacta) is given as a once-daily pill

- **MYHIBBIN**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Generic Cellcept suspension can be found under GCN 47563. Myhibbin is a "ready to use" suspension that doesn't need to be reconstituted and is more expensive than generic Cellcept oral suspension.
- **XGEVA/WYOST/OSENVELT/BOMYNTRA/BILPREVDA – MEDICAL ONLY**
    - **Interim Criteria (*if applicable*):**
    - *Bilprevda® (Denosumab – nxxp), Bomyntra® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), Wyost® (Denosumab-bbdz), and Xgeva® (Denosumab) Approval Criteria:*

1. *An FDA approved indication of 1 of the following:*
    - *Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or*
    - *Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and*
        - *Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or*
    - *Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and*
        - *Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy; and*
2. *For Bilprevda® (denosumab-nxpp), Bomyntra® (denosumab-bnht), Osenvelt® (denosumab-bmwo), and Wyost® (denosumab-bbdz), a patient-specific, clinically*

significant reason why the member cannot use Xgeva® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

- **Additional Internal Notes (*for consideration toward approval*):**
- Medical billing only
- Contraindicated in patients with clinically significant hypersensitivity to any component of the medication. Xgeva can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Osteonecrosis of the jaw (ONJ) and atypical femoral fracture have been reported. Xgeva can cause fetal harm. Females of reproductive potential should use highly effective contraception during therapy, and for at least 5 months after the last dose of Xgeva.

- **ALVAIZ**
  - **Interim Criteria (*if applicable*):**
  - ***Alvaiz™ (Eltrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:***

1. *An FDA approved diagnosis of persistent or chronic ITP; and*
2. *Member must have a platelet count of <30 x 109/L; and*
3. *Member must be 6 years of age or older; and*
4. *Member must not have a recent diagnosis of myelodysplastic syndromes; and*
5. *Previous insufficient response to at least 1 of the following treatments:*
   - *Corticosteroids; or*
   - *Immunoglobulins; or*
   - *Splenectomy; and*
6. *A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and*
7. *Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and*
8. *Member must have an eye exam prior to initiation to assess for cataracts; and*
9. *Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz™; and*
10. *Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and*
11. *Quantity limits will apply based on FDA-approved dosing, up to a maximum of 54mg per day, as follows:*
    - *9mg strength: 30 tablets per 30 days; or*
    - *18mg strength: 90 tablets per 30 days; or*
    - *36mg strength: 30 tablets per 30 days; or*
    - *54mg strength: 30 tablets per 30 days.*

- ***Alvaiz™ (Eltrombopag) Approval Criteria [Chronic Hepatitis C-Associated Thrombocytopenia Diagnosis]:***

1. *Member must have diagnosis of chronic hepatitis C-associated thrombocytopenia; and*
2. *Member must have a platelet count of <75 x 109/L; and*
3. *Member must be 18 years of age or older; and*
4. *Member must not have a recent diagnosis of myelodysplastic syndromes; and*
5. *Member must be initiating interferon-based therapy (regimen must be provided); and*
6. *Member must have a trial of corticosteroids that results in insufficient increase in platelet count; and*
7. *A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and*
8. *Member must have eye exam prior to initiation of Alvaiz™ to assess for cataracts; and*
9. *Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz™ and concomitant hepatitis C therapy; and*
10. *Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of hepatitis C-associated thrombocytopenia; and*
11. *Continuation requests will not be approved once antiviral therapy has been discontinued; and*
12. *Quantity limits will apply based on FDA-approved dosing, as follows:*
    - *9mg strength: 30 tablets per 30 days; or*
    - *18mg strength: 120 tablets per 30 days; or*
    - *36mg strength: 60 tablets per 30 days; or*
    - *54mg strength: 30 tablets per 30 days.*

- ***Alvaiz™ (Eltrombopag) Approval Criteria [Refractory Severe Aplastic Anemia Diagnosis]:***

1. *Member must have diagnosis of refractory severe aplastic anemia; and*
2. *Member must have a platelet count of ≤30 x 109/L; and*
3. *Member must not have a diagnosis of Fanconi anemia; and*
4. *Member must be 18 years of age or older; and*
5. *Member must not have a recent diagnosis of myelodysplastic syndromes; and*
6. *Member must have a documented trial of immunosuppressive therapy; and*
7. *A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and*
8. *Member must have eye exam prior to initiation of Alvaiz™ to assess for cataracts; and*
9. *Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz™; and*
10. *Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of aplastic anemia; and*
11. *Quantity limits will apply based on FDA-approved dosing, as follows:*
    - *9mg strength: 30 tablets per 30 days; or*
    - *18mg strength: 120 tablets per 30 days; or*
    - *36mg and 54mg strengths: 60 tablets per 30 days.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Alvaiz™ (eltrombopag) is a thrombopoietin (TPO)-receptor agonist indicated for the treatment of:
    - Thrombocytopenia in adult and pediatric patients 6 years of age and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Alvaiz™ should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
    - Thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Alvaiz™ should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
    - Adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.
- How Supplied: 9mg, 18mg, 36mg, and 54mg oral tablets
- Dosing:
    - Persistent or Chronic ITP:
        - Initial Dose: 36mg PO once daily
        - Dosage adjustments may be necessary based on East-/Southeast-Asian ancestry, hepatic impairment, or platelet counts.
        - The lowest dose possible should be used to achieve a platelet count of ≥50 x 109/L, not to exceed 54mg per day.
    - Chronic Hepatitis C-Associated Thrombocytopenia:
        - Initial Dose: 18mg PO once daily
        - Dosage adjustments may be necessary based on platelet counts.
        - The lowest dose possible should be used to achieve and maintain a platelet count necessary to initiate and maintain antiviral therapy with pegylated interferon and ribavirin, not to exceed a dose of 72mg per day.
        - Alvaiz™ should be discontinued when antiviral therapy is discontinued.
- Refractory Severe Aplastic Anemia:
    - Initial Dose: 36mg PO once daily
    - Dosage adjustments may be necessary based on East-/Southeast-Asian ancestry, hepatic impairment, or platelet counts.
    - The lowest dose possible should be used to achieve a platelet count of ≥50 x 109/L, not to exceed a dose of 108mg per day.
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216774s000lbl.pdf
- Coverage: Alvaiz™ will be covered with a hard PA with the criteria listed below.

- Quantity Limit(s): The following quantity limits are set in ICE; however, the criteria for each indication specifies different quantity limits based on FDA approved max dosing for each indication.
    - 30 tablets per 30 days for the 9mg strength; or
    - 120 tablets per 30 days for the 18mg strength; or
    - 60 tablets per 30 days for the 36mg and 54mg strengths.

- **BOTULINUM TOXINS**
    - **GENERAL INFORMATION**
        - Medical only
        - We often receive Botox petitions with request for a future fill date. Please go ahead and process these requests with the fill date they are requesting. Often times they request a future fill date because they know the member will be coming in for an appointment that day. Additionally, don't forget to add the JW code and waste units to the Botox PA's. They will frequently resubmit with a dosage change and require different waste units.
        - Only available in 100 and 200mg vials, therefore may need to round quantity up to allow for full vial. (If the full vial is not used, they bill the dose amount with J0585 and the discarded amount with J0585 and a JW modifier-billers will know what modifiers are, nurse/doctor may not. If additional questions refer them to provider services.
        - Botox Units Example: Requesting 140 units every 3 months. Approved Units: 140 units X 4 = 560 units
        - JW units: 200-140= 60 X 4= 240 units (Botox only comes in vials of 100 units and 200 units so you will need to subtract the amount of units being given from one of the vial sizes to get the waste units.)
        - Chronic Migraines: If a member is on oral contraceptives, we may need to verify that the migraines are not due to contraceptives. We do not want them to stop birth control just to get access to Botox. If they had migraines prior to starting contraceptives, we know that is not the reason for their migraines. Please do not deny Botox solely for the reason of them being on birth control.
            - The recommended dose for migraine is 155 units Q3months. It was dosed up to 195 units Q3months in clinical studies so this dosing may be appropriate as well.
        - Constipation: Some children with constipation refractory to medical therapy may respond to an intervention to release the internal anal sphincter through injection of botulinum toxin or myectomy. The effect of the botulinum toxin treatment is temporary (lasting up to several months). For patients that respond to initial treatments, additional injections may be given every few months, as needed, to maintain efficacy over the long term. (UpToDate; Chronic Functional Constipation and Fecal Incontinence in Infants and Children: Treatment). If prescriber is a specialist (e.g., gastroenterologist) and indicates member is refractory to medical therapy, please consider for approval of 1 dose to evaluate efficacy.
        - Plyorospasm: uncontrolled studies support botulinum toxin injection at he pyloris, or peroral endoscopic myotomy appear to be efficacious in the treatment of gastroparesis (UpToDate; Pathogenesis of delayed gastric emptying). If the

prescriber is a specialist (e.g., gastroenterologist) and member has tried other therapies, please consider approval of one dose to evaluate efficacy. Further authorization may be considered depending on the response to the trial.

- Spina Bifida: Botox is now FDA approved for pediatric detrusor overactivity associated with a neurological condition (neurogenic bladder). Spina bifida is one of the most common causes of neurogenic overactive bladder in pediatric patients. The clinical trial supporting this new indication primarily included patients with spina bifida, but also included patients with spinal cord injury or transverse myelitis. Botox is not covered for a diagnosis of spina bifida alone, but should be considered for approval if the member has an appropriate diagnosis of neurogenic bladder related to spina bifida and meets the additional approval criteria for this indication.
- BOTOX is now indicated for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), and finger flexors (flexor digitorum profundus and flexor digitorum sublimis). Please note that there are not specific diagnosis codes for upper limb spasticity (in fact the closest codes are for monoplegia of upper limb).

- **DAXXIFY**
  - **Interim Criteria (if applicable):**
    Medical Only - Botulinum Toxins Approval Criteria:

1. *For approval of Daxxify, Myobloc, or Xeomin, a patient-specific clinically significant reason the member cannot use Botox or Dysport must be provided; and*
2. *Cosmetic indications will not be covered; and*
3. *A diagnosis of chronic migraine (tension headaches are not a covered diagnosis), neurogenic detrusor overactivity, and non-neurogenic overactive bladder will require manual review (see specific criteria below); and*
4. *The following indications listed below have been determined to be appropriate and are covered:*
    - *Spasticity associated with:*
        - *Cerebral Palsy; or*
        - *Paralysis; or*
        - *Generalized weakness/incomplete paralysis; or*
        - *Larynx; or*
        - *Anal fissure; or*
        - *Esophagus (achalasia and cardiospasms); or*
        - *Eye and eye movement disorders; or*
    - *Cervical Dystonia*.

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Daxxify® (daxibotulinumtoxinA-lanm) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adult patients.
  - Please note: Daxxify® is also FDA approved for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or

procerus muscle activity in adult patients; however, that indication is considered cosmetic and will not be covered by SoonerCare.

- How Supplied: Sterile lyophilized powder in 50 unit or 100 unit single-dose vials
- Dosing and Administration:
  - The recommended dose for cervical dystonia is 125-250 units given intramuscularly (IM) as a divided dose among affected muscles.
  - The potency units for Daxxify® are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of Daxxify® cannot be compared to or converted into units of any other botulinum toxin product.
  - Daxxify® should be administered no more frequently than every 3 months for any indication.
- Prescribing Information:
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761127s002lbl.pdf
- Coverage: Daxxify® will be covered as Medical Only with a hard PA with criteria similar to other non-preferred botulinum toxin products.

- **COMPLEMENT INHIBITORS & MISC IMMUNOMODULATORY AGENTS**
  - **EMPAVELI**
    - **Interim Criteria (*if applicable*):**
    - *Empaveli® (Pegcetacoplan) Approval Criteria [Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) Diagnosis]:*

1. *An FDA approved indication to reduce proteinuria in members with C3G or primary IC-MPGN; and*
2. *The diagnosis must be confirmed by a kidney biopsy; and*
3. *Member must be 12 years of age or older and weigh at least 30kg; and*
4. *Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and*
5. *Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and*
6. *Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m2; and*
7. *Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and*
8. *Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
9. *For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and*
10. *Member must not be receiving Empaveli® in combination with another complement inhibitor (i.e., Fabhalta); and*
11. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **UPLIZNA**
  - **Interim Criteria (*if applicable*):**
  - *Imaavy™ (Nipocalimab-aahu) Approval Criteria:*
  1. *An FDA approved diagnosis of generalized myasthenia gravis (gMG); and*
  2. *Member must be 12 years of age or older; and*
  3. *Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and*
  4. *Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and*
  5. *MG-Activities of Daily Living (MG-ADL) total score ≥6; and*
  6. *Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor, corticosteroid, or immunosuppressive therapies (ISTs); and*
  7. *Imaavy™ must be prescribed by, or in consultation with, a neurologist, or a specialist with expertise in the treatment of gMG; and*
  8. *Member must not be receiving Imaavy™ in combination with a complement inhibitor (i.e. Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker use to treat gMG (i.e. Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and*
  9. *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and*
  10. *Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST) requirement: gMG medications requires a stable dose of an AChE or an IST; however, please also consider if the member had a previous trial and could not tolerate or it was not appropriate to continue long term
    - AChE inhibitor: pyridostigmine
    - IST: azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate mofetil, or tacrolimus
  - MGFA classification and MG-ADL score: If the member met criteria at baseline or when off treatment, this would be acceptable for our criteria
  - Subsequent approvals – improvement in MG-ADL score: Consider approval if the prescriber attests to improvement w/o an improved MG-ADL score (may be maintaining and/or preventing further decline)
  - Concomitant therapy: There is currently no evidence to support the safety and efficacy of using multiple gMG therapies concomitantly. Requests for concomitant use of gMG therapies (e.g., Immavy, Rystiggo, Soliris, Ultomiris, Vyvgart, or Zilbrysq) will be reviewed on a case-by-case basis and will require patient-specific information to support concomitant use.
- **UPLIZNA**

- **Interim Criteria (*if applicable*):**
- *Uplizna® (Inebilizumab-cdon) Approval Criteria [Immunoglobulin G4-Related Disease (IgG4-RD) Diagnosis]:*

1. *An FDA approved diagnosis of IgG4-RD; and*
2. *Member must be 18 years of age or older; and*
3. *Member must have a confirmed history of organ involvement; and*
4. *Uplizna® must be prescribed by, or in consultation with, a gastroenterologist, rheumatologist, or a specialist with expertise in the treatment of IgG4-RD; and*
5. *Member must have previously been treated with glucocorticoid therapy or have a patient specific, clinically significant reason why glucocorticoid therapy is not appropriate; and*
6. *Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and*
7. *Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and*
8. *Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and*
9. *Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and*
10. *Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and*
11. *The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the member must be observed for at least 1 hour after the completion of each infusion; and*
12. *Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and*
13. *Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and*
14. *Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and*
15. *A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and*
16. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- *Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:*

1. *An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and*
2. *Member must be 18 years of age or older; and*

3. *Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and*
4. *Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and*
5. *Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and*
6. *Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and*
7. *Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and*
8. *Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and*
9. *Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and*
10. *Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and*
11. *The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and*
12. *Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and*
13. *Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and*
14. *Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and*
15. *Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Ultomiris®); and*
16. *A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and*
17. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):** n/a

- **FABHALTA**
  - **Interim Criteria (*if applicable*):**
  - *Fabhalta® (Iptacopan) Approval Criteria [Complement 3 Glomerulopathy (C3G) Diagnosis]:*

1. *An FDA approved indication to reduce proteinuria in adults with C3G; and*
2. *The diagnosis of C3G must be confirmed by a kidney biopsy; and*
3. *Member must be 18 years of age or older; and*
4. *Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and*

5. *Member must not have monoclonal gammopathy of undetermined significance; and*
6. *Member must not have previously received a kidney transplant; and*
7. *Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and*
8. *Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m2; and*
9. *Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and*
10. *Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
11. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **BKEMV, SOLIRIS**
  - **Interim Criteria (*if applicable*):**
  - *Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:*

1. *An FDA approved diagnosis of aHUS; and*
2. *Prescriber must confirm the member does not have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HS); and*
3. *Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;*
4. *Prescriber must verify member does not have unresolved Neisseria meningitidis infection; and*
5. *Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
6. *For use of Bkemv™ or Soliris®, a patient-specific, clinically significant reason why the member cannot use Epysqli must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and*
7. *Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement inhibitor used to treat aHUS (i.e., Ultomiris®); and*
8. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- *Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:*

1. *An FDA approved diagnosis of gMG; and*

2. *Member must be 6 years of age and older; and*
3. *Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and*
4. *Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and*
5. *Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and*
6. *Member must meet 1 of the following:*
    - *Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or*
    - *Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and*
7. *Bkemv™, Epysqli®, Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and*
8. *Prescriber must verify member does not have unresolved Neisseria meningitidis infection; and*
9. *Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
10. *For use of Bkemv™ or Soliris®, in members 18 years of age or older, a patient-specific, clinically significant reason why the member cannot use Epysqli must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and*
11. *Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Ultomiris®, Zilbrysq®); and*
12. *Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.*

- *Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:*

1. *An FDA approved diagnosis of PNH; and*
2. *Member must be 18 years of age or older; and*
3. *Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and*
4. *Prescriber must verify member does not have unresolved Neisseria meningitidis infection; and*
5. *Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*

6. *For use of Bkemv™ or Soliris®, a patient-specific, clinically significant reason why the member cannot use Epysqli must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and*
7. *Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Ultomiris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and*
8. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- As of 4/2025 **Epysqli® (eculizumab-aeeb)** is available, and the net cost is lower than Bkemv™, Soliris®, and Ultomiris®. **Epysqli® will now be our preferred product.**
- Medical coverage of Epysqli should be added in July 2025 under HCPCS code Q5151. If they need Epysqli now they can fill it as a pharmacy claim or consider approving Soliris temporarily.
- Soliris (gMG dx) has received an age expansion and is now approved for patients 6 years of age and older for gMG. The biosimilars (Bkemv and Epysqli) did not receive this age expansion and are only approved in adults for gMG. Epysqli is preferred due to net cost. Epysqli is only approved in adults, so please approve Soliris for members 6-17 years of age without a reason they can't use Epysqli as it is not indicated for those members.
- Bkemv and Epysqli are not FDA approved for NMOSD; however, Soliris is. If a provider requests Bkemv or Epysqli for NMOSD, please send the request back and ask them to use Soliris as there are no criteria for Bkemv and Epysqli for a diagnosis of NMOSD.

- **RYSTIGGO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes(*for consideration toward approval*):**
  - Acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST) requirement: gMG medications require a stable dose of an AChE or an IST or a reason why the member cannot use them. Please take into consideration if the member had a previous trial of an Ache or IST, and could not tolerate it or it was not appropriate to continue long term.
    - AChE inhibitor: pyridostigmine
    - IST: azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate mofetil, or tacrolimus
  - MGFA classification and MG-ADL score: If the member met criteria at baseline or when off treatment, this would be acceptable for our criteria.
  - Subsequent approvals – improvement in MG-ADL score: Consider approval if the prescriber attests to improvement w/o an improved MG-ADL score (may be maintaining and/or preventing further decline).

- Concomitant therapy: There is currently no evidence to support the safety and efficacy of using multiple gMG therapies concomitantly. Requests for concomitant use of gMG therapies (e.g., Rystiggo, Vyvgart, Ultomiris) will be reviewed on a case-by- case basis and will require patient-specific information to support concomitant use.

- **ULTOMIRIS**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Please give special consideration to PA's submitted by specialists for pediatric patients if submitting for paroxysmal nocturnal hemoglobinuria.
  - Acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST) requirement: gMG medications require a stable dose of an AChE or an IST or a reason why the member cannot use them. Please take into consideration if the member had a previous trial of an Ache or IST, and could not tolerate it or it was not appropriate to continue long term.
    - AChE inhibitor: pyridostigmine
    - IST: azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate mofetil, or tacrolimus
  - MGFA classification and MG-ADL score: If the member met criteria at baseline or when off treatment, this would be acceptable for our criteria.
  - Subsequent approvals – improvement in MG-ADL score: Consider approval if the prescriber attests to improvement w/o an improved MG-ADL score (may be maintaining and/or preventing further decline)
  - Concomitant therapy: There is currently no evidence to support the safety and efficacy of using multiple gMG therapies concomitantly. Requests for concomitant use of gMG therapies (e.g., Vyvgart and Ultomiris) will be reviewed on a case-by-case basis and will require patient-specific information to support concomitant use

- **VYVGART, VYVGART HYTRULO**
  - **Interim Criteria (*if applicable*):**
  - *Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Diagnosis]:*

1. *An FDA approved diagnosis of CIDP; and*
2. *Member must be 18 years of age or older; and*
3. *Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and*
4. *Member must have previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use intravenous immunoglobulin (IVIG) must be provided; and*
5. *For member self-administration or caregiver administration of Vyvgart® Hytrulo prefilled syringe, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and*

6. *Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*

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- *<u>Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:</u>*

1. *An FDA approved diagnosis of gMG; and*
2. *Member must be 18 years of age or older; and*
3. *Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and*
4. *Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and*
5. *MG-Activities of Daily Living (MG-ADL) total score ≥5; and*
6. *Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and*
7. *Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and*
8. *Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Rystiggo®); and*
9. *For member self-administration or caregiver administration of Vyvgart® Hytrulo prefilled syringe, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and*
10. *Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST) requirement: gMG medications require a stable dose of an AChE or an IST or a reason why the member cannot use them. Please take into consideration if the member had a previous trial of an AChE or IST, and could not tolerate it or it was not appropriate to continue long term.
    - AChE inhibitor: pyridostigmine
    - IST: azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate mofetil, or tacrolimus
- MGFA classification and MG-ADL score: If the member met criteria at baseline or when off treatment, this would be acceptable for our criteria

- Subsequent approvals – improvement in MG-ADL score: Consider approval if the prescriber attests to improvement w/o an improved MG-ADL score (may be maintaining and/or preventing further decline).
- Concomitant therapy: There is currently no evidence to support the safety and efficacy of using multiple gMG therapies concomitantly. Requests for concomitant use of gMG therapies (e.g., Vyvgart and Ultomiris) will be reviewed on a case-by-case basis and will require patient-specific information to support concomitant use.

- **<u>ATOPIC DERMATITIS AGENTS</u>**
  - **ANZUPGO**
    - **Interim Criteria (*if applicable*):**
    - *Anzupgo® (Delgocitinib 2% Cream) Approval Criteria:*

1. *An FDA approved diagnosis of moderate-to-severe chronic hand eczema (CHE) meeting 1 of the following:*
    - *Hand eczema has persisted for >3 months; or*
    - *Hand eczema has returned twice or more within the last 12 months; and*
2. *Member must be 18 years of age or older; and*
3. *Must be prescribed by or in consultation with a dermatologist, allergist, or immunologist (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and*
4. *Prescriber must attest that the member has been adherent to standard non-medicated skin care, including but not limited to:*
    - *Frequent use of emollients/moisturizers; and*
    - *Washing hands in lukewarm (not hot) water; and*
    - *Avoidance of known and relevant irritants and allergens; and*
5. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):*
    - *1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and*
    - *1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and*
6. *Concurrent use with other Janus kinase (JAK) inhibitors or potent immunosuppressants will not generally be approved; and*
7. *Member must be counseled to apply Anzupgo® only to the hands and wrists. Anzupgo® will not be approved for application to any other area; and*
8. *Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and*
9. *A quantity limit of 60 grams per 30 days will apply.*

  - **ADBRY**
    - **Interim Criteria (*if applicable*):**
    - *Adbry® (Tralokinumab-ldrm Injection) Approval Criteria:*

1. *An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and*

2. *Member must be 18 12 years of age or older; and*
3. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):*
    - *1 medium potency to very-high potency Tier-1 topical corticosteroid; and*
    - *1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and*
4. *Adbry® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and*
5. *Requests for concurrent use of Adbry® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry® has not been studied in combination with other biologic therapies); and*
6. *Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.*

- **Additional Internal Notes (*for consideration toward approval*):**
- For initial approvals of Adbry, please approve a quantity limit override for the full 16 weeks of the initial approval.
- Adbry® (tralokinumab-ldrm) was approved for an age expansion in patients 12 years of age and older for the treatment of moderate-to-severe atopic dermatitis in patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Recommended Dosing for Patients 12 to 17 Years of Age: 300mg [(2) 150mg injections) as an initial dose followed by 150mg every other week.

- **RINVOQ**
    - **Interim Criteria (*if applicable*):**
    - *Rinvoq® (Upadacitinib) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:*

1. *An FDA approved diagnosis of GCA; and*
2. *Member must be 50 years of age or older; and*
3. *History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and*
4. *Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and*
5. *Must be taken in combination with a tapering course of corticosteroids upon initiation; and*
6. *Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling; and*
7. *A trial of Tyenne® (tocilizumab-aazg) used in combination with a tapering course of corticosteroids or a patient-specific, clinically significant reason why the member cannot use Tyenne® must be provided; and*

8. *Approvals will be for a dose of 15mg once daily and a quantity limit of 30 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **NEMLUVIO**
  - **Interim Criteria (*if applicable*):**
  - *Nemluvio® (Nemolizumab-ilto) Approval Criteria:*

1. *An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and*
2. *Member must be 12 years of age or older; and*
3. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):*
   - *1 medium potency to very-high potency Tier-1 topical corticosteroid; and*
   - *1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and*
4. *Member must agree to continue using a topical corticosteroid and/or a topical calcineurin inhibitor in combination with Nemluvio® until the disease has sufficiently improved; and*
5. *Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and*
6. *A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and*
7. *Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and*
8. *Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and*
9. *Initial approvals will be for the initial dosing for the duration of 16 weeks; and*
10. *Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and*
    - *A dosage of 30mg every 8 weeks will be approved for reauthorization; or*
    - *If a dosage of 30mg every 4 weeks is requested for reauthorization, additional patient-specific information will be required to support the need for continuing the every 4 week dosing regimen.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- **<u>TARGETED IMMUNOMODULATOR AGENTS (BIOLOGICS)</u>**
  - **GENERAL INFORMATION**
    - **Unbranded Infliximab (Remicade) - Based on discussions with the Oklahoma Arthritis Center, providers are unable to purchase & dispense Inflectra (tier 2**

preferred infliximab) without significant financial loss. The state has agreed to allow coverage of unbranded infliximab (which is unbranded Remicade and currently has the NDC of 57894016001) as the tier 2 infliximab product. <u>This coverage exception only applies to the Arthritis Center Providers with NPIs listed below.</u>

Provider:	**Individual NPI:**
Craig Carson, M.D.	1043288673
Ana Kumar, M.D.	1215905971
Graciella Gallardo, M.D.	1639211261
Linda Zacharias, M.D.	1861535908
Jama Shoemaker PA	1093783805
Cindy Chtay Hagan PA	1992773709
Eric Campbell, PA	1861482887
Sheril Mathew NP	1023488913
Christy Weaver NP	1386019537
Emily John PA	1700248101
Sharon Bolton PA	1174558738
Keshav Panday MD	1710171194
David Schulze PA	1447766407
Sterling Riggs M.D.	1144456005
Shawna Seelbach NP	1578069407
DavidSpeegle MD	1477695864
Amanda Bibbs NP	1609396944
Kelsey Landon PA	1033764360
Jocelyn Eslick NP	1730725649
Robert J Tyndall MD	1225066830
Leslie Hornick NP	1487889374
Chad Schroeder PA	1861761199
Mark Hulsey MD	1932142361
Latosha Redd NP	1780281568
Jonathan Robinson MD	1891286589
Sean Anderson NP	1164829057
Stephanie Pennie NP	1255976643
Mary Denton NP	1821169590
Michelle Dockray NP	1982343489
Bradley Toews PA	1609244664
Katie Robinson NP	1326441775
Sylvie Fisher PA	1578038857
Sara Hubbard NP	1588147680
Trevor Maxwell PA	1275163735
Lea Bryan NP	1073020988
Samuel Kimbrough PA	1265134498

        - Renee Weatherford NP 1417317140
        - Stacy Ellis PA 1548448087
        - Connie Whitaker NP 1083238612
        - Bethany Sallee PA 1578100566
        - Megan Johnson PA 1346015369
        - Christopher Carson M.D. 1235717802
        - Ashley Dyson PA 1336973106
        - Sydnee Scott PA 1174241251
    - Topical steroids can be used prior to consideration of a biologic for plaque psoriasis; the guidelines recommend at least a week of usage however, we cannot force a long time requirement on them, as we do not have one for the other Tier-1 medications.
    - AGA 2020 Guidelines for Moderate-To-Severe Ulcerative Colitis recommend infliximab and vedolizumab as preferred over standard-dose adalimumab as first-line options for biologic-naïve patients. Infliximab, adalimumab, golimumab, vedolizumab, ustekinumab, and tofacitinib are all recommended treatment options for inducing and maintaining remission in adult outpatients with moderate-to-severe UC. The AGA does not make a recommendation for mesalamine for moderate-to-severe UC.
    - Many medications in the Targeted Immunomodulator Class require an initial loading dose, depending on the indication, which may require approving a QLO for the initial fill. Please always verify the member's dosing and approve a one-time QLO (if necessary based on the QL settings on the requested NDC) for the initial fill only. You may need to re-process the request to approve the remaining fills (without a QLO added) if the same NDC will be used for subsequent fills. If they are requesting a starter NDC it may not require a QLO, but please do not approve the starter kit NDC long-term.
- **ENBREL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please consider approval of Enbrel for a diagnosis of graft versus host disease (GVHD) after stem cell transplant (without Tier-1 trials) as an off-label use; particularly if written by Dr. David Crawford. Dosing of Enbrel for this diagnosis was studied as 0.4mg/kg (maximum dose, 25mg) per dose twice weekly for 8 weeks.
- **CIMZIA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Cimzia® (certolizumab pegol) has the most data of the targeted immunomodulatory agents on use in pregnancy and nursing. Prescribers may request to move to Cimzia® if the patient is pregnant or nursing. This could be appropriate, but each case should be evaluated individually.
- **COSENTYX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

- Cosentyx: Cosentyx is available as 150mg Sensoready pens and syringes that come in packages of 1 for 150mg dose and 2 for a 300mg dose. Cosentyx is also available as a 300mg UnoReady pen. When approving for Cosentyx 150mg Sensoready pens or syringes please ask them to use the package with 2 pens or syringes whether or not they want the 300mg dose. The package for 1 pen is the same price as the package for 2 pens, so we might as well give them 2 pens in case they need the larger dose or something happens to 1 of the pens. We can't ask them to fill the package of 2 pens and then divide them up over 2 months due to package labeling. The 300mg UnoReady pen may also be approved for patients using the 300mg dose. If they are requesting the 300mg UnoReady pen to administer a 300mg dose, we do not need to ask them to use the 2-pack of 150mg pens or syringes.

- **ACRALYST**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Arcalyst J2793 (1 J code unit = 1 mg) approval x 1 year
  - Dosing and Regimen: 320 mg x 1 dose then 160 mg every week
  - Calculation: (comes as a 220 mg vial SUV)
  - Provider will use #2–220 mg vl wk #1 then #1-220 mg vl wkly x 51 wks=11,660mg
  - J code units: 11,660 units
- **BENLYSTA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - IV formulation = Medical Only (J0490)
  - Sub-Q formulation = Pharmacy only
  - Only the IV formulation and sub-Q autoinjector formulation of Benlysta are approved for pediatric patients. The sub-Q prefilled syringe is only approved for use in adults. Please ensure the requested product is appropriate for the member's age.
    - A dose and vial calculator for billing with J0490 is available at: https://www.benlystahcp.com/dosing/vial-calculator/
- **ILARIS**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Ilaris is FDA approved for SJIA while current Tier-2 and Tier-3 medications are only indicated for JIA. The criteria states appropriate Tier-2 or Tier-3 medications, so we will not ask them to use any of these medications if the diagnosis is SJIA
- **RITUXAN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Medical Only
  - Rituximab does not require a PA when submitted as a medical claim. No PA is required for any oncology indications. If they request a PA with a HCPCS code for one of the non-oncology diagnoses, follow criteria. Non-oncology diagnoses should follow the PA criteria; however, there is no way to enforce it on the medical side. If

you received a PA request for rituximab, or a request for a different med noting that they've been on rituximab, please check their medical claims even if they don't have an approved PA. They may have been getting it paid without a PA.
    - Quantity Limit Initial: Two 1,000mg IV infusions separated by two weeks and a 500mg infusion at month 12
- **XELJANZ**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Do not approve the 10mg strength BID for a diagnosis of RA. This 10mg BID is only approved for UC. RA patients receiving 10mg BID puts them at increased risk of PE. Max dose for RA dx is 5mg BID (IR tabs) or 11mg QD (ER tabs); Boxed Warning: RA pts with CV risk factor(s) had a higher rate of all-cause mortality and thrombosis (including PE and DVT) with the 10mg BID dose vs 5mg BID dose.
- **ZYMFENTRA**
    - **Interim Criteria (*if applicable*):**
    - *Tier 2 TIA Criteria*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Zymfentra® (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker indicated in adults for maintenance treatment of:
    - Moderately-to-severely active ulcerative colitis following treatment with an infliximab product administered intravenously (IV); or
    - Moderately-to-severely active Crohn's disease following treatment with an infliximab product administered IV.
    - How Supplied: 120mg/mL single-dose prefilled pen or syringe
    - Dosage and Administration:
        - Patients must complete an IV induction regimen with an infliximab product before starting Zymfentra®.
        - Starting at week 10 and thereafter, the recommended dose of Zymfentra® is 120mg by subcutaneous (sub-Q) injection every 2 weeks.
        - For patients already responding to maintenance therapy with IV infliximab, the first sub-Q dose of Zymfentra® may be administered in place of the next scheduled IV infusion.
    - Prescribing Information: https://zymfentra.b-cdn.net/zymfentra_prescribing_information_final.pdf
    - Coverage: Zymfentra® will be placed into Tier-2 of the Targeted Immunomodulator Agents Tier chart.
    - Quantity Limit: 2 pens or syringes per 28 days
- **BIMZELX**
    - **Interim Criteria (*if applicable*):**
    - *Bimzelx® (Bimekizumab-bkzx) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:*

1. *A diagnosis of moderate-to-severe HS; and*
2. *Hurley Stage II or III disease; and*

3. *Member must have at least 5 abscesses or inflammatory nodules; and*
4. *Previous failure of at least 2 of the following categories:*
    - *Topical or systemic antibiotics; or*
    - *Oral or intralesional corticosteroids; or*
    - *Dapsone; or*
    - *Cyclosporine; or*
    - *Antiandrogens (e.g., spironolactone, oral contraceptives); or*
    - *Finasteride; or*
    - *Surgery; and*
5. *Previous failure of Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry™ (adalimumab-aqvh) for at least 12 weeks at recommended dosing (or documented intolerance); and*
6. *A patient-specific, clinically significant reason why the member cannot use Cosentyx® (secukinumab) must be provided.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Bimzelx® (bimekizumab) was approved for a new indication for the treatment of adult patients with moderate-to-severe hidradenitis suppurativa (HS).
- HS Dosing: The recommended dosing for HS is 320mg by subcutaneous (sub-Q) injection at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, followed by 320mg every 4 weeks thereafter.
- Prescribing Information:
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761151s010lbl.pdf
- Coverage: Bimzelx® is covered in the **Special PA Tier** of the Targeted Immunomodulator Agents (TIA) Tier Chart. However, for a diagnosis of HS, the unique criteria listed above will apply.

▪ **OTULFI, PYZCHIVA, SELARSDI, STELARA, WEZLANA**

- **Interim Criteria (*if applicable*):**
- *Otulfi™ (Ustekinumab-aauz), Unbranded Pyzchiva® (Ustekinumab-ttwe), Unbranded Selarsdi™ (Ustekinumab-aekn), Stelara® (Ustekinumab), and Wezlana™ (Ustekinumab-auub) Approval Criteria:*

1. *Member must meet Special Prior Authorization (PA) approval criteria; and*
2. *A patient-specific, clinically significant reason why the member cannot use Stelara® (ustekinumab) Imuldosa® (ustekinumab-srlf), branded Pyzchiva® (ustekinumab-ttwe), branded Selarsdi™ (ustekinumab-aekn), Steqeyma® (ustekinumab-stba), and Yesintek™ (ustekinumab-kfce) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

- Based on net cost and supplemental rebate participation, **effective 10/1/2025**, several Stelara® biosimilar products are being moved to Tier-2 based on net cost and will be preferred over Stelara®.
    - Please be aware that some of the Stelara® biosimilars are available in both branded and unbranded formulations and coverage may vary.
- All new starts for any Special PA ustekinumab product will need to provide a reason why they cannot use all of the Tier-2 ustekinumab products even if they meet the other Special PA criteria.

▪ **ACTEMRA/AVTOZMA/TOFIDENCE/TYENNE**

- **Interim Criteria (*if applicable*):**
- *Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), and Tofidence™ (Tocilizumab-bavi) Approval Criteria:*

1. *Member must meet Special Prior Authorization (PA) approval criteria; and*
2. *A patient-specific, clinically significant reason why the member cannot use Tyenne® (tocilizumab-aazg) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*

- *Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), and Tyenne® (Tocilizumab-aazg) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:*

1. *An FDA approved diagnosis of CAR T cell-induced CRS; and*
2. *Requests for Actemra® or Avtozma® will require a patient-specific, clinically significant reason why the member cannot use Tyenne® (tocilizumab-aazg). Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*

- *Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), Tofidence™ (Tocilizumab-bavi), and Tyenne® (Tocilizumab-aazg) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:*

1. *An FDA approved diagnosis of GCA; and*
2. *Member must be 50 years of age or older; and*
3. *History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and*
4. *Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and*
5. *Must be taken in combination with a tapering course of corticosteroids upon initiation; and*
6. *Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and*
7. *Member must not have severe hepatic impairment; and*

8. *Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and*
9. *Requests for Actemra®, Avtozma®, or Tofidence™ will require a patient-specific, clinically significant reason why the member cannot use Tyenne®. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and*
10. *Approval quantity will be based on package labeling and FDA approved dosing regimen(s).*

- **Additional Internal Notes (*for consideration toward approval*):**

▪ **OTEZLA/OTEZLA XR**

- **Interim Criteria (*if applicable*):**
- *Otezla® (Apremilast) and Otezla XR™ [Apremilast Extended-Release (ER)] Approval Criteria [Behçet's Disease (BD) Diagnosis]:*

1. *An FDA approved indication for the treatment of oral ulcers associated with BD; and*
2. *Member must have had oral ulcers at least 3 times in the last 12 month period; and*
3. *Member must have had a 2 week trial of the following that resulted in inadequate efficacy or intolerable adverse effects (or be contraindicated for the member):*
    - *Topical corticosteroids (applied topically to the mouth); and*
    - *Colchicine; and*
4. *For Otezla XR™, a patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided; and*
5. *Quantity limits according to package labeling will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

Updated Tier Chart 10/03/25

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)+± - **Brand Preferred**	abatacept (Orencia®, Orencia® ClickJect™)¤	adalimumab-aacf (Idacio®)±
azathioprine	adalimumab-aqvh (Yusimry™)+±	certolizumab pegol (Cimzia®)	adalimumab-aaty (Yuflyma®)±
hydroxychloroquine	adalimumab-bwwd (Hadlima™)+±	deucravacitinib (Sotyktu™)	adalimumab-adaz (Hyrimoz®)±
leflunomide	anakinra (Kineret®)	golimumab (Simponi®, Simponi Aria®)	adalimumab-adbm (Cyltezo®)±
mesalamine	apremilast (Otezla®)ß	infliximab (Remicade®)±	adalimumab-afzb (Abrilada™)±
methotrexate	etanercept (Enbrel®)±	infliximab-abda (Renflexis®)±	adalimumab-atto (Amjevita™)±
minocycline	infliximab-dyyb (Inflectra®)±	infliximab-axxq (Avsola®)±	adalimumab-fkjp (Hulio®)±
NSAIDs	rituximab (Rituxan®)~±	sarilumab (Kevzara®)§	adalimumab-ryvk (Simlandi®)±
oral corticosteroids	rituximab-abbs (Truxima®)±	tocilizumab-aazg (Tyenne®)±	anifrolumab-fnia (Saphnelo®)**

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
sulfasalazine	rituximab-arrx (Riabni®)±	tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	**apremilast ER (Otezla XR™)ß**
topical corticosteroids	rituximab-pvvr (Ruxience®)±	vedolizumab intravenous (IV) (Entyvio®)**	avacopan (Tavneos®)**
	ustekinumab-aekn (Selarsdi™)± - Branded only		baricitinib (Olumiant®)€
	ustekinumab-kfce (Yesintek™)±		belimumab (Benlysta®)**
	ustekinumab-srlf (Imuldosa®)±		bimekizumab-bkzx (Bimzelx®)Δ
	ustekinumab-stba (Steqeyma®)±		brodalumab (Siliq®)**
	ustekinumab-ttwe (Pyzchiva®)± - Branded Only		canakinumab (Ilaris®)¥
			deuruxolitinib (Leqselvi™)€
			etanercept-szzs (Erelzi®)±
			etanercept-ykro (Eticovo®)±
			etrasimod (Velsipity™)
			guselkumab (Tremfya®)
			infliximab-dyyb (Zymfentra®)±
			ixekizumab (Taltz®)
			mirikizumab-mrkz (Omvoh™)
			rilonacept (Arcalyst®)**
			risankizumab-rzaa (Skyrizi®)
			ritlecitinib (Litfulo™)€
			secukinumab (Cosentyx®)Δ
			spesolimab-sbzo (Spevigo®)**
			tildrakizumab-asmn (Ilumya®)
			tocilizumab (Actemra®)π±
			tocilizumab-bavi (Tofidence™)±
			upadacitinib (Rinvoq®, Rinvoq® LQ)#
			ustekinumab (Stelara®)±
			ustekinumab-aauz (Otulfi™)±
			ustekinumab-aekn (Selarsdi™)± - **Unbranded Only**
			ustekinumab-auub (Wezlana™)±
			ustekinumab-ttwe (Pyzchiva®)± - **Unbranded Only**
			vedolizumab subcutaneous (sub-Q) (Entyvio®)**
			voclosporin (Lupkynis®)**

CARDIOVASCULAR

- **HEART FAILURE AGENTS**
  - **CAMZYOS**
    - **Interim Criteria (*if applicable*):**
    - *Camzyos® (Mavacamten) Approval Criteria:*

1. *An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and*
2. *Member must be 18 years of age or older; and*
3. *Member must have New York Heart Association (NYHA) class II to III heart failure; and*
4. *Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and*
5. *Member must have left ventricular ejection fraction (LVEF) ≥55%; and*
6. *Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and*
7. *Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and*
8. *If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber must verify that the Camzyos® dose will be adjusted according to the package labeling; and*
9. *Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and*
10. *Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos®; and*
11. *Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
12. *Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment; and*
13. *Subsequent approvals will be for the duration of 1 year.*

    - **Additional Internal Notes (*for consideration toward approval*):**
  - **ENTRESTO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Claims for Entresto should auto-PA through DUR+ for members 1 year of age or older with diagnosis of HF in their claims history in the last 120 days; DUR+ will also auto-PA for current utilizers.

- **ENTRESTO SPRINKLE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Claims for Entresto Sprinkle should NOT auto-PA through DUR+. The manufacturer chose not to add Entresto Sprinkle to their supplemental rebate, so the sprinkle formulation is non-preferred and isn't being added to the DUR+ module.
    - Of note, Entresto Sprinkle oral pellets cannot be administered via nasogastric, gastrostomy, or other enteral tubes because obstruction may occur. The manufacturer, Novartis, said in a response to a medical inquiry that there is no data for administering the suspension prepared from Entresto tablets through enteral tubes. Novartis said providers must weigh the risks and benefits and use clinical judgment.
    - Also note that the suspension prepared from Entresto tablets has a dilute concentration of 4mg/mL (sacubitril/valsartan 1.96/2.04mg/mL), must be prepared from tablets by a pharmacy, and has a stability of 15 days once prepared. May also consider if the member was stabilized inpatient on a specific formulation and has difficulty switching to the preferred product.
- **FUROSCIX**
    - **Interim Criteria (*if applicable*):**
    - *Furoscix® (Furosemide On-Body Infusor) Approval Criteria:*

1. *An FDA approved indication for the treatment of edema in members with chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and*
2. *Member must be 18 years of age or older; and*
3. *Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and*
4. *Member is currently showing signs of edema; and*
5. *Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:*
    - *Bumetanide oral tablets; or*
    - *Furosemide oral tablets; or*
    - *Torsemide oral tablets; and*
6. *Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and*
7. *Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:*
    - *Oxygen saturation ≥90% on exertion; and*
    - *Respiratory rate <24 breaths per minute; and*
    - *Resting heart rate <100 beats per minute; and*
    - *Systolic blood pressure >100mmHg; and*

8. *Member must have an adequate environment for at-home administration, have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and*
9. *Member must not have any contraindications for use of Furoscix® including anuria, or hepatic cirrhosis, or ascites; and*
10. *Member must not have conditions that require immediate hospitalization; and*
11. *Approvals will be issued per incident of fluid overload; and*
12. *Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.*

- **Additional Internal Notes (*for consideration toward approval*):**
- There is no quantity limit set for this product. However, in the study, Furoscix was delivered once to twice daily for 3-4 days. Requests should be for 6-8 kits per incident, possibly even 12 kits since average hospital stays for diuresis could last 6 days. Please use your clinical judgement when reviewing the quantity being requested to determine if appropriate.

- **CORLANOR**
  - **Interim Criteria (*if applicable*):**
  - *Corlanor® (Ivabradine) Approval Criteria:*

1. *A diagnosis of 1 of the following:*
   - *To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or*
   - *For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; and or*
   - *For the treatment of inappropriate sinus tachycardia (IST); and*
2. *For a diagnosis of worsening HF in adults:*
   - *Prescriber must verify that the member has LVEF ≤35%; and*
   - *Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and*
   - *Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and*
3. *For a diagnosis of DCM in members 6 months of age or older:*
   - *Prescriber must verify that the member has LVEF ≤45%; and*
   - *Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:*
     - *Age 6 to 12 months, HR ≥105 bpm; or*
     - *Age 1 to 3 years, HR ≥95 bpm; or*
     - *Age 3 to 5 years, HR ≥75 bpm; or*
     - *Age 5 to 18 years, HR ≥70 bpm; and*
   - *Prescriber must verify that dose titration will be followed according to package labeling; and*

        - *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
    4. *Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and*
    5. *For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and*
    6. *For Corlanor® solution, a quantity limit of 280mL (56 ampules) per 28 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **<u>HEREDITERY ANGIOEDEMA AGENTS</u>**
    - **ANDEMBRY/CINRYZE/DAWNZERA/HAEGARDA/ORLADEYO/TAKHZYRO**
        - **Interim Criteria (*if applicable*):**
        - *Andembry® (Garadacimab-gxii), Cinryze® (C1 Esterase Inhibitor), Dawnzera™ (Donidalorsen), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:*
    1. *An FDA approved diagnosis of hereditary angioedema (HAE); and*
    2. *Must be used for prophylaxis of HAE; and*
    3. *Not currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and*
    4. *Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or*
    5. *Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and*
    6. *Authorization of Andembry® or Dawnzera™ will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, Orladeyo®, or Takhzyro®; and*
    7. *Authorization of Cinryze® or Haegarda® (C1 esterase inhibitor) will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo® (berotralstat); and*
    8. *Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and*
    9. *Andembry® Dosing:*
        - *The recommended dose of Andembry® is an initial loading dose of 400mg subcutaneously (sub-Q) followed by a maintenance dose of 200mg sub-q once monthly; and*
        - *A quantity limit of 1.2mL per 30 days will apply. A quantity limit override will be granted for the initial 400mg dose; and*
    10. *Cinryze® Dosing:*
        - *The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and*

        - *Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and*
        - *A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); and*
            - *For requests exceeding the quantity limit, clinical documentation supporting the need for the dose increase (i.e., up to a maximum of 16,000 units per month) must be provided for a quantity limit override; or*
    11. *Dawnzera™ Dosing:*
        - *The recommended dose of Dawnzera™ is 80mg sub-Q every 4 weeks or a dosage of 80mg sub-Q every 8 weeks may be considered; and*
        - *A quantity limit of 0.8mL per 28 days will apply; or*
    12. *Haegarda® Dosing:*
        - *The recommended dose of Haegarda® is 60 IU/kg (sub-Q) twice weekly; and*
        - *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
        - *A quantity limit of 2 treatments per week or 8 treatments 28 days will apply; or*
    13. *Orladeyo Dosing:*
        - *The recommended dose of Orladeyo® is 150mg by mouth once daily; and*
        - *A quantity limit of 28 capsules per 28 days will apply; or*
    14. *Takhzyro® Dosing:*
        - *For members 12 years of age and older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and*
        - *For members 6 to 11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and*
        - *For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and*
        - *Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and*
        - *A quantity limit of (2) vials per 28 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Cinryze – Dosing of up to 2000 units (not to exceed 80 units/kg) every 3 to 4 days may be considered based on individual patient response.
- **BERINERT, EKTERLY, FIRAZYR, KALBITOR, RUCONEST, SAJAZIR**
    - **Interim Criteria (*if applicable*):**
    - *Berinert® (C1 Esterase Inhibitor), Ekterly® (Sebetralstat), Firazyr® (Icatibant), Kalbitor® (Ecallantide), Ruconest® (C1 Esterase Inhibitor), and Sajazir™ (Icatibant) Approval Criteria:*

1. *An FDA approved diagnosis of hereditary angioedema (HAE); and*
2. *Requested medication must be used for the treatment of acute attacks of HAE; and*
3. *For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or*
4. *For authorization consideration of Ekterly® (sebetralstat), Ruconest® (C1 esterase inhibitor) or Sajazir™ (icatibant), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Firazyr syringes are 3mls
- The rebate agreement for Ekterly starts on 10/01/2025; therefore, this medication will not be covered until then. If we receive requests prior to 07/01/2025 please respond with messages #2523 or #2524.
- FDA approved ages for HAE Medications:
  - For prophylaxis:
    - Andembry – 12 years of age and older
    - Cinryze and Haegarda - 6 years of age and older
    - Orladeyo – 12 years of age and older
    - Takhzyro – 2 years of age and older
  - For acute treatment:
    - Berinert – studied in children as young as 5 years of age; approved for adult and pediatric patients (age undefined in Prescribing Information)
    - Ekterly – 12 years of age and older
    - Firazyr – 18 years of age and older
    - Ruconest – 13 years of age and older
    - Kalbitor – 12 years of age and older

<u>PULMONARY HYPERTENSION AGENTS</u>

- **OPSUMIT/OPSYNVI**
  - **Interim Criteria (*if applicable*):**
  - *Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:*
  1. *An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and*
  2. *Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:*
     - *Adcirca® (tadalafil) or Revatio® (sildenafil); and*
     - *Letairis® (ambrisentan) or Tracleer® (bosentan); and*
  3. *Medical supervision by a pulmonary specialist or cardiologist; and*
  4. *Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and*

5. *Female members of reproductive potential must have a negative pregnancy test prior to initiation of Opsumit® or Opsynvi® and, if pregnancy occurs during therapy, Opsumit® or Opsynvi® must be discontinued immediately; and*
6. *A quantity limit of 30 tablets per 30 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**

- **ADCIRCA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Requests for compounded tadalafil suspension utilizing generic tadalafil 20mg tablets can be considered for approval (without a reason for why they can't use sildenafil) for patients with a diagnosis of PAH and prescribed by a pulmonary specialist or cardiologist.
    - ***Please double check the GCN to ensure that it is a covered product.***
    - Alyq is a generic of tadalafil.
- **ORENITRAM**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - There are 3 titration packs now available. If PA requests are submitted for all 3 packs at the same time, please approve all 3 but stagger the approval dates based on when the member will need to fill the subsequent packs.
- **REVATIO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Drug interactions and contraindications for sildenafil:
    - The use of nitrates and/or alpha-blockers is contraindicated due to the potential of potentiation of hypotensive effects.
    - Substantial increase in AUC and Cmax of sildenafil occurs with coadministration with ritonavir due to CYP450 3A4 inhibition.
    - Epistaxis was increased with concomitant use of vitamin K antagonists.
    - Inhibitors of CYP450 3A4 and 2C9 may increase bioavailability and Cmax of sildenafil.
    - Bosentan is an inducer of CYP3A4 resulting in a decrease of sildenafil bioavailability; in turn, sildenafil is an inhibitor of 3A4 and 2C9 which increases Bosentan bioavailability.
- **TADLIQ**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please consider approval of Tadliq for members who are stable on tadalafil from the hospital and discharging on the medication as long as it is an appropriate diagnosis and the member is being supervised by a specialist. Please also consider approval of Tadliq for members who have been stable on compounded tadalafil suspension prior to Tadliq availability. For members who have been on tadalafil, it may still be appropriate to ask if they can use the oral tablet formulation, depending on the age

of the member. Please use your clinical judgment based on the age and the dose requested.

- **TYVASO DPI AND YUTREPIA**
  - **Interim Criteria (*if applicable*):**
  - *Tyvaso DPI® (Treprostinil Powder for Inhalation) and Yutrepia™ (Treprostinil Powder for Inhalation) Approval Criteria:*

1. *An FDA approved diagnosis of 1 of the following:*
   - *Pulmonary arterial hypertension (PAH); or*
   - *Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and*
     - *Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and*
2. *Medical supervision by a pulmonary specialist or cardiologist; and*
3. *For a diagnosis of PAH, Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:*
   - *Revatio® (sildenafil) or Adcirca® (tadalafil); and*
   - *Letairis® (ambrisentan) or Tracleer® (bosentan); and*
4. *A patient-specific clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and*
5. *For a diagnosis of PH-ILD, a patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - The rebate agreement for Yutrepia™ starts on 10/01/2025; therefore, this medication will not be covered until then.
  - Please keep in mind that many patients will remain on other PAH therapies (e.g., endothelin receptor antagonists, PDE-5 inhibitors) and Tyvaso DPI® would likely be an add on therapy. We won't ask them to discontinue these medications prior to starting Tyvaso DPI®. However, if the member is on another medication acting on the prostacyclin pathway (e.g., oral or injectable treprostinil, selexipag, iloprost, epoprostenol), please verify if the other medication will be discontinued first if all other Tyvaso DPI® criteria are met. The safety and efficacy of using multiple prostacyclin agents concurrently have not been determined.
- **UPTRAVI**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Keep in mind that many patients will remain on other PAH therapies (example: endothelin receptor antagonist, PDE-5 inhibitor) and Uptravi® will be an add on therapy. We won't ask them to dc these medications prior to starting Uptravi®.
- **REVCOVI**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**

- Most patients will only require a couple months of this until they can do a stem cell transplant (very young babies). If they are requesting for long-term therapy we just need to know why. It might prevent potential off-label use of this medication. Overall if requests follow the package labeling we should consider approval.

- **RYPLAZIM**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Please note: Treatment consideration should be given to members with documented clinical symptoms of plasminogen deficiency type 1 and a plasminogen activity level <75% if all other criteria are met.
- **LODOCO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes(*for consideration toward approval*):**
  - Lodoco is currently not a covered product due to no federal drug rebate agreement with the manufacturer. Criteria will only apply if the manufacturer obtains a federal drug rebate.
  - Clinical ASCVD is defined by the American Heart Association as:
    - Coronary heart disease (CHD): myocardial infarction, angina, and coronary artery stenosis
    - Cerebrovascular disease: transient ischemic attack, ischemic stroke, and carotid artery stenosis
    - Peripheral artery disease (PAD): claudication
    - Aortic atherosclerotic disease: abdominal aortic aneurysm and descending thoracic aneurysm.
  - Lodoco is indicated for patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease; however, the 2023 AHA/ACC Guidelines for the Management of Patients with Chronic Coronary Disease (https://doi.org/10.1161/CIR.0000000000001168) only recommends the use of colchicine for secondary prevention. Also, the clinical trial for Lodoco only included patients with stable coronary artery disease meaning they already had clinical ASCVD, and it was only studied in secondary prevention. Therefore, we will be limiting the use of Lodoco to members with clinical ASCVD.
  - Guideline directed therapy includes ACE/ARBs, antiplatelets or anticoagulants, beta blockers, or lipid-lowering agents (i.e. statins, PCSK9 inhibitors).
  - There are several off-label diagnoses for colchicine that may be appropriate (please check Micromedex); however, due to cost do not approve Lodoco for off-label diagnoses. In the past, 0.6mg tablets have been used, if appropriate that could be an alternative. In the past, 0.6mg tablets have been used, if appropriate that could be an alternative and the 0.6mg tablet no longer requires a PA.
  - The DUR board recommended we add criteria #8, and after further research, there is support to use the 0.6mg tablet in the literature (Deftereos SG, Beerkens FJ, Shah B, et al. Colchicine in Cardiovascular Disease: In-Depth Review. Circulation 2022; 145(1): 61-78.). Although the 0.6mg tablet has not be studied in the CV prevention setting this was likely due to the availability of the 0.6mg tablet in the study location

of Australia where only the 0.5mg tablet is available. Historically, both the 0.5mg and 0.6mg tablets have been considered low dose colchicine products, so the use of the 0.6mg will be preferred based on cost.

- **WINREVAIR**
  - **Interim Criteria (*if applicable*):**
  - *Winrevair™ (Sotatercept-csrk) Approval Criteria:*

1. *An FDA approved diagnosis of pulmonary arterial hypertension; and*
2. *Member must be 18 years of age or older; and*
3. *Previous failed trials of at least 1 of each of the following categories (alone or in combination):*
   - *Revatio® (sildenafil), Adcirca® (tadalafil), or Adempas® (riociguat); and*
   - *Letairis® (ambrisentan), Tracleer® (bosentan), or Opsumit® (macitentan); and*
   - *Orenitram® (treprostinil) or Uptravi® (selexipag); and*
4. *Medical supervision by a pulmonary specialist and/or cardiologist; and*
5. *Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation and subcutaneous (sub-Q) administration and proper storage of Winrevair™; and*
6. *Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and*
7. *Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and*
8. *A quantity limit of 1 kit every 3 weeks will apply.*

- **Additional Internal Notes(*for consideration toward approval*):**
- Is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class and reduce the risk of clinical worsening events.
- How Supplied: 45mg and 60mg lyophilized cake or powder in a single dose vial
- Dosing:
  - The recommended starting dose is 0.3mg/kg by subcutaneous (sub-Q) injection and a recommended target dose of 0.7mg/kg sub-Q every 3 weeks.
  - Dosage modifications due to increased hemoglobin (Hgb) and decreased platelets may be necessary. Hgb and platelets should be checked before each dose for the first 5 doses, or longer if values are unstable, and monitor periodically thereafter.
- Prescribing Information: https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf
- Coverage: Winrevair™ will be covered with a hard PA with the criteria listed below
- Quantity Limit: 1 kit every 3 weeks

- **<u>ANTICOAGULANTS & PLATLET AGGREGATION INHIBITORS</u>**
  - **ELIQUIS SPRINKLE & SUSPENSION**
    - **Interim Criteria (*if applicable*):**

- *Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension Approval Criteria:*

1. *Eliquis® tablet for oral suspension and Eliquis® Sprinkle capsule for oral suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use Eliquis® tablets must be provided; and*
2. *Clinical exceptions for the age restriction may be considered (e.g., documented dysphagia, weight-based dose cannot be achieved with the tablet formulation).*

- **Additional Internal Notes (*for consideration toward approval*):**

- **PRADAXA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Consider approval for members stable on a platelet aggregation inhibitor (e.g., new to SoonerCare/HAP, inpatient stabilization) even if it is not an FDA approved dx, as discontinuing the med would likely do more harm than continuing it.
  - Per the Journal of the American College of Cardiology, Non–vitamin K oral anticoagulants (NOACs) are recommended over warfarin in NOAC-eligible patients with atrial fibrillation (except with moderate-to-severe mitral stenosis or a mechanical heart valve).
  - Valvular atrial fibrillation: moderate-to-severe mitral stenosis, mechanical heart valve
  - Non-valvular atrial fibrillation: mild mitral stenosis, mitral regurgitation, aortic stenosis, aortic regurgitation, and tricuspid regurgitation, valve repair, valvuloplasty, bioprosthetic valves
  - Link to American College of Cardiology article: http://www.onlinejacc.org/content/early/2019/01/21/j.jacc.2019.01.011?_ga=2.176975328.450739321.1559936301-453488338.1559936301
- **SAVAYSA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Genotype testing is not covered.
  - Consider approval for members stable on a platelet aggregation inhibitor (e.g., new to SoonerCare/HAP, inpatient stabilization) even if it is not an FDA approved dx, as discontinuing the med would likely do more harm than continuing it.
  - Per the Journal of the American College of Cardiology, Non–vitamin K oral anticoagulants (NOACs) are recommended over warfarin in NOAC- eligible patients with atrial fibrillation (except with moderate-to-severe mitral stenosis or a mechanical heart valve).
  - Valvular atrial fibrillation: moderate-to-severe mitral stenosis, mechanical heart valve
  - Non-valvular atrial fibrillation: mild mitral stenosis, mitral regurgitation, aortic stenosis, aortic regurgitation, and tricuspid regurgitation, valve repair, valvuloplasty, bioprosthetic valves

- Link to American College of Cardiology article: http://www.onlinejacc.org/content/early/2019/01/21/j.jacc.2019.01.011?_ga=2.176975328.450739321.1559936301-453488338.1559936301

- **ANTIHYPERLIPIDEMIA AGENTS**
  - **LEQVIO**
    - **Interim Criteria (*if applicable*):**
    - *Leqvio® (Inclisiran) Approval Criteria:*

1. *An FDA approved indication as an adjunct to diet and exercise for the treatment of 1 of the following:*
    - *Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:*
      - *Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
      - *Both of the following:*
        - *Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and*
        - *History of tendon xanthomas in either the member, first degree relative, or second degree relative; or*
      - *Dutch Lipid Clinic Network Criteria score of >8; or*
    - *Established atherosclerotic cardiovascular disease (ASCVD); and*
      - *Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or*
    - *Primary hyperlipidemia; and*
      - *Member's untreated LDL-C level must be ≥190mg/dL; and*
      - *Current LDL-C level is ≥100mg/dL; and*
2. *Member must be 18 years of age or older; and*
3. *Documented trial of all of the following for at least 12 weeks in duration each:*
    - *High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and*
    - *Ezetimibe; and*
    - *Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and*
4. *Members with statin intolerance must meet 1 of the following:*
    - *Creatine kinase (CK) labs verifying rhabdomyolysis; or*
    - *An FDA labeled contraindication to all statins; or*
    - *Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or*
    - *Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*

5. *Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and*
6. *Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and*
    - *Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and*
        - *Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or*
        - *Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and*
7. *Initial approvals will be for the duration of 6 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Per the 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk, patients who have <50% reduction in LDL-C, LDL-C ≥55, or HDL-C ≥85 with maximally tolerated statin therapy should be considered for the addition of a nonstatin therapy. Ezetimibe and PCSK9 inhibitors (e.g., Repatha, Praluent) are the next typical options. Our criteria currently asks members to have tried ezetimibe with or without a statin before approval consideration of some antihyperlipidemic medications. The guidelines state that if a patient still needs >25% additional LDL-C lowering, that a PCSK9 inhibitor is preferred over ezetimibe due to their potential for greater LDL-C lowering compared to ezetimibe. Please take this into consideration when reviewing requests for a reason that ezetimibe may not be appropriate for the member.

- **EVKEEZA**
    - **Interim Criteria (*if applicable*):**
    - *Evkeeza® (Evinacumab-dgnb) Approval Criteria:*

1. *An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:*
    - *Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
    - *An untreated LDL >500mg/dL and at least 1 of the following:*
        - *Documented evidence of definite HeFH in both parents; or*
        - *Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and*
2. *Member must be 5 1 years of age or older; and*
3. *Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and*
4. *Members with statin intolerance must meet 1 of the following:*

        - *Creatine kinase (CK) labs verifying rhabdomyolysis; or*
        - *An FDA labeled contraindication to all statins; or*
    - *Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or*
    - *Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*
5. *Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and*
6. *Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and*
7. *Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for 5 months after discontinuation of therapy; and*
8. *Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.*

- **LIVALO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Claims to have fewer drug interactions. Pitavastatin is marginally metabolized by CYP2C9 and to a lesser extent by CYP2C8. Livalo® (pitavastain) and pravastatin are both OATP1B1 substrates and have very similar drug interaction profiles. Livalo® does however seem to have a few advantages over pravastatin but if a provider asks for Livalo® due to drug interaction, ask for names of the medications they are concerned about that may have an interaction and check to find another lower tiered alternative without the drug interaction on Lexicomp or Micromedex.
- **ALTOPREV**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - This is a long acting formulation of lovastatin. Ask for a clinically significant reason why member cannot use the Tier 1 immediate release lovastatin that does not require a PA. Immediate release lovastatin is also dosed once daily in the evening (same as long acting dosing).
- **OMEGA-3 FATTY ACIDS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - For use of Vascepa as an adjunct to maximally tolerated statin therapy to reduce CV risk, members should be on concurrent treatment with a statin. For this indication, Vascepa was not studied in patients with an intolerance or inability to take statins.

All patients in the clinical trials had to be on a stable dose of a maximally tolerated statin for at least 4 weeks prior to starting on Vascepa.

- **REPATHA**
    - **Interim Criteria (*if applicable*):**
    - *Repatha® (Evolocumab) Approval Criteria:*

1. *An FDA approved indication of 1 of the following:*
    - *Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:*
        - *Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
        - *Both of the following:*
            - *Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and*
            - *History of tendon xanthomas in either the member, first degree relative, or second degree relative; or*
        - *Dutch Lipid Clinic Network Criteria score of >8; or*
    - *Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:*
        - *Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
        - *An untreated LDL >500mg/dL and at least 1 of the following:*
            - *Documented evidence of definite HeFH in both parents; or*
            - *Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or*
    - *To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events; and*
        - *Supporting diagnoses/conditions/risk factors signifying increased risk of major adverse CV events must be submitted; or*
    - *Primary hyperlipidemia; and*
        - *Member's untreated LDL-C level must be ≥190mg/dL; and*
        - *Current LDL-C level is ≥100mg/dL; and*
2. *For HeFH or HoFH, member must be 10 years of age or older; and*
3. *For FDA approved indications other than HeFH or HoFH, the member must be 18 years of age or older; and*
4. *Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and*
    - *Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*
    - *LDL-C levels should be included following at least 12 weeks of treatment; and*
5. *Members with statin intolerance must meet 1 of the following:*

        - *Creatinine kinase (CK) labs verifying rhabdomyolysis; or*
        - *An FDA labeled contraindication to all statins; or*
        - *Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or*
        - *Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*
    6. *Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and*
    7. *Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and*
    8. *Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and*
    9. *A quantity limit of 2 syringes or auto-injectors per 28 days will apply; and*
    10. *Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.*
- **PRALUENT**
    - **Interim Criteria (*if applicable*):**
    - *Praluent® (Alirocumab) Approval Criteria:*
    1. *An FDA approved indication of 1 of the following:*
        - *Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:*
            - *Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
            - *Both of the following:*
                - *Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and*
                - *History of tendon xanthomas in either the member, first degree relative, or second degree relative; or*
            - *Dutch Lipid Clinic Network Criteria score of >8; or*
        - *Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:*
            - *Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or*
            - *An untreated LDL >500mg/dL and at least 1 of the following:*
                - *Documented evidence of definite HeFH in both parents; or*

        - *Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or*
    - *To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease (CVD); and*
        - *Documentation of established CVD; and*
        - *Supporting diagnoses/conditions and date of occurrence signifying established CVD; or*
    - *Primary hyperlipidemia; and*
        - *Member's untreated LDL-C level must be ≥190mg/dL; and*
        - *Current LDL-C level is ≥100mg/dL; and*
2. *For HeFH, member must be 8 years of age or older; and*
3. *For FDA approved indications other than HeFH, the member must be 18 years of age or older; and*
4. *Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and*
    - *Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*
    - *LDL-C levels should be included following at least 12 weeks of treatment; and*
5. *Members with statin intolerance must meet 1 of the following:*
    - *Creatinine kinase (CK) labs verifying rhabdomyolysis; or*
    - *An FDA labeled contraindication to all statins; or*
    - *Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or*
    - *Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and*
6. *Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and*
7. *Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and*
8. *Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and*
9. *A quantity limit of 2 syringes or pens per 28 days will apply; and*
10. *Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.*

- **<u>ANTIHYPERTENSIVE AGENTS</u>**
    - **Updated Tier Chart 10/03/25**

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)		lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
perindopril (Aceon®)		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	**Tier-2**	**Special PA**
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	fosinopril/HCTZ (Monopril-HCT®)
enalapril/HCTZ (Vaseretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		
Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Special PA**
candesartan (Atacand®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan (Edarbi®)
irbesartan (Avapro®)	telmisartan/HCTZ (Micardis® HCT)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)		candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		eprosartan (Teveten®)
losartan/HCTZ (Hyzaar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan (Benicar®)		**losartan oral suspension (Arbli™)**
olmesartan/amlodipine (Azor®)		telmisartan/amlodipine (Twynsta®)
olmesartan/HCTZ (Benicar HCT®)		valsartan 4mg/mL oral solution
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	amlodipine/celecoxib (Consensi®)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	diltiazem CD 360mg (Cardizem® CD)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	levamlodipine (Conjupri®)

diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	perindopril/amlodipine (Prestalia®)
benazepril/amlodipine (Lotrel®)		

- **ARBLI**
    - **Interim Criteria (*if applicable*):**
    - *Arbli™ (Losartan Oral Suspension) Approval Criteria:*
    1. *An age restriction of 11 years and older will apply with the following criteria:*
        - *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation in place of the oral suspension, even when the tablets are split or crushed, must be provided (e.g., dose stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and*
        - *Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and*
        - *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.*
        - *A quantity limit of 330mL per 33 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **HEMICLOR**
    - **Interim Criteria (*if applicable*):**
    - *Hemiclor™ (Chlorthalidone 12.5mg Tablet) Approval Criteria:*
    1. *An FDA approved diagnosis of hypertension; and*
    2. *Member must be 18 years of age or older; and*
    3. *A patient-specific, clinically specific reason (beyond convenience) why the member cannot split a generic chlorthalidone 25mg tablet to achieve a 12.5mg dose must be provided; and*
    4. *A quantity limit of 240 tablets per 30 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **BISOPROLOL FUMARATE 2.5 MG TABLET**
    - **Interim Criteria (*if applicable*):**
    - *Bisoprolol Fumarate 2.5mg Tablet Approval Criteria:*
    1. *A patient-specific, clinically specific reason (beyond convenience) why the member cannot split the 5mg tablet to achieve the 2.5mg dose must be provided; and*
    2. *A quantity limit of 30 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **CAROSPIR**
  - **Interim Criteria (*if applicable*):**
  - *CaroSpir® (Spironolactone Oral Suspension) Approval Criteria:*
    1. *An FDA approved indication; and*
    2. *A patient-specific, clinically significant reason why the member cannot use spironolactone oral tablets must be provided, including but not limited to the following:*
       - *Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or*
       - *Clinically indicated dose cannot be achieved with available tablet formulations; or*
       - *Dose was stabilized inpatient; and*
    3. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Spironolactone suspension is not therapeutically equivalent to spironolactone tablets. Additionally, the National Institute for Occupational Safety and Health (NIOSH) recommends appropriate procedures for handling of spironolactone tablets in healthcare settings. When cutting, crushing, manipulating, or handling uncoated tablets, NIOSH recommends the use of double gloves and a protective gown. Therefore, if member is unable to swallow tablets or requires a dose that is not commercially available in the oral tablet formulation, they would not be required to provide reason they could not cut, crush, or otherwise manipulate the tablets and these should be considered for approval of the oral suspension if other criteria is met.
  - Per terms of CY24 supplemental rebate agreement, we cannot require a trial of spironolactone tablets, but we can ask why the member cannot use the tablet formulation.

- **TRYVIO**
  - **Interim Criteria (*if applicable*):**
  - *Tryvio™ (Aprocitentan) Approval Criteria:*

1. *An FDA approved diagnosis of hypertension; and*
2. *Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate occasions within the last month (documentation of blood pressure readings with dates must be submitted); and*
3. *Prescriber must rule out other causes of elevated blood pressure including:*
   - *Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and*
   - *White coat hypertension; and*
   - *Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio; and*

4. *Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and*
5. *Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and*
6. *Female members of reproductive potential must not be pregnant or breastfeeding during treatment with Tryvio™ and must be willing to use an effective method of contraception during treatment and for 1 month after discontinuing Tryvio™; and*
7. *Female members of reproductive potential must have a negative pregnancy test prior to initiation of Tryvio™ and if pregnancy occurs during therapy, Tryvio™ must be discontinued immediately; and*
8. *Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh Class B or C); and*
9. *Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and*
10. *Member must not have severe anemia prior to initiation of Tryvio™; and*
11. *A quantity limit of 30 tablets per 30 days will apply; and*
12. *Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.*
    - **Additional Internal Notes (*for consideration toward approval*):**

- **HEMANGEOL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The Hemangeol bottle is stable for 2 months after first opening. The cost of each bottle is the same whether they fill the 50mL or 120mL bottle, so we should ask them to use the 120mL bottle regardless of the dosing regimen.
    - Approval Length: 1 year
    - Quantity Limit: 120/30
- **TEKTURNA, TEKTURNA HCT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Tekturna is available as 37.5mg Oral Pellets and 150mg Tablets or 300mg Tablets. The criteria is different depending on the formulation.

- **VALSARTAN ORAL SOLUTION**
    - **Interim Criteria (*if applicable*):**
    - ***Valsartan 4mg/mL Oral Solution Approval Criteria:***

1. *An FDA approved diagnosis of 1 of the following:*
    - *Hypertension in adults and pediatric members 6 years of age and older; or*
    - *Heart failure; or*
    - *Post-myocardial infarction; and*
2. *A patient specific, clinically significant, reason why the member cannot use valsartan tablets, or the oral suspension prepared from the tablets (i.e., dose was stabilized inpatient), must be provided; and*
3. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and*
4. *A quantity limit of 360mL per 36 days will apply.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Valsartan tablets are film coated so they cannot be crushed. Consider approving the solution for members who cannot swallow the tablets or pediatric members who are on a dose that is not available in the tablets.
- **LABETALOL 400MG TAB**
    - **Interim Criteria (*if applicable*):**
    - *Labetalol Hydrochloride 400mg Tablet Approval Criteria:*

1. *An FDA-approved indication of the management of hypertension; and*
2. *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use labetalol hydrochloride 200mg tablets, which are available without prior authorization, to achieve a 400mg dose must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Labetalol Hydrochloride (HCL) is an adrenergic receptor blocking agent that has both selective alpha1-adrenergic and non-selective beta-adrenergic receptor blocking actions in a single substance. It is indicated in the management of hypertension. Labetalol HCl tablets may be used alone or in combination with other antihypertensive agents, especially thiazide and loop diuretics. A new 400mg strength is now being marketed.
    - How Supplied: 100mg, 200mg, 300mg, and 400mg tablets
    - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27e4ab03-c17b-4268-912c-e45a5e8f8dd8
    - Coverage: Labetalol HCL 400mg tablet will be covered with a hard PA with the criteria listed. The other strengths of labetalol are available without a PA.
    - Quantity Limit: 60 tablets per 30 days
- **INZIRQO**
    - **Interim Criteria (*if applicable*):**
    - *Inzirqo™ (Hydrochlorothiazide Oral Suspension) Approval Criteria:*

1. *For members 7 years of age or older, the following criteria will apply:*
    - *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation in place of the oral*

suspension, even when the tablets are crushed, must be provided (e.g., dose stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and

2. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Inzirqo™ (hydrochlorothiazide oral suspension) is an oral suspension formulation of hydrochlorothiazide indicated in adult and pediatric patients for the treatment of hypertension or the treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease, including the nephrotic syndrome.
- How Supplied: Powder for oral suspension that is reconstituted to 10mg/mL
- Dosing and Administration:
  - Adults: 25mg to 100mg orally daily as single or divided doses
  - Pediatrics: 1mg/kg to 2mg/kg per day in single or divided doses not to exceed 37.5mg/day in patients <2 years of age or 100mg/day in children 2 to <13 years of age
  - Patients <6 months of age may require doses up to 3mg/kg/day in 2 divided doses
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219141s000lbl.pdf
- Coverage: Inzirqo™ will be covered without a PA for members younger than 7 years of age. For members 7 years of age or older, a PA will be required to override the age restriction, with the criteria listed below.
  - Quantity Limit: 240mL per 30 days

- **10/2024 ANTIHYPERTENSIVE LIQUID FORMULATION UPDATES**
  - The criteria for the antihypertensive medications is being updated to clarify the use of liquid formulation products.
  - Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:
    - Angiotensin I Converting Enzyme Inhibitors (ACEIs):
    - **Epaned® (Enalapril Solution) Approval Criteria:**
      1. *An age restriction of 7 years or older will apply with the following criteria:*
      2. *A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided; and*
      3. *Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and*
      4. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.*
    - **Qbrelis® (Lisinopril Oral Solution) Approval Criteria:**
      1. *A patient-specific, clinically significant reason why the member cannot use lisinopril oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient,*

clinically indicated dose cannot be achieved by splitting available tablet formulations); and

2. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.*

- ACEI/Hydrochlorothiazide (HCTZ) Combination Products:
- **Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:** *A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.*
- Calcium Channel Blockers (CCBs):
- **Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:** *A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.*
- **Conjupri® (Levamlodipine Tablets) Approval Criteria:** *A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.*
- **Consensi® (Amlodipine/Celecoxib Tablets) Approval Criteria:** *A patient-specific, clinically significant reason why the member cannot use the individual components separately, which are available without prior authorization, must be provided; and a quantity limit of 30 tablets per 30 days will apply.*
- **Lopressor® (metoprolol tartrate oral solution) Approval Criteria**
- *A patient-specific, clinically specific reason (beyond convenience) why the member cannot use generic metoprolol tartrate tablets, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and*

- *A quantity limit of 1,200mL per 30 days will apply; and*
    - *For members who require increased doses above 400mg/day, a quantity limit override may be approved with the submission of supporting clinical documentation.*

Internal comment: *Once a bottle has been opened, it should be used within 30 days. Solution concentration is 10mg/mL.*

- **Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:**
    1. *An FDA approved diagnosis of 1 of the following:*
        - *Hypertension in adults and pediatric members 6 years of age and older; or*
        - *Coronary artery disease; or*
        - *Chronic stable angina; or*
        - *Vasospastic angina; and*
    2. *A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are crushed, must be provided; and*

3. *Clinical exceptions for age restrictions may be considered for doses stabilized inpatient or for clinically indicated doses that cannot be achieved by splitting available tablet formulations; and*
4. *For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and*
5. *A quantity limit of 300mL per 30 days will apply.*

- ACEI/CCB Combination Products:
  - **Prestalia® (Perindopril/Amlodipine) Approval Criteria:**
    1. *An FDA approved diagnosis; and*
    2. *Documented trials of inadequate response to 2 Tier-1 angiotensin I converting enzyme inhibitors (ACEIs) in combination with amlodipine; and*
    3. *A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided; and*
    4. *A quantity limit of 30 tablets per 30 days will apply.*
  - **Sotylize (Sotalol Oral Solution) Approval Criteria:**
    1. An FDA approved diagnosis of life-threatening ventricular arrhythmias or for the maintenance of normal sinus rhythm in members with highly symptomatic atrial fibrillation/flutter; and
    2. A patient-specific, clinically significant reason why the member cannot use sotalol oral tablets in place of the oral solution formulation (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
    3. For pediatric members, a recent weight or body surface area (BSA) must be provided on the prior authorization request; and
    4. A quantity limit of 64mL per day or 1,920mL per 30 days will apply.

- **Additional Internal Comments (*for consideration toward approval*)**:
- Valsartan tablets are film coated so they cannot be crushed. Consider approving the solution for members who cannot swallow the tablets or pediatric members who are on a dose that is not available in the tablets. The Diovan package labeling recommends the use of an extemporaneously compounded valsartan 4mg/mL suspension for pediatric patients aged 1 to 5 years, for patients >5 years who cannot swallow tablets, and in pediatric patients for whom the calculated dose (mg/kg) does not correspond to the available tablet strengths. Lexicomp has dosing information for using the suspension for patients down to 6 months of age weighing ≥6kg. According to package labeling the compounded suspension can be stored for 30 days at room temperature or up to 75 days in the refrigerator if in an amber glass bottle.

- **<u>CARDIOVASCULAR DISEASE (CVD/MASH)</u>**
  - **WEGOVY**
    - **Interim Criteria (*if applicable):***

- *Wegovy® (Semaglutide) Approval Criteria [Metabolic Dysfunction-Associated Steatohepatitis (MASH) Diagnosis]:*

1. *An FDA approved indication of noncirrhotic MASH; and*
2. *Member must be 18 years of age or older; and*
3. *Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):*
    - *FibroScan with vibration controlled transient elastography (VCTE) ≥8kPa and controlled attenuation parameter (CAP) ≥280dB/min; or*
    - *Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or*
    - *Liver biopsy showing stage F2 or F3 fibrosis with NASH; and*
4. *Member must not have chronic liver disease other than metabolic dysfunction-associated steatotic liver disease (MASLD); and*
5. *Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and*
6. *Wegovy® must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and*
7. *Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:*
    - *Type 2 diabetes; and*
    - *Dyslipidemia; and*
    - *Hypertension; and*
8. *Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and*
9. *Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and*
10. *Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and*
    - *Approvals will be for 4 weeks at a time to allow for proper dose escalation; and*
    - *An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and*
    - *Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and*
11. *Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:*
    - *Member is tolerating maintenance dosing; and*
    - *Member has not developed T1DM or T2DM; and*
    - *Member is continuing a reduced calorie diet and increased physical activity in conjunction with Wegovy®; and*

12. *A quantity limit of 4 pens per 28 days will apply; and*
13. *Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.*

- **Additional Internal Notes (*for consideration toward approval):***
- The OK Wegovy-specific criteria should be used to review cases submitted with any FDA-approved diagnosis. If the submitted diagnosis is *not* FDA-approved, then the off-label policy may be applied.

- **AMYLOIDOSIS AGENTS**
  - **ATTRUBY**
    - **Interim Criteria (*if applicable*):**
    - *Attruby™ (Acoramidis) Approval Criteria:*

1. *An FDA approved indication for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and*
2. *Diagnosis confirmed by:*
   - *Genetic confirmation of transthyretin (TTR) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and*
   - *Cardiac imaging (including ultrasound or MRI) confirming cardiac involvement; and*
3. *Presence of amyloid deposits confirmed by:*
   - *Nuclear scintigraphy; or*
   - *Endomyocardial biopsy; and*
4. *Member must be 18 years of age or older; and*
5. *Member must have medical history of heart failure (NYHA Class I to III); and*
6. *Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and*
7. *Attruby™ must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and*
8. *Attruby™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis), or Wainua™ (eplontersen); and*
9. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and*
10. *A quantity limit of 112 tablets per 28 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Attruby™ (acoramidis) is a transthyretin (TTR) stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization. Attruby™ is believed to preserve the native function of TTR by stabilizing its structure and preventing the deposition of the harmful protein deposits characteristic of the pathology ATTR-CM.
- How Supplied: 356mg film-coated tablet
- Dosage and Administration:
  - 712mg orally twice daily with or without food

        - Should be swallowed whole without cutting, crushing, or chewing
        - Should avoid concomitant use with UDP-glucuronosyltransferases (UGT) inducers and strong CYP3A4 inducers
        - Consider more frequent monitoring for evidence of increased exposure to CYP2C9 substrates when co-administered with Attruby™
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216540s000lbl.pdf
    - Coverage: Attruby™ will be covered with a hard PA with the criteria listed above.
    - Quantity Limit: 112 tablets per 28 days
- **AMVUTTRA**
    - **Interim Criteria (*if applicable*):**
    - *Amvuttra® (Vutrisiran) Approval Criteria:*

1. *An FDA approved indication of 1 of the following:*
    - *The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis or*
    - *The treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular mortality, cardiovascular hospitalizations, and urgent heart failure visits; and*
2. *For the diagnosis of hATTR-PN:*
    - *Diagnosis confirmed by genetic testing identifying a transthyretin (TTR) gene mutation (results of genetic testing must be submitted); and*
    - *Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and or*
3. *For the diagnosis of ATTR-CM:*
    - *Diagnosis confirmed by:*
        - *Genetic confirmation of transthyretin (TTR) gene mutation or wild-type amyloidosis (results of genetic testing must be submitted); and*
        - *Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and*
    - *Presence of amyloid deposits confirmed by:*
        - *Nuclear scintigraphy; or*
        - *Endomyocardial biopsy; and*
    - *Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and*
4. *Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and*
5. *Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and*
6. *Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and*
7. *Prescriber must confirm the member has not undergone a liver transplant; and*

8. *Amvuttra® will not be approved for concomitant use with Attruby™ (acoramidis), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), Vyndamax® (tafamidis), or Wainua™ (eplontersen); and*
9. *Authorization for Amvuttra® for the diagnosis of hATTR-PN will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and*
10. *A quantity limit of 0.5mL per 90 days will apply; and*
11. *Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **ONPATTRO**
  - **Interim Criteria (*if applicable*):**
  - *Onpattro® (Patisiran) Approval Criteria:*

1. *An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; and*
2. *Diagnosis confirmed by genetic testing identifying a transthyretin (TTR) gene mutation (results of genetic testing must be submitted); and*
3. *Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and*
4. *Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and*
5. *Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and*
6. *Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and*
7. *Prescriber must confirm the member has not undergone a liver transplant; and*
8. *Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and*
9. *Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua™ (eplontersen); and*
10. *Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
11. *Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.*

- **Additional Internal Notes (*for consideration toward approval*):**

CENTRAL NERVOUS SYSTEM/BEHAVIORAL HEALTH

- **FIBROMYALGIA AGENTS**
  - **SAVELLA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Savella + Lyrica: Use of Savella and Lyrica concomitantly is typically not covered together if they are using both for the same diagnosis (fibromyalgia). They could be covered together in a very unique circumstance (example if member were stable on Lyrica for seizures and wanted Savella for fibromyalgia), but these should be evaluated on a case-by-case basis. The pharmacist would need to use clinical judgment in these circumstances. The pharmacist should evaluate if member is stable, prescriber specialty, trials in history, etc. The prescriber should be very specific on the diagnosis of each.
    - Savella + duloxetine: Use of Savella and duloxetine concomitantly is not typically covered together due to duplication of therapy (SNRI).
  - **LYRICA CR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Lyrica CR is NOT FDA approved for fibromyalgia or as treatment of seizures. In general it should not be approved for these diagnoses. Please use clinical judgement to evaluate requests for seizures if the patient is stable.
- **MEDICATION ASSISTED TREATMENT AGENTS**
  - **BUPRENORPHINE PRODUCTS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Effective July 31, 2019, generic buprenorphine/naloxone SL tablets and Vivitrol are available without prior authorization; single ingredient buprenorphine also available without a PA for female members of childbearing age (see below). Brand Suboxone films were included, but became non-preferred 01/01/2021.
    - For single-ingredient buprenorphine (Subutex) only: Instead of members with a pregnancy diagnosis going through without a PA, OHCA decided to let members who are female of childbearing age to process without a PA
    - If you receive a request for Subutex that is denying for QL (>16mg/day) for a female 16-50 years of age or any dose for a male or for a female >50 years of age, please ask why they cannot use Suboxone if it is not documented. This applies even if the member has been filling Subutex without a PA (for 16mg/day or less). The intent is to cover generic Subutex for pregnant members, and if the member is not pregnant (or breastfeeding) or has a serious allergy/ADR to naloxone, they should be using Suboxone. This applies even if they have been filling Subutex at a lower dose without a PA; however, we do not want to cut members off completely and have them relapse, so a good approach would be to approve the request x1 month and ask for documentation of why they can't use Suboxone (along with high dose info, if applicable).
    - For pregnant members prescribed Subutex, if prescriber provides the estimated date of delivery (EDD) please approve the duration of the pregnancy. Buprenorphine

is appropriate for nursing mothers as the risk of naloxone to the infant cannot be ruled out.
    - Zubsolv, and Suboxone do not count towards the brand limit since these medications are frequently dispensed in 7-day supplies.
    - If the day supply on Suboxone is less than 10, the claim will bypass the early refill (5113) rejection.
    - Zubsolv (buprenorphine/naloxone tablets) – Are non-preferred products; however, If they have been on a Zubsolv, we can continue the medication (as long as it is clinically appropriate). Also, if they would like to use Zubsolv due to the patient being high risk or wanting a lower abuse potential product we can approve (as long as it is clinically appropriate). [The computer has been letting PA's for Zubsolv process automatically if they have a claim for any of the three medications in the past 31 days (as long as it doesn't exceed the quantity limit and they don't have recent opioid claims). We have been handling manual PA's differently than the computer. OHCA would like us to handle these similarly to the computer due to the reduced abuse potential with Zubsolv.]
    - Chronic Pain: Please be careful with Suboxone and other buprenorphine PA's. If they have recent approved PA's for a diagnosis of opioid use disorder and they happen to write chronic pain on a PA, that is NOT grounds for denial or incompletion. Additionally, if they write both opioid dependence and chronic pain that should be considered for approval. They have the diagnosis we are looking for in that case and these drugs can help with pain.
- **Opioid Treatment Programs (OTPs):**
    - In collaboration with the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS), OHCA has decided to start covering quantity limit overrides (QLOs) x1 year for medication-assisted treatment (MAT) medications (once the required information to justify the high dose is submitted) for members receiving treatment in an Opioid Treatment Program (OTP), as members would receive additional counseling and monitoring through the OTP. OTPs are federally certified through the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). OHCA is planning to monitor these PAs going forward to determine if the approval length needs to be updated for members receiving treatment through an OTP due to frequent prescriber changes or other issues.
    - OTPs can currently bill for MAT medications as a medical claim without any limitations on quantity per day.
    - The OTP will need to make a prominent note on the QLO form "the member is under the care of XXXX OTP along with the OTP SoonerCare Provider ID and location code". The requirement to document that the member is receiving treatment at an OTP and provide the OTP's name and SoonerCare Provider ID on the QLO form was communicated to ODMHSAS (and the SoonerCare-contracted OTPs) by OHCA.
    - All other PA criteria will still apply; the only difference is the approval length (1 year vs. 3 months). Additionally, similar to normal MAT approvals, MAT claims will still deny if the member has a recent opioid claim. If you receive a QLO/high dose

request for a MAT medication that is approvable (prescriber has submitted the required high dose info, UDS, etc.), and it's documented that the member is receiving treatment through an OTP, please approve the request for 1 year.
    - Check the provider ID (specific to the service location) that is documented for the OTP on the QLO form in ICE to ensure that "136- OTP" is listed as the specialty prior to approving the QLO for 1 year (see example in ICE below). Only those with "136-OTP" as the provider specialty should be approved for 1 year (after meeting all other criteria).
- **LUCEMYRA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - While Lucemyra™ is the first and only non-opioid treatment for management of opioid withdrawal symptoms, it may not completely prevent symptoms and is only approved for use up to 14 days. Lucemyra™ is not a treatment for opioid use disorder (OUD), but can be used as part of a broader, long-term treatment plan for managing OUD. The cost of Lucemyra™ is significant ($23.27 per tablet resulting in a daily cost of $279.24 or $3,909.36 per 14-day treatment course). We want this to be available to those who need it, we just have to make sure the right patient gets it. Lucemyra™ is an alpha-2 adrenergic agonist very similar to clonidine. MicroMedex has clonidine as IIb or better recommendation for opioid withdrawal. Up-to-Date states the following: In the United States, clonidine is the most widely used of these agents for opioid withdrawal. The centrally-acting lofexidine is the preferred agent in the United Kingdom. While tizanidine is a centrally-acting alpha-2 adrenergic agonist, it has not been widely studied as a primary detoxification agent, but is used to relieve muscle spasms occurring during opioid withdrawal. Direct comparison of lofexidine and clonidine has not been definitive, but available research suggests equal efficacy between the two drugs with a trend towards less hypotension with lofexidine. Clonidine can be taken orally or administered via a clonidine patch, changed weekly, at doses equivalent to oral clonidine 0.1, 0.2, and 0.3 mg twice daily. Many programs do not use clonidine patches for supervised withdrawal because of the potential need to make frequent dose adjustments, while other programs prefer clonidine patches because they minimize interruptions and do not require patient requests for medication, which can be difficult to distinguish from drug seeking. The transdermal patch does not provide adequate blood levels for the first 72 hours after application, so oral dosing is required for the first three days regardless of whether the patch is used.
- **BRIXADI, SUBLOCADE**
    - **Interim Criteria (*if applicable*):**
    - *Brixadi™ [Buprenorphine Extended-Release (ER) Injection] and Sublocade® (Buprenorphine ER Injection) Approval Criteria:*

1. *An FDA approved diagnosis of moderate-to-severe opioid use disorder; and*
2. *Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and*
3. *Concomitant treatment with opioids (including tramadol) will be denied; and*

4. *Medication should only be prepared and administered by a health care provider; and*
5. *A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and*
6. *In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and*
7. *Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and*
8. *The following quantity limits will apply:*
    - *Brixadi™ 8mg/0.16mL, 16mg/0.32mL, 24mg/0.48mL, and 32mg/0.64mL: 4 weekly doses per 28 days; or*
    - *Brixadi™ 64mg/0.18mL, 96mg/0.27mL, and 128mg/0.36mL: 1 monthly dose per 28 days; or*
    - *Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days; and*
        - *A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Please give consideration to patients who prescribers indicate are at risk for abuse of the transmucosal buprenorphine products; this product is mailed directly to the prescriber from the pharmacy and then injected. This limits abuse and potential distribution of the tablet formulations.
- The Sublocade label was updated to allow initiation after a single dose of transmucosal buprenorphine or for patients already being treated with buprenorphine. Additionally, the dosing was also updated to allow the second 300mg dose to be administered as early as 1 week after the first injection.
- The initial dosing for Sublocade is 2 doses of the 300mg strength. The second initial dose may be administered as early as 1 week after the first injection, so to prevent delays please pay attention to the dosing regimen they provide and add a quantity limit override to the initial approval if they need the second dose before 28 days. Also, before completing the request please double-check the dosing regimen is clear and ask for the regimen if it is not provided. Additionally, they may not know until after the first dose is given that they will need the second dose early, so please consider approving early refill overrides for members needing the second dose earlier than 28 days.

- **<u>MULTIPLE SCLEROSIS AGENTS</u>**
    - **GENERAL INFORMATION**
        - Please use special consideration when evaluating prior authorizations for multiple sclerosis medications.
        - This is a sensitive class of medications and the prescribers are usually specialists.
        - When considering members who are just starting therapy with these medications or who are newly diagnosed, we should be cognizant that the diagnosis may need to be investigated on our end. You may need to call for clarification.

- Frequently when a person is newly diagnosed, they have had relapses but they aren't aware what they were because they haven't been diagnosed with MS yet. Relapse Remitting Multiple Sclerosis (RRMS) is based on symptoms experiencing (relapse), and the clinical findings on the brain MRI.
- The ICD-9 code only states "multiple sclerosis" so isn't specific, but there are 4 subtypes, so one wouldn't just be diagnosed as having MS, it would be a specific subtype (RRMS, primary progressive MS, secondary progressive MS, or progressive relapsing).
- This means if they send in notes, you should be sure and read them as frequently the office notes provide the specific subtype.
- Helpful information on the National MS society website: http://www.nationalmssociety.org/What-is-MS/Types-of-MS.

- **BRIUMVI**
  - **Interim Criteria (*if applicable*):**
  - *Briumvi® (Ublituximab-xiiy) Approval Criteria:*

1. *An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and*
2. *Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and*
3. *Approvals will not be granted for concurrent use with other disease-modifying therapies; and*
4. *Briumvi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Briumvi® will be administered; and*
    - *Briumvi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or*
    - *Briumvi® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Briumvi®; and*
5. *Verification from the prescriber that all baseline assessments have been completed prior to initiating Briumvi® and continued monitoring while on therapy, where applicable, will be performed as per package labeling, including:*
    - *Hepatitis B virus (HBV) testing and verification that the member does not have active HBV; and*
    - *Quantitative serum immunoglobulin testing at baseline, during, and after discontinuation of treatment until B-cell repletion; and*
    - *Liver function tests (LFTs) at baseline and monitoring for signs and symptoms of hepatic injury during treatment ; and*
6. *Prescriber must confirm that the member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and*
7. *Verification from the prescriber that member has no active infection(s); and*

8. *Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and*
9. *Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Briumvi® therapy and for 6 months after the last infusion of Briumvi®; and*
10. *Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **AMPYRA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - If we get an Ampyra request where the doctor doesn't do the EDSS score but provide us other information about the member's functional systems and disability, is a fairly good explanation of the EDSS score and different functional systems.
  - The link is: http://www.va.gov/MS/Professionals/Diagnosis/Kurtzke_Expanded_Disabilit y_ Status_Scale.asp
  - Not considered a disease modifying drug and may be used with other therapies and vice versa.
- **COPAXONE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Glatopa is the new generic version of Copaxone 20mg/mL. When taking the federal rebate into account the brand Copaxone is preferred. If you receive requests for the generic Glatopa 20mg/mL, please ask them to use the branded Copaxone 20mg/mL.
- **GILENYA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Gilenya is contraindicated in pts with certain pre-existing or recent (within last 6 months) heart conditions or stroke, or who are taking certain antiarrhythmic medications. FDA also recommends cardiovascular monitoring be extended past 6 hours in patients who are at higher risk or who may not tolerate bradycardia. Extended monitoring should include continuous ECG monitoring overnight.
- **KESIMPTA**
  - **Interim Criteria (*if applicable*):**
  - *Kesimpta® (Ofatumumab) Approval Criteria:*

1. *An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and*
2. *Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and*

3. *Approvals will not be granted for concurrent use with other disease-modifying therapies; and*
4. *Verification from the prescriber that all baseline assessments have been completed prior to initiation of Kesimpta® and continued monitoring while on therapy, where applicable, will be performed as per package labeling, including:*
    - *Hepatitis B virus (HBV) testing and verification that the member does not have active HBV; and*
    - *Quantitative serum immunoglobulin testing at baseline, during, and after discontinuation of treatment until B-cell repletion; and*
    - *Liver function tests (LFTs) at baseline and monitoring for signs and symptoms of hepatic injury during treatment ; and*
5. *Prescriber must verify the member has no active infection(s); and*
6. *Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and*
7. *Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and*
8. *Kesimpta® must be shipped via cold chain supply and the member or member's caregiver must be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and*
9. *Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta; and*
10. *Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and*
11. *A quantity limit of 1 syringe or prefilled Sensoready Pen per month will apply. Initial dosing titration will be approved for a quantity limit override upon meeting Kesimpta® approval criteria; and*
12. *Compliance will be checked for continued approval every 6 months.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Kesimpta has a QL of 0.4mL per 28 days based on maintenance dosing. Please approve a quantity limit override for initial dosing (20mg at week 0, 1, and 2, followed by 20mg once monthly dosing starting at week 4).

- **LEMTRADA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Lemtrada dosing: First course: 12mg/day on 5 consecutive days; one year later Second course: 12mg/day on 3 consecutive days 12 months after first treatment course. May require subsequent yearly doses beyond the second course but they must be 12 months since the previous approval and once they have done the 5 initial days all subsequent doses should only be approved for 3 days.
- **MAVENCLAD**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

- Limited to 1 year of therapy, to include 2 treatment courses

- **OCREVUS**
  - **Interim Criteria (*if applicable*)**
  - *Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) Approval Criteria:*

1. *An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and*
2. *Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and*
3. *Approvals will not be granted for concurrent use with other disease modifying therapies; and*
4. *Verification from the prescriber that all baseline assessments have been completed prior to initiation of ocrelizumab and continued monitoring while on therapy, where applicable, will be performed as per package labeling, including:*
    - *Hepatitis B virus (HBV) testing and verification that the member does not have active HBV; and*
    - *Quantitative serum immunoglobulin testing at baseline, during, and after discontinuation of treatment until B-cell repletion; and*
    - *Liver function tests (LFTs) at baseline and monitoring for signs and symptoms of hepatic injury during treatment ; and*
5. *Ocrevus® and Ocrevus Zunovo® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion/injection reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how the requested product will be administered; and Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or*
6. *Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of the requested product; and*
7. *Prescriber must confirm that member will be monitored appropriately per package labeling after each infusion or injection; and*
8. *Verification from the prescriber that member has no active infection(s); and*
9. *Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and*
10. *Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving ocrelizumab therapy and for 6 months after the last dose of ocrelizumab; and*
11. *Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- (ocrelizumab/hyaluronidase-ocsq) is a subcutaneous (sub-Q) injection approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults and primary progressive MS in adults.
- Dosing and Administration:
- MS relapsing or primary progressive loading dose/maintenance doseL
    - 300 mg once IV on day 1, followed by 300 mg once IV 2 weeks later; subsequent doses of 600 mg IV are administered once every 6 months (beginning 6 months after the first 300 mg dose).
    - Ocrevus 300mg/10mL (loading dose) would be 20mL for a 14 day supply. Maintenance dose=20mL for 180 day supply.
    - If either the loading or maintenance dose falls above the max cost threshold, ok to override.
- Recommended dosing of 920mg (23mL) sub-Q in the abdomen over approximately 10 minutes every 6 months
- Ocrevus Zunovo™ should be administer by a health care professional
- Ocrevus Zunovo™ has different dosage and administration instructions than the intravenous formulation
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761371s000lbl.pdf
- Coverage: Ocrevus Zunovo™ will be covered with a hard PA with the criteria listed below.

- **OPIOID ANALGESICS**
    - **GENERAL INFORMATION**
        - Opioid Tolerant: Please note that just because a member tries a codeine or tramadol product, they may still be considered opioid naïve. The point of the Tier-1 trial is to make sure that the member is not opioid naïve before they start a potent long-acting medication. It is your job when looking at these PA's to make a clinical decision if the long-acting is appropriate for the member. Some questions you may want to consider include the following:
        - Does the member require a long-acting because they have a chronic condition?
        - If the member has only tried low-dose IR medications, tramadol, or codeine, what strength of the long-acting are they requesting? If it is a high dose, it may not be appropriate.
        - Please also note, that nurse practitioners and PA's can only write for codeine medications, tramadol, and Butrans as Tier-1 medications, and they can only write for tramadol ER as Tier-2 products (due to scheduling). Please keep this in mind when evaluating these PA's
        - Cancer Patients: Please remember that cancer patients are exempt from the opioid tier structure. Most of the time claims for medications for them will go through without a PA, but please be aware of this if you receive a manual request. Quantity limits still apply for these patients but special consideration can be given for a cancer diagnosis.

- Optometrists: Oklahoma pharmacies may fill prescriptions written by doctors of optometry (optometrists) for Hydrocodone containing medications for up to a 5 day supply by virtue of a state law which went into effect November 1, 2014.
- Age Restriction for Narcotics: Tier 1 oral liquid narcotics have an age restriction for members older than 12 years of age and oral solid dosage forms have an age restriction for all members younger than 10 years of age. Please consider approving an age restriction override if clinically appropriate and a reason is given to why the member needs that particular dosage form (i.e. an adult member needs a liquid opioid due to recent jaw surgery).
- Short-Acting Opioids QLO: Are limited to a quantity of 120 units for a 30-day supply. If a member requires a quantity greater than 4/day the prescribers office needs to call the Helpdesk to initiate an override. PMC Clinical Pharmacists will be transferred the call and a Statement of Medical Necessity for Opioid Quantity Limit Override will be completed. The only 3 covered diagnoses that will be considered for approval are a current oncology-related diagnosis, sickle cell disease diagnosis, or hemophilia diagnosis.

- **OPIOID ANALGESICS SPECIAL PRIOR AUTHORIZATION APPROVAL CRITERIA:**
  - *Actiq® and Fentora® are approved for oncology-related diagnoses only.*
  - *ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:*
    - *A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.*
  - *Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:*
    - *Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age; or*
    - *For members older than 12 years of age, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.*
  - *Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:*
    - *A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/ caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.*
  - *Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:*
    - *For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or*
    - *For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and*

        - *For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.*
    - *Levorphanol Tablet Approval Criteria:*
        - *A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.*
    - *Methadone Oral Solution Approval Criteria:*
        - *For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or*
        - *For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.*
    - *Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:*
        - *For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and*
        - *For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.*
    - *Oxymorphone ER Tablet Approval Criteria:*
        - *A patient specific, clinically significant reason why the member cannot use any other available extended-release opioid analgesic must be provided.*
    - *Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:*
        - *A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and*
        - *An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and*
        - *A quantity limit of 2,400mL per 30 days will apply.*
        - *If the prior authorization request indicates Qdolo is needed for dose titration, please still ask for a reason why tramadol 50mg tablets cannot be used. The recommended titration regimens for both Qdolo and tramadol 50mg tablets are similar with a starting dose of 25mg/day, and tramadol 50mg tablets can be split for dose titration.*
    - *Seglentis® (Celecoxib 56mg/Tramadol 44mg Tablet) Approval Criteria:*
        - *An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and*

        - *A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and*
        - *A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and*
        - *An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and*
        - *A quantity limit of 28 tablets for a 7-day supply will apply.*
    - *Tramadol 25mg, 75mg, and 100mg Tablet Approval Criteria:*
        - *A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg or 75mg dose must be provided; and*
        - *An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.*
- **HYSINGLA ER**
    - Similar to all hydrocodone medications, Hysingla ER will have an age restriction with a minimum age of 10 years.
    - Hysingla ER and Zohydro ER are hitting ingredient duplication errors when ran with an immediate release hydrocodone product from a different prescriber. You will have to make a clinical decision based on claims data. Keep in mind it can be appropriate since one is a long-acting product and one is a short-acting (like if someone is on Oxycontin and oxycodone IR). Please also keep in mind that the long-acting medications do not contain APAP.
- **OPANA ER**
    - Based on request of FDA no there will be no new shipments of Opana ER. Generic formulations of Opana ER are not abuse deterrent and FDA is evaluating abuse patterns of the generics and will take further action, if necessary. New starts of either brand or generic Opana ER® will no longer be approved. We should not be approving Opana ER generics regularly since it is not abuse-deterrent and previously when the brand was reformulated to be abuse-deterrent members tried to switch to the abusable formulation. OHCA has indicated that we can be a little flexible in this, basically if they appeal we could approve the generic (or if they have a clinical reason for use of the generic).
- **CODEINE/TRAMADOL**
    - Codeine and tramadol are now contraindicated in 12 years and younger; however, there are very few drugs nurse practitioners and physician assistants can write. Additionally, the Board asked us to be flexible with these medications when a member has severe pain (example broken bones, cancer, sickle cell, etc.). In other words, some of these requests are clinically appropriate and approvable, but the

pharmacy/prescriber should be encouraged to counsel the member/caregiver. This lets them know that even though we have approved they need to watch for appropriate safety issues.
    - Tramadol is contraindicated in children under the age of 18 years when used to treat pain following surgery to remove the tonsils and/or adenoids.
    - Codeine or tramadol are not recommended in breastfeeding mothers due to the risk of excess sleepiness, difficulty breastfeeding, or serious breathing problems in the breastfed infant.
- **OPIOID MME LIMITS**
    - Opioid claims for members with a cancer diagnosis, hemophilia, or sickle cell should not hit MME limits. If for some reason they do hit a MME limit they can submit a PA and it will most likely be approved. The system lookback for a diagnosis of cancer, hemophilia, or sickle cell is 180 days. requests for members exceeding the MME limit per day can be approved when there is documentation of pain associated with end-of-life care, palliative care, or hospice.
    - The opioid MME limits do not apply to buprenorphine medications used for opioid addiction treatment.
    - The opioid MME edit will look back 30 days for overlapping MME claims in order to calculate the cumulative opioid MME. The edit allows for a member to get a fill of the same medication they were receiving previously and does it not count towards the MME if they fill it within three days prior to the date exhausted. This only applies to refills when the member had a previous claim with the exact same GCN. If a medication has a new GCN it will hit and if it exceeds the threshold it would require an MME override.
    - If the prescriber or member refuses to taper, we have developed an attestation for provider requests for continued authorization of high-dose opioid therapy (>90MME). See attestation below, and it should go back to those who refuse to taper and still may need high dose opioids. Ask them to answer the questions and the provider themselves must sign and then we can approve longer term (6 months) opioid MME overrides. At the end of the 6-month approval, if the member is still requiring opioids >90 MME, the provider will need to fill out a new attestation (and then we can approve another 6 months). An attestation from the provider is needed at least every 6 months (more frequently for changes to regimen and/or MME) to continue approval of high dose opioid therapy. When sending the attestation for the provider to fill out, please consider a 1- month approval if appropriate so that the member does not run out of medication.
- **<u>NON-OPIOID ANALGESICS</u>**
    - **JOURNAVX**
    - **Interim Criteria (*if applicable*):**
    - *Journavx™ (Suzetrigine) Approval Criteria:*

1. *An FDA approved diagnosis of moderate to severe acute pain; and*
2. *Member must be 18 years of age or older; and*
3. *The underlying cause of the acute pain must be provided; and*

4. *Member must have a current numeric pain rating scale (NPRS) score ≥4 (NPRS score must be provided on the request); and*
5. *Member must not be taking any strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and*
6. *Member must not have severe hepatic impairment (Child-Pugh class C); and*
7. *If member is using hormonal contraceptives containing progestins, other than levonorgestrel and norethindrone, prescriber must confirm the member has been counseled to use an additional nonhormonal contraceptive method or an alternative hormonal contraceptive during treatment with Journavx™ and 28 days after Journavx™ discontinuation; and*
8. *A patient specific, clinically significant reason why the member cannot use other non-opioid pain relievers, including acetaminophen and a non-steroidal anti-inflammatory drug (NSAID), must be provided; and*
9. *Journavx™ will not be approved for concurrent use with an opioid; and*
10. *A quantity limit of 30 tablets for a 14-day supply will apply. The use of Journavx™ for acute pain has not been studied for longer than 14 days. Journavx™ will not be approved for use beyond 14 days or for chronic pain.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Regardless of their pain score, a reason why the member cannot use acetaminophen or an NSAID must be provided.
- Due to SB1344 in regard to non-opioid alternatives for pain we cannot ask why they can't use an opioid.
    - https://www3.oklegislature.gov/cf_pdf/2023-24%20ENR/SB/SB1344%20ENR.PDF

- **PARKINSON'S DISEASE AGENTS**
    - **ONAPGO**
    - **Interim Criteria (*if applicable*):**
    - *Onapgo™ (Apomorphine Subcutaneous Injection) Approval Criteria:*

1. *An FDA approved indication for the treatment of motor fluctuations with advanced Parkinson's disease; and*
2. *Member must be 18 years of age or older; and*
3. *Must be prescribed by, or in consultation with a neurologist; and*
4. *Provider must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 3 hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and*
5. *Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:*
    - *Dopamine agonist (e.g., pramipexole, ropinirole); or*
    - *Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or*
    - *Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or*
    - *Amantadine; and*
6. *Member must not be taking 5-HT3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) concomitantly with Onapgo™; and*

7. *Onapgo™ must be used with the Onapgo™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Onapgo™ with the Onapgo™ pump prior to starting treatment; and*
8. *Onapgo™ will not be approved for concomitant use with Vyalev™ (foscarbidopa/foslevodopa subcutaneous injection) or Apokyn® (apomorphine injection); and*
9. *Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Onapgo™. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Onapgo must be administered through the Onapgo pump. The Onapgo pump will require prior authorization. The NDC is only for the cartridges and does not include the pump.
- Prescribing Information: https://www.onapgohcp.com/onapgo_PI.pdf
- Coverage: Onapgo™ will be covered with a hard PA with the criteria listed below.
    - Quantity Limit: 600mL per 30 days
- **VYALEV**
- **Interim Criteria (*if applicable*):**
- *Vyalev™ (Foscarbidopa/Foslevodopa Subcutaneous Injection) Approval Criteria:*

1. *An FDA approved indication for the treatment of motor fluctuations with advanced Parkinson's disease; and*
2. *Member must be 18 years of age or older; and*
3. *Must be prescribed by, or in consultation with a neurologist; and*
4. *Provider must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 2 and half hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and*
5. *Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:*
    - *Dopamine agonist (e.g., pramipexole, ropinirole); or*
    - *Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or*
    - *Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or*
    - *Amantadine; and*
6. *Member must not be taking nonselective monoamine oxidase inhibitors (MAOIs) concomitantly with Vyalev™ or within 2 weeks prior to initiating Vyalev™; and*
7. *Vyalev™ must be used with the Vyafuser™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Vyalev™ with the Vyafuser™ pump prior to starting treatment; and*
8. *Vyalev™ will not be approved for concomitant use with Onapgo™ (apomorphine subcutaneous injection); and*
9. *Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Vyalev™. Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**

- Vyalev must be administered through the Vyafuser pump. The Vyafuser pump will require a prior authorization if approved for Vyalev. The HCPCS code that will be used for the pump is E0781. If a request is received for the pump, please deny.
- Prescribing Information: https://www.rxabbvie.com/pdf/vyalev_pi.pdf
- Coverage: Vyalev™ will be covered with a hard PA with the criteria listed below.
    - Quantity Limit: 600mL per 30 days
- **NUPLAZID**
- **Interim Criteria (*if applicable*): n/a**
- **Additional Internal Notes (*for consideration toward approval*):**
    - Do not approve any PA's for Nuplazid from Dr. Morton (NPI: 1336222504) unless they have a diagnosis in history, and they have concomitant medications to confirm diagnosis. For example, don't approve Nuplazid unless they have a Parkinson's diagnosis in history and some Parkinson medications (examples: carbidopa/levodopa, Sinemet, Mirapex, Requip, etc). Do not approve these if they don't meet criteria even if they were stabilized inpatient. If they do not meet the criteria listed above, we should give a firm denial. Once we deny he (Dr. Morton) will need to submit a letter for reasoning, and we should be very careful not to approve these unless there is detailed Parkinson's diagnosis and disease management information. He has been creative in the past with workarounds. OHCA is aware that he may have to take these to the judge for appeal.
    - Per OHCA regarding Dr. Morton's Nuplazid PA's:
        - Most of his patients are on multiple antipsychotics and taking Nuplazid. In these cases, in addition to proving diagnosis OHCA would like us to ask for supporting information on use of Nuplazid with multiple antipsychotics. I clarified that this is appropriate even though it goes beyond our criteria and OHCA confirmed this was allowed.
        - If he submits something stating they were diagnosed with Parkinson's while inpatient OHCA would like us to ask for inpatient notes verifying diagnosis of Parkinson's disease while inpatient. I clarified that this is appropriate even though it goes beyond our criteria and OHCA confirmed this was allowed.
        - Lastly all of his prior authorizations must be signed by him. I clarified that this is appropriate even though it goes beyond our policies for non-CII's and OHCA confirmed this was allowed.
    - Please see below for messaging:
    - Member's claims history indicates current use of multiple antipsychotics and Nuedexta. Please provide supporting information regarding the safety of using multiple antipsychotics, Nuedexta, and Nuplazid concomitantly.
    - The member's diagnosis summary and pharmacy claims do not include Parkinson's disease or associated medications. Please provide office records to support the diagnosis. If the member received medications other than through SoonerCare, please submit pharmacy records along with the prior authorization form.
    - Requests for Nuplazid must be signed by the requesting prescriber.
    - Your request for Nuplazid is incomplete. Authorization requires the following:

- An FDA approved diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis; and
- Member must have concomitant diagnosis of Parkinson's disease verifiable in the member's diagnosis claims history and concomitant medications used to treat Parkinson's disease verifiable in the member's pharmacy claims history; and
- Nuplazid will not be approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis; and
- Initial approvals will be for the duration of three months. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.
- A quantity limit of two tablets daily will apply.

- **REQUIP XL**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - XL is not FDA indicated for restless leg syndrome.

- **<u>SMOKING CESSATION PRODUCTS</u>**
  - **GENERAL INFORMATION**
    - There are two generic varenicline NDCs (manufactured by Par) that are now FDA approved and available on the market. These NDCs (listed below) are covered in ICE without PA for smoking cessation (for up to 180 days per calendar year for members 17 years of age and older).
      - 49884015576 – varenicline 0.5mg tabs (Par; covered/no PA)
      - 49884015676 – varenicline 1mg tabs (Par; covered/no PA)
    - As a reminder, Chantix (varenicline) is covered for smoking cessation for up to 180 days per calendar year for members 17 years of age and older. Members with a recent paid claim for Chantix may be approvable for the generic NDC, depending on the duration of therapy that they've received this calendar year. For members with recent paid claims for Chantix or the generic manufactured by Par, the NDCs below are approvable for the remainder of the 180 days of coverage.

- **<u>ALZHEIMER'S AGENTS</u>**
  - **GENERAL INFORMATION**
    - At implementation, it was agreed upon that the off-label dx we would approve for were Down 's syndrome, mental retardation, and autism ONLY if they were also coded in dx hx.
    - Please consider approval of IR memantine for migraine prophylaxis on a case-by-case basis if clinically appropriate (e.g., prescriber is neurologist, member has failed multiple other meds).
    - The following special formulation medications are set up to auto-PA for members age 51 and older if they've already been getting them filled. (This will allow members to keep getting auto PAs and continue therapy, as long as they fill the med at least once every 100 days. If not filled in the last 100 days, these medications will require manual PA):

        - ODTs: Aricept (donepezil) ODT
        - Solutions: Exelon (rivastigmine) solution, Namenda (memantine) Solution, Razadyne (galantamine) solution
        - Patches: Exelon patch
        - Extended Release: Razadyne ER caps
        - Aricept 23mg Tabs and Namenda Titration Packs: Not set to auto PA and will always require manual PA.
- **LEQEMBI/LEQEMBI IQLIK**
    - **Interim Criteria (*if applicable*):**
    - *Leqembi® (Lecanemab-irmb) Approval Criteria:*

1. *An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:*
    - *Mini-Mental State Exam (MMSE) score between 22 and 30; or*
    - *Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or*
    - *Montreal Cognitive Assessment (MoCA) score ≥19; or*
    - *Quick Dementia Rating System (QDRS) score ≤5; and*
2. *Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and*
3. *Lecanemab-irmb must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and*
4. *Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and*
5. *Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and*
6. *Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and*
7. *Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the concomitant use have been discussed and are acceptable to the member prior to initiating lecanemab-irmb; and*
8. *Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and*
9. *Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and*
10. *Member must not have risk factors for intracerebral hemorrhage, including the following:*
    - *Prior cerebral hemorrhage >1cm in greatest diameter; or*
    - *>4 microhemorrhages; or*
    - *An area of superficial siderosis; or*

- *Evidence of vasogenic edema; or*
- *Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or*
- *Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and*

11. *Member must have a recent (within 1 year) brain MRI prior to initiating treatment with lecanemab-irmb and prior to the 3rd, 5th, 7th, and 14th infusions; and*
12. *Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with lecanemab-irmb; and*
13. *If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and*
14. *Requests for the Leqembi® intravenous (IV) formulation will require the following:*
    - *Must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and*
    - *Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and*
    - *Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and*
    - *For a maintenance dose of 10mg/kg every 4 weeks, prescriber must verify the member has received treatment with Leqembi® at a dose of 10mg/kg every 2 weeks for 18 months; and*
15. *Requests for the Leqembi® Iqlik™ subcutaneous (sub-Q) formulation will require the following:*
    - *Member has received treatment with the IV formulation at a dose of 10mg/kg every 2 weeks for 18 months; and*
    - *Member or caregiver has been trained by a health care professional on the sub-Q administration and proper storage of Leqembi® Iqlik™; and*
16. *Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 5th and 7th infusions is required for continuation; and*
17. *Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and*
18. *Approval quantities will be dependent on the member's weight and dosing based on package labeling; and*
19. *The maximum dose approvable is 10mg/kg per 14 days for the IV formulation and 7.2mL per 28 days for the sub-Q formulation; and*

20. *Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **ZUNVEYL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Zunveyl is a prodrug of galantamine that is enteric-coated and designed to be inactive until after first-pass metabolism in the liver before it is converted to active galantamine and thereby potentially reducing tolerability issues seen with galantamine (e.g., GI related issues, insomnia). We should not be approving just based on general GI or CNS concerns. Approvals may be considered if a member has tried galantamine and experienced adverse effects or they provide an actual patient specific and clinically significant reason for Zunveyl.

- **<u>ANTICONVULSANTS</u>**
    - **GENERAL INFORMATION**
        - Please consider approval of seizure medications if the member is stable on the medication, regardless of method of stabilization (including samples).
    - **AFINITOR**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Oncology specialists may also be considered for approval.
        - Afinitor® Disperz® (everolimus) received a new indication for the treatment of adjunctive treatment of adult and pediatric patients older with TSC-associated partial-onset seizures. Previously Afinitor® was approved for various oncology related diagnoses including in patients with TSC who have subependymal giant cell astrocytoma (SEGA). Only the Disperz® formulation is approved for the TSC-associated partial-onset seizures; however, if they want to use the tablet formulation we should not discriminate (same price and less chance for administration error with the tablet formulation). This is a very costly medication so it really should be after they have tried other seizure medications. Also, there are quite a few safety issues with this drug.
    - **CARBAMAZEPINE CHEWABLE TABLETS**
        - **Interim Criteria (*if applicable*):**
        - *Carbamazepine 200mg Chewable Tablet Approval Criteria:*
        1. *A patient-specific, clinically significant reason why the member cannot use all other forms of carbamazepine that are available without a prior authorization, including using 2 of the 100mg chewable tablets to achieve the 200mg dose must be provided; and*
        2. *A quantity limit of 720 chewable tablets per 90 days will apply.*
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Carbamazepine chewable tablet is an anticonvulsant and specific analgesic for trigeminal neuralgia. A new 200mg strength has now been approved.
        - How Supplied: 100mg and 200mg chewable tablet

- Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0526a054-3eda-49b4-b390-7d5d16e30af8
- Coverage: Carbamazepine 200mg chewable tablet will be covered with a hard PA with the criteria listed below.
- Quantity Limit: 720 tablets per 90 days

- **EPIDIOLEX**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - We have received input from an OHCA medical director indicating that in cases where Epidiolex is being written by a neurologist for an off-label diagnosis such as intractable seizures to please consider approval if they have tried multiple other therapies. In general, we are flexible when seizure therapies are written by neurologists and we should continue to be.
  - Epidiolex is set up with a SmartPA if the member has an FDA approved diagnosis or a diagnosis of intractable seizures OR has at least 2 AEDs (brand or generic) in pharmacy claims history within the last 12 months:
    - ICD-10s: G40811, G40812, G40813, G40814, G4083, G40833, G40834, Q851, G40.411, G40.419, G40.803, or G40.804
    - AEDs: clobazam, levetiracetam, valproate derivatives, lamotrigine, topiramate, rufinamide, or felbamate.
- **SABRIL**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Vigadrone (vigabatrin powder for oral solution) is an "authorized" generic for Sabril® (vigabatrin tablets and powder for oral solution). Vigpoder (vigabatrin powder for oral solution) is another branded generic of Sabril. Vigadrone and Vigpoder will have a hard PA and be treated as nonpreferred (see Sabril Criteria above).
- **TOPIRAMATE 50MG SPRINKLE CAPSULE**
  - **Interim Criteria (*if applicable*):**
  - *Topiramate 50mg Sprinkle Capsule Approval Criteria:*

1. *An FDA approved diagnosis; and*
2. *A patient-specific, clinically significant reason why the member cannot use other available generic topiramate products, including using 2 topiramate 25mg sprinkle capsules to achieve the 50mg dose, must be provided; and*
3. *An age restriction of 11 years of age and younger will apply. Members 12 years of age and older will require a patient-specific, clinically significant reason why a special formulation product is needed; and*
4. *A quantity limit of 240 capsules per 30 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Topiramate 50mg sprinkle capsule is a new strength of the topiramate sprinkle formulation. The 50mg strength is more expensive than the generic topiramate 15mg and 25mg sprinkle capsules which are available without a prior authorization for members 11 years of age and younger.

- **ANTIDEPRESSANTS**
  - **UPDATED TIER CHART EFFECTIVE 10/17/25**

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps
escitalopram tabs & soln (Lexapro®)			**escitalopram 15mg caps**
fluoxetine caps & soln (Prozac®)			fluoxetine tabs
fluvoxamine (Luvox®)			fluoxetine DR (Prozac® Weekly™)
paroxetine (Paxil®)			fluvoxamine CR (Luvox CR®)
Sertraline tabs & soln (Zoloft®)			paroxetine CR (Paxil CR®)
			sertraline 150mg & 200mg caps
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Forfivo XL®)
bupropion ER (Aplenzin®)		levomilnacipran (Fetzima®)	duloxetine (Drizalma Sprinkle™)
duloxetine (Cymbalta®)		nefazodone (Serzone®)	duloxetine 40mg (Irenka™)
mirtazapine (Remeron®, Remeron SolTab®)		vilazodone (Viibryd®)	**trazodone oral soln (Raldesy™)**
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)			trazodone 300mg tabs (Desyrel®)
venlafaxine ~~tabs &~~ ER caps (~~Effexor®,~~ Effexor XR®)			venlafaxine besylate ER 112.5mg tablets
venlafaxine IR tabs (Effexor®)			venlafaxine ER 225mg tabs (Effexor XR® tabs)
venlafaxine ER 37.5mg, 75mg &150mg tabs (Effexor XR®)			
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/bupropion (Auvelity™)
			esketamine nasal spray (Spravato®)
			gepirone (Exxua™)

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
			zuranolone (Zurzuvae™)

- **GENERAL INFORMATION**
  - Please consider approval of antidepressant medications if the member is stable on the medication, regardless of method of stabilization (including samples).
- **ESCITALOPRAM CAPSULES**
  - **Interim Criteria (if applicable):**
  - *Escitalopram Capsule Approval Criteria:*
  1. *An FDA approved indication; and*
  2. *Member must have initiated treatment with escitalopram tablets for dose titration; and*
  3. *A patient-specific, clinically significant reason why the member cannot use escitalopram tablets, including splitting an escitalopram 10mg tablet to achieve a 15mg dose, must be provided; and*
  4. *Escitalopram capsules will not be approved for members 65 years of age or older or for members with hepatic impairment; and*
  5. *A quantity limit of 30 capsules per 30 days will apply.*
- **DESVENLAFAXINE ER, PRISTIQ**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - There are several NDCs for desvenlafaxine ER 50mg and 100mg that are not generic equivalents to Tier-2 Pristiq (desvenlafaxine succinate ER), these products are Tier-3 medications. Please check the GCN for all requests for generic desvenlafaxine ER 50mg and 100mg. Please be sure to use the correct criteria when reviewing PA requests for desvenlafaxine ER.
  - The GCNs for Tier-2 Pristiq and the generic equivalents (desvenlafaxine succinate ER 50mg and 100mg) are 99451 and 99452.
  - The GCNs for the generic Tier-3 products (desvenlafaxine ER & desvenlafaxine fumarate ER 50mg and 100mg) are 36272, 36273, 34470, & 34482.
- **VIIBRYD**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Viibryd is listed as a dual-acting antidepressant; however, it is a little unique compared to others in the dual-acting class. Viibryd has mostly serotonin activity and very little norepinephrine activity compared to the other dual-acting antidepressants. We may receive requests from prescribers who do not want to use a dual-acting antidepressant due to risk of cardiovascular effects associated with norepinephrine (this would have to be documented by the prescriber on the PA request and each case has to be evaluated individually). Since we do not have a Tier-2 SSRI, Viibryd could be considered as an option for those who cannot take duloxetine or another dual-acting medication. They still would have to try multiple

Tier-1 SSRI medications and document why duloxetine is not appropriate for the member before they could jump to Viibryd.

- **PROZAC WEEKLY**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Clients currently stabilized on Prozac® Weekly should be continued.
  - New start clients must meet all of the following criteria:
  - Client must have been stabilized on 20mg daily of fluoxetine for at least 12 weeks.
  - Start date should be 7 days after the last daily dose.
  - Client must have a compelling clinical reason for use of this convenience only medication. This medication should not be approved for patients in nursing homes or assisted living centers (because medications are administered to patients, so compliance/convenience should not be an issue).
  - Prior authorization can be given for a 12 week supply per petition.
  - The quantity limit for Prozac® Weekly is 3 packs of 4 tablets each (12 week supply).
- **CITALOPRAM**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Citalopram 20mg/10mL (GCN 34671) requires a PA; citalopram 10mg/5mL (GCN 16344) does not require a PA
  - No dosing > 40 mg/day
  - Maximum dose of 20mg/day for the following conditions:
  - Older than 60 years of age
  - If member is currently stable on medication then we can consider approval for ONE MONTH to allow time for dose taper.
  - Ingredient duplication edit active for citalopram 20mg and
  - 40mg for those >60 years of age
- **SPRAVATO**
  - **Interim Criteria (*if applicable*):**
  - *Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:*

1. *An FDA approved indication of treatment-resistant depression in adults; and*
2. *Member must be 18 years of age or older; and*
3. *Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and*
4. *Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and*
5. *Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with the prescribing information; and*
6. *Member must not have any contraindications to therapy [i.e., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral*

arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and

7. *Member must not have severe hepatic impairment (Child Pugh C); and*
8. *Prescriber must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and*
9. *Prescriber must verify member is not breastfeeding; and*
10. *Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and*
11. *Member must be enrolled in the Spravato® REMS program; and*
12. *Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and*
13. *Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated an adequate response during the induction phase; and*
14. *A quantity limit of 4 kits per 28 days will apply for maintenance dosing.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Emergency Dose: For requests for MDD with acute suicidal ideation or behavior, please consider approving an emergency dose (quantity of #3 devices for an 84mg dose) if noted on the PA request. Prescribers may dispense/administer the dose in a true emergency (based on the diagnosis) prior to submitting the PA request. If the prescriber has not already dispensed a dose but notes "emergency" on the PA request, it may be appropriate to approve x1 dose (#3 devices) and then ask for additional information (if all information is not provided).
- Pharmacy Billing: Pharmacy dispenses the medication (using the NDCs below) and the prescriber bills for administration/monitoring only:
  - Spravato 56mg (NDC 50458002802) – Contains (2) 28mg devices (NDC is billed as a quantity of #2 units per 56mg dose) (QL #8/28)
  - Spravato 84mg (NDC 50458002803) – Contains (3) 28mg devices (NDC is billed as a quantity of #3 units per 84mg dose) (QL #24/28)
- Medical Billing (Buy and Bill): The prescriber bills for the medication in addition to administering and monitoring the member (no pharmacy claim or NDCs approved), using the following HCPCS codes:
  - G2082 – Used for ≤56mg of Spravato (1 unit per 56mg dose)
  - G2083 – Used for >56mg of Spravato (1 unit per 84mg dose)
  - Note: These codes include the drug and administration/monitoring associated with it, so do not approve CPT codes 99415/99416 if the medication is being billed by the physician/facility with these HCPCS codes.

- **RALDESY**
  - **Interim Criteria (*if applicable*):**
  - *Raldesy™ (Trazodone Oral Solution) Approval Criteria:*

1. *An FDA approved diagnosis of major depressive disorder (MDD); and*
2. *Member must be 18 years of age or older; and*
3. *A patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided; and*

4. *Requests for the 150mL package size will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size; and*
5. *The following quantity limits will apply:*
    - *150mL package size: 450mL per 30 days; or*
    - *300mL package size: 1,200mL per 30 days.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **<u>ANTIMIGRAINE AGENTS</u>**
    - **ANTI-MIGRAINE MEDICATIONS SPECIAL PRIOR AUTHORIZATION APPROVAL CRITERIA:**
        - **Interim Criteria (*if applicable*):**
        - *Anti-Migraine Medications Special Prior Authorization Approval Criteria:*

1. *Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and*
    - *Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and*
    - *A quantity limit of 20 tablets per 28 days will apply.*
2. *Use of Brekiya® [dihydroergotamine (DHE) injection], D.H.E. 45® [dihydroergotamine (DHE) injection),] or Trudhesa® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.*
3. *Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:*
    - *Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and*
    - *Nurtec® ODT will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor; and*
    - *A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.*

   **The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates. +Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.*
4. *Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and*
    - *Reyvow® will not be approved for concurrent use with a prophylactic CGRP inhibitor.*

5. *Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.*
6. *Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).*
7. *Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications, Nurtec® ODT (rimegepant), and Reyvow® (lasmiditan); and*
    - *Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.*
8. *Use of Imitrex® STATdose System (sumatriptan injection), Onzetra® Xsail® (sumatriptan nasal powder), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.*
9. *Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Cluster Headaches: **Imitrex (sumatriptan) injection** is FDA approved for cluster headache; zolmitriptan has compendia support; sumatriptan nasal spray has compendia support. Please keep this in mind when reviewing requests for this specific diagnosis.
- Please consider approval of **Nurtec ODT, Reyvow, Ubrelvy, or Zavzpret** if any of the following contraindicated diagnoses are documented as a patient-specific, clinically significant reason why the member cannot use a triptan medication:
    - Cerebrovascular syndromes, including strokes of any type or transient ischemic attacks
    - Coronary artery vasospasm, including Prinzmetal angina
    - Ischemic bowel disease
    - Ischemic coronary artery disease, including confirmed silent ischemia, angina pectoris, and history of myocardial infarction
    - Peripheral vascular disease
    - Significant and underlying cardiovascular disease
    - Uncontrolled hypertension (also consider approval if member has a documented diagnosis of hypertension due to vasoconstriction associated with triptans)
    - Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
- # of triptan trials is not as important as the reason why the member can't use triptans (as well as why not Nurtec ODT)

- If Nurtec ODT is approved for acute use (based on # of trials) and then the member wants to switch to Reyvow/Ubrelvy/Zavzpret, we still need a reason why they can't use triptans since Nurtec ODT only requires 2 trials and doesn't require a reason why they can't use triptans

- **AIMOVIG, AJOVY, EMGALITY**
  - **Interim Criteria (*if applicable*):**
  - *Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm) and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:*

1. *An FDA approved indication for the preventive treatment of migraine in adults; and*
2. *Member must be 18 years of age or older; or*
   - *For Ajovy®, pediatric members must be 6 to 17 years of age, weigh at least 45kg, and have a diagnosis of episodic migraine, as defined below; and*
3. *Member has documented chronic migraine or episodic migraine headaches:*
   - *Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or*
   - *Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and*
4. *Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:*
   - *Red flags; and*
   - *Possible indicators of secondary headache; and*
   - *Medication overuse; and*
5. *Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and*
6. *Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and*
7. *Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and*
8. *Quantity limits will apply based on FDA-approved dosing:*
   - *For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and*
   - *For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for adults only for a quantity limit override upon meeting Ajovy® approval criteria; and*
   - *For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- Chronic Migraines: If a member is on oral contraceptives, we may need to verify that the migraines are not due to contraceptives. We do not want them to stop birth control just to get access to CGRPs. If they had migraines prior to starting contraceptives, we know that is likely not the reason for their migraines. Please do not deny CGRPs solely based on the member being on birth control.

- **NURTEC ODT, QULIPTA, VYEPTI**
  - **Interim Criteria (*if applicable*):**
  - *Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant), and Vyepti® (Eptinezumab-jjmr) Approval Criteria:*

1. *An FDA approved indication for the preventive treatment of migraine in adults; and*
2. *Member must be 18 years of age or older; and*
3. *Member has documented chronic migraine or episodic migraine headaches:*
   - *Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or*
   - *Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT is only FDA approved for the preventive treatment of episodic migraines.); and*
4. *Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:*
   - *Red flags; and*
   - *Possible indicators of secondary headache; and*
   - *Medication overuse; and*
5. *Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and*
6. *For Vyepti®, prescriber must verify the medication will be prepared and administered according to the Vyepti® package labeling; and*
7. *For Vyepti® (eptinezumab-jjmr), a patient-specific, clinically significant reason (beyond convenience) why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) must be provided; and*
8. *For Nurtec® ODT (rimegepant) and Qulipta® (atogepant), a patient-specific, clinically significant reason (beyond convenience) why member cannot use 2* of the preferred CGRP inhibitors [i.e., Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), Emgality® (galcanezumab-gnlm)] must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement; *the manufacturer of Nurtec® ODT and Qulipta® has currently provided a supplemental rebate to only require 2 preferred injectable CGRP inhibitors; however, Nurtec® ODT and Qulipta® will follow the original criteria and require a reason why the member cannot use all preferred CGRP inhibitors if the manufacturer chooses not to participate in supplemental rebates); and*
9. *For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP*

inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and

10. *Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and*
11. *Quantity limits will apply based on FDA-approved dosing:*
    - *For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and*
    - *For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and*
    - *For Vyepti®, a quantity limit of 3 vials per 90 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Chronic Migraines: If a member is on oral contraceptives, we may need to verify that the migraines are not due to contraceptives. We do not want them to stop birth control just to get access to CGRPs. If they had migraines prior to starting contraceptives, we know that is likely not the reason for their migraines. Please do not deny CGRPs solely based on the member being on birth control.

- **SYMBRAVO**
  - **Interim Criteria (*if applicable*):**
  - *Anti-Migraine Medications Special Prior Authorization Approval Criteria:*

1. *Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and*
    - *Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and*
    - *A quantity limit of 20 tablets per 28 days will apply.*
2. *Use of D.H.E. 45® [dihydroergotamine (DHE) injection] or Trudhesa® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.*
3. *Use of Migranal® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications.*
4. *Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:*
    - *Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and*
    - *Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and*
    - *A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.*
        - **The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and*

to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

- *+Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.*

5. *Use of Reyvow® (lasmiditan), Ubrelvy® (ubrogepant), or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and*
    - *Reyvow®, Ubrelvy®, and Zavzpret™ will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor*
6. *Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.*
7. *Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.*
8. ***Use of Symbravo®** (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID).*
9. *Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.*
10. *Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Will be added to Special PA category – apply "Anti-Migraine Medication Special Prior Authorization Approval Criteria" (with additional/new step 8 specific to Symbravo)

- **<u>ATYPICAL ANTIPSYCHOTICS</u>**
    - **GENERAL INFORMATION**
        - Please consider approval of antipsychotic medications if the member is stable on the medication, regardless of method of stabilization (including samples).
        - Diagnosis with a strong indication for prescribing an atypical antipsychotic medication include: schizophrenia, bipolar disorder, delusional disorders, other nonorganic psychoses, autism spectrum disorder, mood disorder, obsessive-compulsive disorder, and severe depression with or without psychotic features.
        - Current Users/Inpatient Discharges:
            - Members currently stabilized on a higher tiered medication defined by paid claim(s) for the higher tiered medication in the past 90 days will be approved.

        - Members being released from a hospital and stabilized on a higher tiered medication will be approved.
        - (Currently psych facilities are told to fill out the provider portion of the petition and send with prescription with member to take to pharmacy, where pharmacy will complete and fax to us)
    - Clinical Exceptions:
        - Approvals will be granted for members with clinical conditions for which lower tiered drugs are contraindicated.
        - Approvals will be granted for members whose current regimen includes drugs known to adversely interact with all lowered tiered drugs.
        - Lurasidone (Latuda®) may be approved for pregnant women with appropriate diagnosis.
        - Olanzapine for Nausea in Pediatric Patients: Olanzapine is recommended to be used for the prevention and treatment of cancer-related nausea and vomiting while receiving chemotherapy. If we receive a request for a pediatric member under 5 years of age for this indication, please do NOT send this to Dr. R. These have been coming from Jimmy Everest and are being prescribed appropriately. Please consider adding the age code (as long as dosing doesn't seem crazy) and approving.
        - Aristada: Patients who have never taken aripiprazole, tolerability must be established with oral aripiprazole prior to initiating treatment with Aristada™. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability. It can be initiated at a dose of 441mg, 662mg or 882mg administered monthly or 882mg dose every 6 weeks.
        - Aristada Initio: Only to be used as a single dose and is not for repeated dosing. We need to watch for repeat doses of the INITIO formulation since it should only be dosed upon initiation.
        - Long-acting injectables: Some of the psychiatrists don't want to administer the long-acting injectable antipsychotic drugs and they may not have a nurse in their office. Pharmacies can give these medications (if willing).
    - Atypical antipsychotics can be approved up to 2X the maximum FDA approved dose.
    - **Clozapine products**: The FDA issued an update in February 2025 stating that the Risk Evaluation and Mitigation Strategy (REMS) program for clozapine has been removed. Although the risk of severe neutropenia with clozapine use still exists the removal of the REMS program was to help decrease the burden on the healthcare delivery system and improve access to clozapine. The FDA still recommends that prescribers monitor patients' absolute neutrophil count (ANC) according to the monitoring frequencies described in the prescribing information. Information about severe neutropenia will remain in the prescribing information for all clozapine medicines, including in the existing Boxed Warnings. Based on this update, the atypical antipsychotic criteria is being updated to remove the verbiage of clozapine not counting as a Tier-1 trial.
        - FDA update: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine

- Updated Tier Chart for Atypical Antipsychotic Medications:

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Asimtufii®)^	iloperidone (Fanapt®)	aripiprazole oral film (Opipza™)+
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada®)^	paliperidone (Invega®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		cariprazine (Vraylar®)
clozapine (Clozaril®)Φ		clozapine (Fazaclo®)+
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Hafyera™)^		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Sustenna®)^		olanzapine/fluoxetine (Symbyax®)+
paliperidone palmitate IM inj (Invega Trinza®)^		olanzapine/samidorphan (Lybalvi®)β
quetiapine (Seroquel®)		paliperidone palmitate IM inj (Erzofri®)^∞
quetiapine ER (Seroquel XR®)		quetiapine 150mg tablets+
risperidone (Risperdal®)		risperidone IM inj (Risperdal Consta®)^∞
risperidone ER sub-Q inj (Perseris®)^		risperidone IM inj (Risvan®)^∞
risperidone sub-Q inj (Uzedy™)^		risperidone IM inj (Rykindo®)^∞
ziprasidone (Geodon®)		xanomeline/trospium (Cobenfy™)

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- **Atypical Antipsychotic Medications Tier-2 Approval Criteria:**

1. *A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and*
    - ~~*Clozapine does not count towards a Tier-1 trial; and*~~
2. *Members currently stable on a Tier-2 medication may be approved for continuation of therapy.*

- ***Atypical Antipsychotic Medications Tier-3 Approval Criteria:***

1. *A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and*
    - ~~*Clozapine does not count towards a Tier-1 trial; and*~~
2. *Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or*

3. *A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and*
4. *Members currently stable on a Tier-3 medication may be approved for continuation of therapy; and*
5. *Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) or requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and*
6. *Use of Opipza (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and*
7. *Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and*
8. *Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and*
9. *Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.*

- **ADHD AND NARCOLEPSY AGENTS**
  - **GENERAL INFORMATION**
    - 2nd Opinion (Psych Consult) Requirement: Members between 0-4 years of age TXIX: All ADHD meds require PA for members 21 years of age and older.
    - Please consider approval of stimulants for multiple sclerosis (MS)-related fatigue (tier structure applies).
    - Rapid Metabolizer Testing: OHCA does not cover rapid metabolizer testing. If a request states they need BID dosing of long-acting stimulants due to rapid metabolizing, they really should have tried everything before we can approve. That means trying a long-acting with an immediate-release for supplementation or maybe trying a different long-acting. We really should rarely approve long-acting BID (almost never). In the past, we have had a SIGNIFICANT amount of prescribers who write "rapid metabolizer" on every request they submit. We cannot open a can of worms and start approving all who write that. They need to have lots of different options they have tried and failed for us to consider BID with a long-acting (it should be a last resort and almost never approved).
    - **IN THE ABSENCE OF DRUG-SPECIFIC CRITERIA ON OHCA WEBSITE:**
      - **NON-STIMULANT ADHD MEDICATIONS FOR MEMBERS <5 YEARS SHOULD BE REVIEWED WITH THE OFF-LABEL POLICY CP.PMN.53.**

- PA denials for non-stimulant ADHD medication (ie-Kapvay, Intuniv, Strattera) must be routed to OK Market Medical Director for additional review.
- **STIMULANT ADHD MEDICATIONS FOR MEMBERS <5 YEARS SHOULD BE REVIEWED WITH THE ANTIPSYCHOTIC & STIMULANT MEDICATION IN CHILDREN UNDER 5 POLICY OK.CP.PMN.01**
- **ANY ADHD MEDICATIONS (STIMULANT OR NON-STIMULANT) FOR MEMBERS >20 SHOULD BE REVIEWED WITH THE NO COVERAGE CRITERIA POLICY CP.PMN.255**

  - Stimulant & Strattera Dosing:
    - Strattera: Dosing >100mg/day is not covered
    - Stimulants are only approved for up to 1.5X the maximum FDA approved dose.
    - BID dosing of once daily medications will NOT be approved.
  - ADHD reference: http://www.adhdmedicationguide.com/

- **TIER 1 ADHD STIMULANTS FOR MEMBERS >20 YEARS OF AGE**
  - **Medical Necessity Review/No Coverage Criteria Applicability (*CP.PMN.255*)**
  - *Initial Approval Criteria:*
  - *A. Pharmacy Benefit: Labeled Use without Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all):*
  - *1. Request is for a PDL drug;**
  - *2. Request is not for a benefit excluded use (e.g., cosmetic);*
  - *3. Requested drug does not have a drug-specific clinical policy or custom coverage criteria;*
  - *4. Diagnosis of one of the following (a or b):*
    - *a. A condition for which the product is FDA-indicated and -approved;*
    - *b. A condition supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;*
  - *5. Member has no contraindications to the prescribed agent per the prescribing information;*
  - *6. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;*
  - *7. Request meets one of the following (a or b):*
    - *a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;*
    - *b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
  - *Approval duration: Duration of request or 6 months (whichever is less)*
  - *Continued Therapy*
  - *Pharmacy or Medical Benefit: Labeled Use without Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all):*

- *1. Member meets one of the following (a, b, or c):*
  - *a. Currently receiving medication via Centene benefit;*
  - *b. Member has previously met initial approval criteria*
  - *c. State or health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology, depression, transplant) with documentation that supports that member has received this medication for at least 30 days (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
- *2. Member is responding positively to therapy;*
- *3. If request is for a dose increase, request meets one of the following (a or b):*
  - *a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;*
  - *b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
- *Approval duration: Duration of request or 12 months (whichever is less)*

- **QELBREE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Please consider approval of Qelbree for adults who are not a candidate for all stimulants and have completed a trial of Strattera. Clinical trials for Intuniv and Kapvay did not enroll adult patients with ADHD. Trials of Intuniv and Kapvay could be waived for an adult member if they mention this as a reason for using Qelbree. There is currently a lack of guidelines addressing adult treatment of ADHD in the U.S. so we could reasonably rely on the international standards of care from NICE, the European Consensus Statement, and the British Association of Psychopharmacology.
  - Qelbree will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history.
- **RELEXXI & UNBRANDED METHYLPHENIDATE ER**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - In addition to the brand name Relexxii products, there are some non- branded formulations of methylphenidate ER now available in some of the same strengths as Relexxii that are also in the Special PA Tier. As always, please verify the correct Tier using the GCN for any non-branded methylphenidate products that could fall into multiple Tiers. Some strengths of Relexxii (and the corresponding non-branded formulations) will overlap with Concerta strengths, so it will be important to always check the GCN to verify the correct Tier.
  - Please note: All strengths of Relexxii are considered Special PA. Due to a system limitation in ICE, the strengths of Relexxii that are common to Concerta (Relexxii 18mg, 27mg, 36mg, 54mg) will show Step Therapy "A" in ICE because they are in the same GCNs as Concerta and OHCA is not able to change the Step Therapy status

on individual NDCs within a GCN. The Relexxii NDCs have a hard PA on them for all ages (0-999), so they should not process like a Tier-1 medication (despite being listed as Step "A") and any PA requests for Relexxii should be reviewed as a Special PA Tier product regardless of the Step "A" listed in ICE.
    - Methylphenidate ER 72mg tablet is much more expensive than taking (2) generic Concerta® 36mg tablets so methylphenidate ER 72mg is in Special PA.
- **QUILLIVANT XR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - QL is based on bottle size; the bottles must be reconstituted and are dispensed in their original packaging. The bottle size should be chosen based on the member's dose. In general, we should not approve QL overrides for multiples of a smaller bottle if they could fill a larger bottle based on the dose the member is taking.
- **ONYDA XR**
    - **Interim Criteria (*if applicable*):**
    - *Onyda™ XR [Clonidine Extended-Release (ER) Suspension] Approval Criteria:*

1. *An FDA approved diagnosis; and*
2. *Member must be 6 years of age or older; and*
3. *Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv, and Strattera, unless contraindicated, that did not yield adequate results; and*
4. *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided; and*
5. *A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - (clonidine extended-release oral suspension) is a centrally acting alpha2-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.
    - How Supplied: 0.1mg/mL oral suspension in 30mL, 60mL, and 120mL bottles
    - Dosage and Administration:
    - Recommended starting dosage is 0.1mg orally once daily at bedtime with or without food
    - Dose may be increased in increments of 0.1mg per day at weekly intervals depending on clinical response up to the maximum recommended dose of 0.4mg once daily at bedtime
    - Prescribing Information: https://www.trispharma.com/generic/ONYDA%20XR%20Full%20Prescribing%20Information.pdf
    - Coverage: Onyda™ XR will go into the Special PA Tier of the Non-Stimulants category of the ADHD Medications Tier chart. The additional criteria below in purple will also apply.
    - Quantity Limit(s):

        - 30mL Bottle: 30mL per 30 days
        - 60mL or 120mL Bottle: 120mL per 30 days
    - **VYVANSE chewable tablets**
        - Members currently utilizing Vyvanse® chewable tablets will need to switch to brand Vyvanse® capsules or a PA request will need to be submitted for the chewable tablets with patient-specific information addressing why the member cannot use Vyvanse® capsules, which can be opened and mixed with yogurt, water, or orange juice.
- **IDIOPATHIC HYPERSOMNIA AGENTS**
    - **GENERAL INFORMATION**
        - Based on recent clinical practice guidelines from the American Academy of Sleep Medicine, modafinil is currently the only agent with a strong recommendation for idiopathic hypersomnia (IH). Other agents with a conditional recommendation include clarithromycin, methylphenidate, pitolisant, and sodium oxybate. Other stimulants may reasonably be considered. The guidelines do not specifically address pediatric IH. Both pediatric and adult members would still need to meet ICSD-3 criteria. Guideline is available online at:
        - https://jcsm.aasm.org/doi/epdf/10.5664/jcsm.9328.
        - Nuvigil (armodafinil) and Provigil (modafinil) require PA for all members; the narcolepsy criteria or idiopathic hypersomnia criteria applies to Nuvigil and Provigil PA requests.
        - Idiopathic hypersomnia medications include:
            - Stimulants (see ADHD Tier chart), clarithromycin, Nuvigil (armodafinil), Provigil, (modafinil) – criteria only
            - Xyrem (sodium oxybate) – criteria and trials
            - Xywav (calcium/magnesium/potassium/sodium oxybates) – criteria, trials, and reason why member can't use Xyrem.
        - Approval length: 1 year
- **NARCOLEPSY AGENTS**
    - **GENERAL INFORMATION**
        - Please note: Xyrem, Xywav, and Wakix are currently the only FDA approved therapies for the treatment of cataplexy in patients with narcolepsy. Please keep this in mind when reviewing requests for these medications when the member has this specific diagnosis.
        - Nuvigil (armodafinil) and Provigil (modafinil) require PA for all members; the narcolepsy criteria or idiopathic hypersomnia criteria applies to Nuvigil and Provigil PA requests.
        - Narcolepsy medications include:
            - Stimulants (see ADHD Tier chart), Nuvigil (armodafinil), Provigil (modafinil) – criteria only
            - Sunosi (solriamfetol), Wakix (pitolisant), Xyrem (sodium oxybate) – criteria and trials
            - Lumryz (sodium oxybate), Xywav (calcium/magnesium/ potassium/sodium oxybates) – criteria, trials, and reason why member can't use Xyrem

    - Approval length: 1 year
    - Quantity Limit: 30 tablets per 30 days. If the patient is to exceed this quantity and a regular PA is approved for more than 30 tablets per month, there will need to be a Super PA quantity limit override done as well.
    - Provigil: The maximum recommended dosing is 200 mg daily. Prescriber should provide adequate supporting documentation if patient is to exceed 200 mg daily. According to the product package insert, "The recommended dose of Provigil is 200 mg given once a day…Doses up to 400 mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200 mg dose."
- **<u>AMYOTROPHIC LATERAL SCLEROSIS (ALS) AGENTS</u>**
  - **EXSERVAN, TIGLUTIK**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please give special consideration for members with ALS who have difficulty swallowing, a common symptom of ALS.
  - **RADICAVA, RADICAVA ORS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Some members may have slowly progressive disease and should be approved for the drug even if they have had the disease longer than 2 years. Please consider approval if the prescriber documents that they believe the member will benefit from treatment even if it is beyond 2 years.
  - **RILUTEK**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Riluzole is only FDA approved for amyotrophic lateral sclerosis (ALS). The intent of adding the PA is to discontinue inappropriate and unsafe use of riluzole for diagnoses other than ALS, for which safety and evidence are lacking or are very limited or inconclusive.
    - Members with a confirmed diagnosis of ALS were approved for a pre-emptive PA to continue therapy.
    - Members must meet the approval criteria, including a diagnosis of ALS. Please be strict with the diagnosis. PA requests should not be approved for other diagnoses based on stability on the medication. If you receive a PA request noting an ALS diagnosis for members with limited or no diagnosis history of ALS from a prescriber who is not a neurologist, please request documentation (e.g., office notes) to confirm the member's ALS diagnosis.
- **<u>BENZODIAZEPINES</u>**
  - **LORAZEPAM, DIAZEPAM, OXAZEPAM, ALPRAZOLAM (& XR), CHLRODIAZEPOXIDE, CLORAZEPATE DIPOTASSIUM**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

    - For members under 19, petitions for a diagnosis of seizures are typically approved for pediatric members requiring these medications. Additionally we typically approve petitions for administration prior to MRI or other procedures.
    - Typically, we would require the original prescription for a diagnosis of anxiety for children under 12 years to be written by a psychiatrist; however, you should always look at the Dr. classification. If a neurologist please consider approval, often anxiety in these children can cause seizures or other neurological symptoms. These should be looked at by a pharmacist.
    - Chronic Physical Diagnoses:
        - Seizures
        - Epilepsy
        - Paralysis
        - Multiple Sclerosis
        - Cerebral Palsy
        - Muscular Dystrophy
        - Chronic Behavioral Health Diagnoses:
        - Post Traumatic Stress Disorder
        - Panic Disorder
        - Obsessive Compulsive Disorder
        - Social Phobia
        - Severe Generalized Anxiety Disorder
        - Major Depression Recurrent
        - Bipolar Disorder
    - Approval Length: Generally 1 year
    - Quantity Limit: 3 units per day for most medications - Alprazolam 2mg set at 2 units per day.
- **<u>BUTALBITAL PRODUCTS</u>**
    - **ESGIC**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Esgic Capsule: GCN 72510 (Requires PA)
        - Preferred tabs: GCN 72530 (No PA)
    - **FIORICET W/ CODEINE**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Fioricet w/Codeine 50/300/40/30mg caps: GCN 34988 (Requires PA)
        - Preferred formulation 50/325/40/30mg caps: GCN 70140 (No PA)
    - **H.P. ACTHAR**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Members 2 years of age or younger should not have to submit a PA for the vial formulation but, if for some reason they do, please give special consideration.
        - Requests for a diagnosis of infantile spasms or West syndrome should be approved even if they are older than 2 years of age. These requests should be approved for 3

months and continued for a longer duration if necessary. The optimal duration of treatment is uncertain. Although some series suggest that hormonal therapy should be continued for many months prolonged therapy may not be necessary. The 2010 consensus statement suggests initiating a taper of ACTH after two weeks of therapy at the maximum. Relapses are not uncommon among patients who responded to an initial treatment course. No data is available to guide therapy in these cases.
    - Typically, a second course (four to six weeks) of the agent that was previously effective in obtaining control is administered. Recommended dosing per PI for infantile spasms: daily dose of 150U/m2 (divided into twice daily injections of 75U/m2) administered over a 2-week period, and then gradually tapered over a 2-week period to avoid adrenal insufficiency
    - GCN 26016 includes the following:
        - H.P. Acthar
        - Acthar
        - Cortrophin
- **<u>INSOMNIA AGENTS</u>**
    - **Interim Criteria (*if applicable*):**
        - *Approval Criteria for Pediatric Patients under 18 years of age:*
        - *Interns and Techs, please forward all these petitions to the pharmacist.*
        - *No agents currently indicated for the treatment of insomnia in the pediatric population.*
        - *Approvals based on previous non-pharmacologic therapies tried and failure of pharmacologic therapies typically used in children such as diphenhydramine or hydroxyzine.*
        - *Per Micromedex, 'SL tablet, Intermezzo(R), 1.75 mg SL for women and 3.5 mg SL for men (MAX dose) taken only once per night.*
        - *Approval Length: 6 months*
        - *Quantity Limit: 30 units per 30 days*
    - **NUDEXTA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes(*for consideration toward approval*):**
        - The DUR Board does not want to use this for dementia unspecified. There is limited data on the use of this medication in this patient population. Some patients with dementia may benefit from treatment, and these should be evaluated on a case-by-case basis. We can approve with Alzheimer's dementia diagnosis, but we should hold them to the criteria.
        - Each request should be evaluated individually on a case-by-case basis. If the member has a clinical reason for use, they should be considered for approval.
        - Approval Length: Initial - 12 weeks
        - Quantity Limit: 60 capsules per 30 days
- **<u>VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITORS</u>**
    - **AUSTEDO, AUSTEDO XR**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**

- Do not approve any PA's for Austedo from Dr. Morton (NPI: 1336222504) unless they have a diagnosis in history, and they have previous medications to confirm diagnosis.
- Don't approve Austedo unless they have the tardive dyskinesia (TD) diagnosis. (G24.0, G24.01, G25.4, G25.70, G25.79, R25.0, R25.8) in history and have medication in history that could cause TD (examples: antipsychotics, metoclopramide). Even if they were "stabilized inpatient" on Austedo we still need the baseline AIMs Scale score.

- **INGREZZA, INGREZZA SPRINKLE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - If the prescriber indicates the member has unstable psychiatric symptoms or is at risk of suicidal behavior please consider for approval on a case-by-case basis as long as they meet other criteria. If approved, please put in your message that Ingrezza was not studied in individuals at significant risk for suicidal or violent behavior and individuals with unstable psychiatric symptoms and to monitor the patient appropriately. (In the clinical trial of Ingrezza individuals at significant risk for suicidal or violent behavior and individuals with unstable psychiatric symptoms were excluded. Based on similar mechanisms of action and multiple overlapping metabolites of Ingrezza and tetrabenazine, and the inclusion of a boxed warning for the risks of depression and suicidality for tetrabenazine's use in Huntington's disease (HD), the FDA's safety review of Ingrezza paid particular attention to signals of depression and suicidal ideation. Although there was 1 case of suicide attempt in the 6-week study, findings from both studies of Ingrezza showed that the occurrence of depression and suicidal ideation in the Ingrezza groups was not significantly different from the placebo-treated patients. Also, psychiatric scale assessments indicated no worsening of symptoms in patients with schizophrenia/schizoaffective disorder or mood disorder during long- term Ingrezza treatment.)
  - Do not approve any PA's for Ingrezza from Dr. Morton (NPI: 1336222504) unless they have a diagnosis in history, and they have medications to confirm diagnosis. Don't approve Ingrezza unless they have the tardive dyskinesia (TD) diagnosis (G24.0, G24.01, G25.4, G25.70, G25.79, R25.0, R25.8) in history and have medication in history that could cause TD (examples: antipsychotics, metoclopramide). Even if they were "stabilized inpatient" on Ingrezza we still need the baseline AIMs Scale score. If they do not meet the criteria listed above, we should give a firm denial. Once we deny he (Dr. Morton) will need to submit a letter for reasoning, and we should be very careful not to approve these unless there is detailed TD diagnosis and disease management information. He has been creative in the past with workarounds. OHCA is aware that he may have to take these to the judge for appeal.
  - Approval Length: 6 months - Initiation pack also available: Please watch to make sure you are not approving the initiation pack long-term.
  - Quantity Limit: Total dose of 80mg/day
  - Ingrezza is available in 40mg and 80mg capsules. The recommended dose is 40mg the first week and then 80mg thereafter (however, continuation of 40mg once daily

may be considered for some patients). A QL of 30/30 will apply to the 40mg and 80mg capsule. If you receive an initial request for titration the 40mg will need a QLO for the first month and then they should switch to the 80mg.

CHELATING/BINDING AGENTS

- **HYPERKALEMIA AGENTS**
  - **LOKELMA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If SPS in shortage and member requires acute hypokalemia treatment can be considered for approval.
  - **VELTASSA**
    - **Interim Criteria (*if applicable*):**
    - *Veltassa® (Patiromer) Approval Criteria:*

    1. *An FDA approved diagnosis of hyperkalemia; and*
    2. *Medications known to cause hyperkalemia [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and*
    3. *A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and*
    4. *Documentation of a low potassium diet; and*
    5. *A patient-specific, clinically significant reason why the member cannot use Lokelma® (sodium zirconium cyclosilicate) must be provided; and*
    6. *Quantity limits will apply as follows:*
       - *1g Packets: A quantity limit of 120 packets per 30 days will apply; or*
       - *8.4g, 16.8g, and 25.2g Packets: A quantity limit of 30 packets per month will apply.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    -
- **HYPERPHOSPHATEMIA AGENTS**
  - **AURYXIA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Generic calcium acetate containing products, brand name Fosrenol (lanthanum carbonate chewable tablet and oral powder packet), PhosLo (calcium acetate gel capsule), Phoslyra (calcium acetate oral solution) and Renvela (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.
    - If member has failed or has reason unable to use 2 of the preferred agents, please consider for approval. Additionally, please give special consideration to requests from nephrologists, including those for patients not on dialysis.
  - **LANTHANUM CARBONATE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

    - Generic calcium acetate containing products, brand name Fosrenol (lanthanum carbonate chewable tablet and oral powder packet), PhosLo (calcium acetate gel capsule), Phoslyra (calcium acetate oral solution) and Renvela (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.
    - Use is not recommended in pediatric patients; lanthanum carbonate is deposited into developing bone, including the growth plate
    - If member has failed or has reason unable to use 2 of the preferred agents, please consider for approval. Additionally, please give special consideration to requests from nephrologists. Fosrenol oral powder may be considered for patients with poor dentition or with difficulty chewing tablets.
- **VELPHORO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Generic calcium acetate containing products, brand name Fosrenol (lanthanum carbonate chewable tablet and oral powder packet), PhosLo (calcium acetate gel capsule), Phoslyra (calcium acetate oral solution) and Renvela (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.
    - If member has failed or has reason unable to use 2 of the preferred agents, please consider for approval. Additionally, please give special consideration to requests from nephrologists, including those for patients not on dialysis.
- **IRON CHELATING AGENTS**
    - **JADENU, FERRIPROX**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Exjade® (deferasirox) tablets for oral suspension will be the preferred product and will not require prior authorization but may be subject to appropriate quantity limits

DIABETES/ENDOCRINE

- **HYPER & HYPO PARATHYROIDISM AGENTS**
    - **SENSIPAR**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Effective 1/1/18 Sensipar is now a part of the dialysis bundle. It is not covered through pharmacy or medical individually when being used for dialysis. Please reference the following:
        - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Consolidated-Billing-ESRD-PPS- 2018-CR-10312.pdf
- **PROGESTERONE PRODUCTS**
    - **GENERAL INFORMATION**

- Following the FDA withdrawal of Makena, ACOG issued a Practice Advisory with updated clinical guidance for the use of progesterone supplementation for the prevention of recurrent preterm birth, which aligns with the FDA withdrawal of Makena. Hydroxyprogesterone injection is no longer recommended for the prevention of preterm birth in patients with a history of spontaneous preterm birth. Vaginal progesterone may be considered for patients with a history of preterm birth, singleton gestation, and a shortened cervix (our current criteria for Crinone and Endometrin aligns with this recommendation).

- **<u>CHORIONIC GONADOTROPIN AGENTS</u>**
  - **NOVAREL, PREGNYL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The time around puberty, we just want to make sure it is not an adult using it for spermatogenesis, but we could see use of this until they are in their 20's.
    - Please give special consideration for individual cases, including requests for hCG stimulation test to assess secretory ability of testicular tissue (usually it is a one-time dose for the test).
- **<u>CUSHINGS DISEASE AGENTS</u>**
  - **RECORLEV**
    - **Interim Criteria (*if applicable*):**
    - *Recorlev® (Levoketoconazole) Approval Criteria:*

1. *An FDA approved indication for the treatment endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative; and*
2. *Member must be 18 years of age or older; and*
3. *Recorlev must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and*
4. *Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and*
5. *Prescriber agrees to obtain baseline liver test and electrocardiogram (ECG) prior to initiating treatment; and*
6. *Prescriber agrees to monitor liver enzymes and bilirubin weekly for at least 6 weeks after initiating treatment, every 2 weeks for the next 6 weeks, monthly for the next 3 months, and then as clinically indicated; and*
7. *Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Recorlev®; and*
8. *Member must not be taking medications that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes (e.g., dofetilide, dronedarone, methadone, quinidine, ranolazine); and*
9. *Member must not be taking medications that are sensitive substrates of CYP3A4 and/or P-gp (e.g., digoxin, lovastatin, simvastatin, tacrolimus, triazolam); and*
10. *If the member is taking medications that are strong CYP3A4 inhibitors (e.g., ritonavir, mifepristone) or strong CYP3A4 inducers (e.g. isoniazid, carbamazepine, rifampicin,*

phenytoin), the prescriber must verify the medication will be stopped 2 weeks before and during treatment with Recorlev® per package labeling; and

11. *For female members, prescriber must verify that the member is not breastfeeding; and*
12. *A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and*
13. *Initial authorizations will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide a recent 24-hour urine free cortisol (UFC) level within the normal range to demonstrate the effectiveness of this medication, and compliance will also be checked at that time. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for surgery.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Cushing's syndrome (CS) is a disorder caused by excess cortisol. The cause of CS can be exogenous (or iatrogenic) through the prolonged use of glucocorticoids or endogenous. Endogenous causes are characterized by ACTH dependency. Some ACTH-dependent causes are from a pituitary tumor (Cushing's disease) or ectopic secretion of a non-pituitary tumor. Some ACTH-independent causes are adrenocortical adenoma or nodular adrenal hyperplasia. Isturisa and Recorlev are only approved for endogenous CS and you can see that we removed adrenal and pituitary from the criteria in order to encompass any tumor not associated with the adrenal or pituitary that could be causing CS based on the new indication. However, Cushing's disease is the most common cause accounting for over 70% of cases and the ectopic tumors are much rarer.

- **ISTURISA**
  - **Interim Criteria (*if applicable*):**
  - *Isturisa® (Osilodrostat) Approval Criteria:*

1. *An FDA approved indication for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative; and*
2. *Member must be 18 years of age or older; and*
3. *Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and*
4. *Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Isturisa; and*
5. *Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline, 1 week after treatment initiation, and as clinically indicated thereafter; and*
6. *Prescriber must verify that dose titration will be followed according to package labeling; and*
7. *If the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or strong CYP3A4 and/or CYP2B6 inducers (e.g., carbamazepine, rifampin, phenobarbital), the prescriber must verify that the Isturisa® dose will be adjusted according to the package labeling; and*

8. *For female members, prescriber must verify that the member is not breastfeeding; and*
9. *Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or be an advanced care practitioner with a supervising physician who is an endocrinologist); and*
10. *A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and*
11. *Initial authorizations will be for the duration of 3 months after which time, compliance and 24-hour urine free cortisol levels within the normal range (to demonstrate the effectiveness of this medication) will be required for continued approval. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for surgery.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Cushing's syndrome (CS) is a disorder caused by excess cortisol. The cause of CS can be exogenous (or iatrogenic) through the prolonged use of glucocorticoids or endogenous. Endogenous causes are characterized by ACTH dependency. Some ACTH-dependent causes are from a pituitary tumor (Cushing's disease) or ectopic secretion of a non-pituitary tumor. Some ACTH-independent causes are adrenocortical adenoma or nodular adrenal hyperplasia. Isturisa and Recorlev are only approved for endogenous CS and you can see that we removed adrenal and pituitary from the criteria in order to encompass any tumor not associated with the adrenal or pituitary that could be causing CS based on the new indication. However, Cushing's disease is the most common cause accounting for over 70% of cases and the ectopic tumors are much rarer.

- **<u>ANTIDIABETICS</u>**
  - **GENERAL INFORMATION**
    - Ozempic: Please approve requests for Ozempic (semaglutide) for IHS (INDIAN HEALTH SERVICES PHARMACY) even if they don't meet tier trials.
    - Alogliptin: Please approve requests for alogliptin for IHS (INDIAN HEALTH SERVICES PHARMACY) even if they don't meet tier trials.
    - Internal Note: For Tier-3 medications, approval may be granted if there is a unique FDA approved indication not covered by Tier-2 medications. A trial of a Tier 1 medication (must include a trial of metformin titrated up to maximum dose), or a patient-specific, clinically significant reason why a Tier-1 medication is not appropriate will continue to apply.
  - **GLP-1 and GIP Special PA Criteria**
    - **Interim Criteria (*if applicable*):**
    - *Glucagon-Like Peptide-1 (GLP-1) Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria:*

1. *An FDA approved diagnosis of type 2 diabetes mellitus; and*
2. *Documentation of members current A1c and goal A1c must be submitted with all requests; and*
3. *Member must meet 1 of the following:*

- *Member must be currently stabilized on the requested product [documentation must be provided (e.g., pharmacy records and clinical documentation of glycemic control and/or reduction in A1c while on therapy)]; or*
- *Member must have failed to achieve glycemic control and/or goal A1c reduction despite a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with all available lower-tiered GLP-1 or GIP/GLP-1 agonists and have a documented clinical reason why the member cannot continue treatment with the lower tier medications; and*
    - *Clinical documentation of follow-up glycemic status after trials (e.g., A1c levels, blood glucose levels) must be provided with the request; and*
    - *For members who did not complete a 3-month trial with a lower-tiered GLP-1 or GIP/GLP-1 agonist (i.e., due to intolerable adverse effects), detailed information regarding adverse effects occurring with the lower-tiered medication(s) that are not expected to occur with the requested medication; and*

4. *Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza (liraglutide); and*
5. *A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- There is no clear definition of what is defined as "failure" in the ADA guidelines since each patient's glycemic goals depend on various factors. Typically, a goal A1c of <7% is appropriate for most non-pregnant adults but this can vary depending on co-morbidities, age, and other factors. Some patients (mostly older adults) may not have an actual A1c goal but their goal may be to achieve better glucose control and to prevent hyper/hypoglycemic episodes, as well as any patient's goals may change over time. **We can accept glucose control or potential other glycemic control for #2 if they submit that for patients who don't have an A1c goal.**

- **KIRSTY/MERILOG**
    - **Interim Criteria (*if applicable*):**
    - *Kirsty™ (Insulin Aspart-xjhz) and Merilog™ (Insulin Aspart-szjj) Approval Criteria:*

1. *An FDA approved diagnosis of diabetes mellitus; and*
2. *A patient-specific, clinically significant reason why the member cannot use Novolog (insulin aspart) or Fiasp (insulin aspart) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*

    - **Additional Internal Notes (*for consideration toward approval*):**
- **KERENDIA**
    - **Interim Criteria (*if applicable*):**

- *Kerendia® (Finerenone) Approval Criteria:*
  - An FDA approved indication of 1 of the following:
    - To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
      - Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
      - Member has albuminuria (urine albumin-to-creatinine ratio ≥30mg/g) despite maximum tolerated dosing of an ACE or ARB; or
    - To reduce the risk of cardiovascular death, hospitalization for HF, and urgent HF visits in adult patients with HF with left ventricular ejection fraction (LVEF) ≥40%; and
  - Member is currently receiving guideline-directed management and therapy (GDMT) appropriate to their stage of HF or have a contraindication or documented intolerance; and
  - Member is currently stabilized on a sodium-glucose cotransporter-2 (SGLT-2) inhibitor or a patient specific, clinically significant reason why the member cannot use a SGLT-2) inhibitor must be provided; and
  - Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
  - Member must not have adrenal insufficiency; and
  - Member must not have severe hepatic impairment (Child Pugh C); and
  - Prescriber must measure serum potassium and eGFR and verify the member meets the following prior to initiation of Kerendia®; and
    - Serum potassium ≤5mEq/L; and
    - eGFR ≥25mL/min/1.73m^2; and
  - Prescriber must agree to monitor serum potassium levels and eGFR 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
  - A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    - Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    - Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2; and
  - A maximum approvable dose will apply based on indication per the package labeling:
    - CKD associated with T2DM: 20mg once daily; or
    - HF with LVEF ≥40%: 40mg once daily; and
  - Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and that serum potassium levels and eGFR are monitored periodically and the

dose is adjusted accordingly per the package labeling. Subsequent approvals will be for 1 year.

- **AFREZZA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Titration packs are available and contain 180 cartridges. You should watch to make sure not approving the titration packs long-term.
- **BASAGLAR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
- **FIASP**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - Fiasp® is a new formulation of NovoLog®, in which the addition of niacinamide (vitamin B3) helps to increase the speed of the initial insulin absorption, resulting in an onset of appearance in the blood in approximately 2.5 minutes.
- **HUMALOG KWIKPEN, LYUMJEV KWIKPEN**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
- **HUMULIN R U-500**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - There were some members using the 100 unit syringe with the 500 unit vials. This is a safety risk and as a result we are PA'ing the vials and asking that they use the Humulin R 500 unit KwikPen® which is available without a PA. Members will need to have a reason why they cannot use the pens.
- **INSULIN GLARGINE U-300**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
- **INSULIN LISPRO U-100, ADMELOG, LYUMJEV**
    - **Interim Criteria (*if applicable*): n/a**

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
- **REZVOGLAR, SEMGLEE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - Please approve insulin glargine-yfgn (generic Semglee; GCN 49992 & 49993) for IHS (INDIAN HEALTH SERVICES PHARMACY) without a reason why the member cannot use Lantus or Levemir.
    - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
- **RYZODEG**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Keep in mind the Tresiba and Ryzodeg have a lower hypoglycemia risk so if that is a problem for a patient taking Lantus that may be a good reason for that patient to switch to Tresiba or Ryzodeg.
    - Insulin does not count as a brand punch but does count towards the script limit.
- **TOUJEO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Insulin does not count as a brand punch but does count towards the script limit.
    - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
- **TRESIBA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Keep in mind the Tresiba and Ryzodeg have a lower hypoglycemia risk so if that is a problem for a patient taking Lantus that may be a good reason for that patient to switch to Tresiba or Ryzodeg.
    - Insulin does not count as a brand punch but does count towards the script limit.
- **TZIELD**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Dependent on member's BSA, 2 vials may be needed for days 5-14
    - Pancreatic islet autoantibodies include:
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - Insulin autoantibody (IAA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)

- Islet cell autoantibody (ICA)

- **<u>ERYTHROPOIETIN STIMULATING AGENTS (ESA)</u>**
  - **ARANESP**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - SoonerCare members with Medicare DO NOT need a Prior Authorization
    - ESRD: All ESA products used for ESRD are bundled with dialysis and will not be reimbursed separately. We will no longer do PAs for these. Coverage of ESAs under the dialysis bundle does not require prior authorization.
    - Jehovah Witness: Please take ESA requests for Jehovah Witness members into special consideration. Due to religious reasons they cannot receive blood transfusions. We always approve (within reason) ESAs short term for Jehovah Witness members who will undergo surgery. They will need to fill out form PHARM-17 and should indicate on the petition that member is Jehovah Witness and why they will need the product.
  - **PROCRIT, EPOGEN, RETACRIT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - SoonerCare members with Medicare DO NOT need a Prior Authorization
    - ESRD: All ESA products used for ESRD are bundled with dialysis and will not be reimbursed separately. We will no longer do PAs for these. Coverage of ESAs under the dialysis bundle does not require prior authorization.
    - Jehovah Witness: Please take ESA requests for Jehovah Witness members into special consideration. Due to religious reasons they cannot receive blood transfusions. We always approve (within reason) ESAs short term for Jehovah Witness members who will undergo surgery. They will need to fill out form PHARM-17 and should indicate on the petition that member is Jehovah Witness and why they will need the product.
    - Most recent Hb levels (and date obtained) should be included on petition.
    - For patients with anemia of CKD who are not on dialysis, the FDA recommends that physicians consider starting ESA treatment only when the hemoglobin level is less than 10 g/dL and when certain other considerations apply. If the hemoglobin level exceeds 10 g/dL, physicians should reduce or interrupt the dose of ESA.
    - For patients who are on dialysis, the FDA recommends that physicians initiate ESA treatment when the hemoglobin level is less than 10 g/dL, and reduce or interrupt the dose if the hemoglobin level approaches or exceeds 11 g/dL.
    - Each approval will be for 16 weeks in duration. Authorization can be granted for up to 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. Authorization for surgery patients will be for a maximum of 4 weeks.
    - Continuation Criteria:
    - Continue dose if Hb is ≤ 11.0 g/dL.
    - If Hb is increasing and approaching 11.0 g/dL then reduce dose.

- If more than 1 g/dL increase (but Hb not greater than upper limits listed below) has occurred in a 2 week period reduce dose by 25 to 50 %.
- Discontinuation Criteria:
- ESRD – Discontinue treatment if Hb is at or above 11.0 g/dL.
- All others – Discontinue treatment if Hb is at or above 11.0 g/dL.
- If a minimum increase of 1 g/dL has not been achieved after initial 8 weeks of therapy for anemia associated with chemotherapy and 12 weeks of therapy for ESRD.
- Reinitiation Criteria:
- If Hb decreases to ≤ 10 g/dL then therapy may be reinitiated at 25 to 50% of the prior dose.

- **DIABETIC SUPPLIES**
  - **GENERAL INFORMATION**
  - **Covered Supplies:**
    - Please refer to OHCA website for list of preferred products: https://oklahoma.gov/ohca/providers/types/pharmacy/diabetic-supplies-for-pharmacy.html
    - In addition to strips and meters, lancets, syringes, pen needles, and control solution (1 additional a year) will also be covered in the pharmacy claims system.
    - Supplies for insulin pumps remain DME claims.
    - Copay/Prescription Limit:
    - Diabetic supplies have a zero copay and do not count against the monthly prescription limit.
  - **Prior Authorization:**
    - An automated prior authorization process looks for insulin and other diabetic medications in the member's claims history. If the medication or diagnosis is not found in claims history or if the quantity submitted exceeds the maximum allowed, the claim will deny for prior authorization. It will also look for a diagnosis of gestational diabetes. Pharmacies should be instructed to submit the medication claims for new orders for insulin or medications first and then the supply claims second.
    - A copy of the prior authorization form can be found on the OHCA website and is available in PA Process. (Form PHARM-35) The form asks all necessary questions to determine if the member needs additional strips. Each request should be evaluated individually based on the information provided. We are not asking for blood sugar logs, but just that the prescriber has verified the member has been compliant with monitoring.
    - Allergy syringes are considered DME and not covered under the pharmacy benefit. The pharmacy must have DME contract and submit the claim to OHCA DME.
  - **Claims Processing:**
    - Diabetic supply claims can be processed by SoonerCare Pharmacy providers only.
    - Claims should be submitted using the product NDC and quantity/day supply requested (50 strips=quantity of 50)

    - Pharmacies should be instructed to submit the medication claims for new orders for insulin or medications first and then the supply claims second.
    - Please note, automated refills of diabetic supplies are not allowed. Refills should be ordered by the member or the member's representative.
    - Since these products are now being run similar to other medications, the split billing will be the same as other medications.
    - Claims for Medicaid/Medicare dual eligible members are not affected by these changes and should continue to be submitted to Medicare Part B.
    - Members who are dually eligible but are only diagnosed with gestational diabetes (vs type 1 or type 2 diabetes) will need a PA for their diabetic testing supplies. Medicare Part B does not cover diabetic supplies for a diagnosis of gestational diabetes. These members' medications will not be in the system because Medicare Part D will be covering those.
    - Nursing homes use pooled diabetic supplies. If the member is listed as a long-term-care patient in ICE under level of care, claims for diabetic supplies will not process. This includes continuous glucose monitors (CGMs) and CGM supplies. The claim rejection in ICE will show DRUG NOT COVERED FOR LTC MEMBER. They are to use the meter and strips the nursing home uses in their pooled supplies. The cost for these should be accounted for in their daily nursing home fee they receive. (The nursing home is responsible for providing these supplies. They are not separately billable items. There is no change for these members. Any paid claims for the diabetic supplies for patients in the nursing home will be RECOUPED.) Please see message #1913.
- **Lost meters:**
    - If a member loses a glucometer, we cannot replace it unless they are a pediatric member (20 and under). Adult members are only granted one glucometer per year. OHCA's stance is that adult members were not previously getting a glucometer through SoonerCare when it was through medical/DME claims (so it is a once per year benefit). As for children, an override can be given for a replacement (these can be requested on an early refill override form, but the early refill override edit code is not required if approved).
- Diabetic meters do NOT pay for a refill at 80% of a year like a typical medication would. It is a hard year from when they last filled it.
- STBS members will be able to receive strips and meters (they are covered even though these are OTC products). Most of these should go through without a PA (even if they don't have meds in istory but as long as they have a pregnancy diagnosis).
- Dual Eligible Members: Diabetic supplies are typically a Part B benefit. For dual eligible members with gestational diabetes we can add a super PA to override error code 2514 (drug covered by Medicare) to a PA for diabetic test supplies this is the only way the claim will pay (not insulin syringes). Part B does not cover diabetic testing supplies for gestational diabetes.
- Omnipod is not covered by SoonerCare. The NDCs are inactive in ICE (indicatingno pharmacy coverage), but Omnipod is also not covered through DME. HCPCS code E0784 is

covered by SoonerCare (requires PA), but only applies to traditional insulin pumps, not to Omnipod. The HCPCS code for Omnipod (A9274) is not covered by SoonerCare.

- Novopen Echo® and Humapen® Luxura™ HD are considered DME items. If you receive a request for one of these products, please refer to the DME department at OHCA for further assistance.
- Glycogen Storage Disease: A prescriber at the children's hospital in Missouri has two SoonerCare patients who have a glycogen storage disease (they are at risk for hypoglycemia and must monitor their blood sugar). We will cover for this diagnosis, but they must submit a PA, and they must still use one of our covered products.
- Somatuline Depot prescribing information recommends glucose monitoring. Glucose monitoring is recommended and antidiabetic treatment adjusted accordingly.
- InPen Smart Insulin Pen: InPen Smart Insulin Pen is not covered through the SoonerCare pharmacy benefit.
- NDCs: InPen (for Humalog) 62088000031, 62088000032, 62088000033. InPen (for Novolog or Fiasp) 62088000034, 62088000035, 62088000036
- Approval Length: 1 year (with exceptions)
- Quantity Limits:
    - If the system finds oral diabetes medications, it will authorize up to 100 strips/100 days and 100 lancets/100 days.
    - If the system finds insulin and/or a diagnosis of gestational diabetes, it will authorize up to 300 strips/30 days and/or 300 lancets/30 days.
    - The system will authorize up to 200 syringes or pen needles/30 days.
    - GLP-1 medications will also trigger authorization for pen needles.
    - Quantities exceeding the options listed above will require manual PA processing.
- **ACCU-CHEK GUIDE TEST STRIPS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Accu-Chek Guide test strips for members on the MiniMed 770G Insulin pump by Medtronics. Member must be on the MiniMed 770G insulin pump in order to qualify for the Contour Next strips.
- **CONTOUR NEXT TEST STRIPS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Contour Next test strips for members on the MiniMed 630G Insulin pump by Medtronics. Member must be on the MiniMed 630G insulin pump in order to qualify for the Contour Next strips.
- **KETONE TESTING**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If a pharmacy calls requesting ketone test strips, please refer them to the urine test strips, not the blood test strips, if they are OVER 4 years of age.
    - Remember the following:
    - Covered blood ketone test strips and meters have an age restriction of 0-4 years of age.

- Members over 4 years of age should use the urine ketone strips [covered 100/34 days, currently for GCN 35600 (always verify in ICE)] or provide a reason why the urine ketone strips are not appropriate.
- Please refer to OHCA website for list of covered products: https://oklahoma.gov/ohca/providers/types/pharmacy/diabetic-supplies-for-pharmacy.html
- For the urine test strips, currently only the 50 count are active since they tend to expire before all used.
- Currently covered products without prior authorization for members 0-4 years of age: SoonerCare is only covering the Precision Xtra ketone strips (NDC 57599-0745-01), not the PrecisionXtra blood glucose strips. Therefore, if a member has the Precision Xtra blood glucose/ketone meter for ketone testing, they'll need a 2nd glucometer (one of the preferred brands) for blood glucose testing.

- **TALKING GLUCOMETER**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Prodigy (08484070120) and strips (08484072500) will have a hard PA and are covered for visually impaired. We will require a reason why the member needs this meter (i.e., blind or vision problems).
  - Easymax Voice (47884-0175-50) and strips (47884-0171-01) have a hard PA and are covered for visually impaired or require a clinically significant reason for use.
  - Embrace meter is a talking glucometer for blind members. We will continue to cover this meter and the strips associated with it, but it will require a PA. We will require reasoning why the member needs this meter (i.e., blind or vision problems).
  - Approval Length: 1 year
- **CONTINUOUS BLOOD GLUCOSE MONITOR (CGM)**
  - **Interim Criteria (*if applicable*):**

1. *INDICATIONS*
    - *Medical Necessity: documentation submitted to request services or substantiate previously provided services must demonstrate, through adequate medical records, evidence sufficient to justify the member's need for the service in accordance with OAC 317:30-3-1(f).*
    - *CGM device requested must be approved by FDA as non-adjunctive and must be used for therapeutic purposes: devices may only be used for members within the age range for which the device has been FDA approved.*
    - *CGM must be prescribed by a physician, physician assistant or an advanced practice registered nurse.*
    - *For a member who has a medically documented diagnosis of diabetes mellitus the provider should submit medical documentation demonstrating the following criteria (1-5):*
        1. *The member has a diagnosis of diabetes meeting the criteria of American Diabetes Association Standards of Medical Care in Diabetes; AND*

2. *The member's treating practitioner has determined that the member (or member's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; AND*
3. *The CGM is prescribed in accordance with its FDA indications for use; AND*
4. *The member for whom a CGM is prescribed, to improve glycemic control, meets at least one of the criteria below:*
    - *The member is insulin-treated; OR*
    - *The member is 20 years of age or under and has a history of problematic hypoglycemia with documentation of at least one of the following:*
        - *Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; OR*
        - *A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.*
5. *Within 6 months prior to ordering the CGM the treating practitioner has an in- person or telehealth visit with the member and/or family to evaluate their diabetes control and determines that criteria (1-4) above are met.*

***NOTE: An implantable CGM device and/or an automated insulin delivery system (artificial pancreas device system) are not a covered benefit.*

2. *FREQUENCY*
    - *The PA for CGM system may be approved for up to 1 year. A maximum of 1 supply allowance claim for therapeutic CGM is allowed for one month's prospective billing; 1 month supply = 1 unit of service. Readers, transmitters and sensors to be replaced as medically necessary.*
3. *CONTINUED MEDICAL NECESSITY*
    - *At least every 6 months following the initial prescription of the CGM, the treating practitioner has an in-person or telehealth visit with the member to assess adherence to their CGM regimen and diabetes treatment plan. CGM requires proper review and interpretation of the data by both the patient and the provider to ensure that data are used in an effective and timely manner.*
    - *Patients should receive ongoing instruction and regular evaluation of technique, results and their ability to use data from self-monitoring of blood glucose to adjust therapy.*
    - *PA request for the initial 1 year will include sensors, a transmitter and a receiver (as applicable). It is important to note the transmitter may not be disposable; however the receiver battery does have a limited life of 3 years or greater.*

        - *To renew the PA after 1 year for additional supplies, request must contain current documentation which substantiates the continued use of the device as prescribed by the provider. All required documentation listed above in I. INDICATIONS must also be submitted.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Items that do not meet the guideline criteria may not be covered. This includes any additional software and/or the coverage of any device that may be utilized for downloading the data such as a personal computer, smart phone and/or a tablet. Coverage is limited to those therapeutic CGM systems where the member uses a receiver classified as DME to display glucose data. If a member uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with the dedicated receiver classified as DME, the non-DME device (smart phone, tablet, etc.) is non-covered.
- **<u>GONADOTROPIN-RELEASING HORMONE (GNRH) AGENTS</u>**
  - **GENERAL INFORMATION**
    - The following changes will apply (effective 2/20/24) - PA requests for gender identity disorder (GID)/gender dysphoria:
    - Adults (ages 18+) – continue coverage for GID/gender dysphoria:
      - Masculinizing hormones (i.e., testosterone) will continue to require PA for adult female members and may be approved when appropriate
      - Feminizing hormones (e.g., estrogen, progesterone) will now require PA for adult male members and may be approved when appropriate
    - Gonadotropin-releasing hormone (GnRH) meds will not have any changes to the current PA criteria/status for adults
    - Minor members (ages 0-17):
      - Current utilizers may be allowed 6 months of therapy to taper off of medications (10/5/23 to 4/5/24)
      - No PAs should be approved after 4/5/24 for minor members when using for GID or a related diagnosis.
      - There are no exceptions (for new requests or for continuation requests for coverage after 4/5/24).
      - The coverage update/restriction is not appealable, as it is due to state law and is not due to clinical criteria (no clinical determination is made).
  - **SUPPRELIN LA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - MEDICAL ONLY - We can cover through pharmacy only if we are secondary insurance. In this case they must have a covered diagnosis and then we must send the information to Jill so she can get a "waiver" to cover the copay via pharmacy; We approved a one-time pharmacy claim/PA for Supprelin LA to allow them to bill it through pharmacy for a patient of Dr. Minu George on 08/2018. They were notified this is a one- time exception. This product is considered medical only.
  - **MYFEMBREE**
    - **Interim Criteria (*if applicable*): n/a**

- **Additional Internal Notes (*for consideration toward approval*):**
- Approval Length: Lifetime approval duration of 24 months
- Quantity Limit: 28 tablets per 28 days

- **ORIAHNN**
  - **Interim Criteria (*if applicable*):**
  - *Oriahnn® (Elagolix/Estradiol/Norethindrone and Elagolix) Approval Criteria:*

1. *An FDA approved diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; and*
2. *Member must be 18 years of age or older; and*
3. *Member must not have any contraindications to therapy including:*
   - *Osteoporosis; and*
   - *Pregnancy; and*
     - *Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and*
     - *Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and*
   - *Hepatic impairment or disease; and*
   - *Undiagnosed abnormal uterine bleeding; and*
   - *High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and*
   - *Current or history of breast cancer or other hormonally-sensitive malignancies; and*
   - *Known hypersensitivity to ingredients in Oriahnn®; and*
   - *Prescriber must verify the member will not use Oriahnn® concomitantly with an organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and*
4. *Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids); and*
5. *A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and*
6. *A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and*
7. *A quantity limit of 56 tablets per 28 days will apply; and*
8. *Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Myfembree®, a combined cumulative maximum treatment duration of 24 months will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- **ORLISSA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**

    - Approval Length: doses of 200mg twice daily will not exceed 6 months and for 150mg once
    - daily will not exceed 24 months
    - Quantity Limit: one 150mg tablet per day or two 200mg tablets per day (refer to criteria)
- **GROWTH HORMONE – GROWTH RELATED DISORDER AGENTS**
  - **GENERAL INFORMATION**
    - Delayed bone age means any delay in bone age (even 1 month counts as delayed).
    - To calculate the height z-score, use the following websites: Members 0 to 36 months https://peditools.org/growthinfant/
    - Members 2 to 20 years https://peditools.org/growthpedi/index.php
    - Epiphyses on average seal at age 15 years for girls and 16 years for boys.
    - For continuation requests:
    - Clinical info missing: If updated height or other clinical information is not provided, please consider short-term approval if the member has an upcoming appointment and needs some to get them through to the next appointment. They should provide the date of the next office visit.
    - Poor compliance: If member is non-compliant, only approve for 3 months with the warning about compliance message. If member is still non- compliant after the 3-month warning, the request should be denied unless the prescriber provides enough compelling documentation regarding the reasons for previous non-compliance and the steps taken to ensure member will remain compliant in the future. Please review the information submitted on a case-by-case basis.
    - GV <2.5cm/year: If GV is <2.5cm/year, approve with a 3-month warning regarding low GV - this does not apply to those on adult dosing.
    - Nearing covered height or epiphyseal closure: Can approve short-term with 3-month warning if they are close to the covered height (when applicable) or if close to the average age of epiphyseal closure.
    - We DO cover non-preferred growth hormone products if we are copay only (or secondary insurance). They must still meet our criteria for growth hormone (height requirements, bone age etc.), but we cover the copay even if it is a non-preferred product.
    - OHCA has asked us to add the following to PA messages for growth hormone that are only approved for short-term treatment due to compliance issues - Prescribers and Pharmacies: You must inform member or guardian of warning regarding non-compliance and continuation of treatment coverage. Please be sure you include this going forward on the GH compliance short- term approvals.
    - If you approve a Norditropin, remember that the 5mg, 10mg, and 15mg cartridges are 1.5mLs, therefore you have to multiply by 1.5 when approving units. We approve this med primarily for infants with hypoglycemia because it can be dosed in smaller increments than the Genotropin pens or Miniquicks. Once they are on a stable dose for which there are Miniquicks available (0.2mg, 0.4mg, etc.) we can ask them to switch to the preferred product.
    - Adults and patients transitioning from pediatric to adult dosing:

- The current AACE/ACE guidelines (https://doi.org/10.4158/GL-2019-0405) for the management of GH deficiency in adults and patients transitioning from pediatric to adult dosing no longer recommend weight-based dosing for these patients. Recommended initial adult doses range from 0.1 to 0.5mg per day depending on age and comorbidities but may be higher for younger transition patients. For transitioning patients, it is recommended to resume GH therapy at 50% of the dose last used in childhood. These initial doses should then be titrated at 1-to-2-month intervals, targeting an IGF-1 level within the age- adjusted reference range provided by the laboratory utilized [IGF-1 standard deviation score (SDS) between -2 and +2]. Please consider the member's age and previous GH dose used when reviewing GH requests for members transitioning to adult dosing. If a prescriber specifically requests weight-based dosing, there are weight-based and non-weight based adult dosing recommendations in the full Prescribing Information of most of the individual GH products. For Genotropin, the initial adult weight-based recommendation is 0.04mg/kg/week (approximately 0.0057mg/kg/day).
- Macrilen (macimorelin for oral solution): Growth hormone (GH) secretagogue receptor agonist indicated for the diagnosis of adult growth hormone deficiency. Will be covered as medical only; there is no J-code (and CMS is not expected to assign one); this means they will have to bill the Macrilen on the unclassified code (J3490). The unclassified code does not require prior authorization, but they will have to submit an invoice with the claim. The unclassified code is closely monitored but we should not give them an "approval" of any sort even if they submit a PA for a medical claim. We cannot guarantee reimbursement via an approved PA. This was set up this way to limit use of the product to prescribers who feel it is very important for their patient (they will have to buy and bill themselves and won't be guaranteed payment beforehand).

- **SKYTROFA**
  - **Interim Criteria (*if applicable*):**
  - *Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:*

1. *Member must have a confirmed diagnosis of 1 of the following:*
   - *Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; or*
   - *Adult GHD confirmed by 1 of the following:*
     - *Insulin tolerance test (ITT) with peak growth hormone (GH) response <5ng/mL; or*
     - *Glucagon stimulation test (GST) with peak growth hormone (GH) response as follows:*
       - *Member's recent body mass index (BMI) must be provided; and*
       - *If BMI is ≤30kg/m2: Peak GH response is ≤3ng/mL; or*
       - *If BMI is >30kg/m2: Peak GH response is ≤1ng/mL; or*

        - *≥3 other pituitary hormone deficiencies (e.g, adrenal, thyroid, gonadal, vasopressin) with insulin-like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and*
    2. *Member's weight must be ≥11.5kg; and*
    3. *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and*
    4. *Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and*
    5. *Initial approvals will be as follows:*
        - *For pediatric members, initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; or*
        - *For adult members, initial approvals will be for 0.7mg, 1.4mg, or 2.1mg per week depending on the member's age and oral estrogen use per package labeling; and*
    6. *Initial approvals will be for the duration of 6 months. For additional approval consideration:*
        - *Dosing should be appropriate; and*
        - *Member should have had a recent office visit with new information regarding heights provided; and*
        - *Member should be compliant; and*
        - *Growth velocity should not be <2.5cm/year if not on adult dosing; and*
        - *For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤+2; and*
        - *For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and*
    7. *A maximum approved dose of 6.3mg per week will apply for members with adult GHD.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If an adult member meets all approval criteria for Skytrofa, the adult dosing of Skytrofa should be handled in a similar way to adult dosing of Genotropin. Once the epiphyses are closed or growth velocity (GV) is <2.5cm/year, the member should switch to adult dosing. Initial adult dosing (regardless of previous dose) should be 0.7mg, 1.4mg, or 2.1mg per week depending on the member's age and use of oral estrogen. This dose can then be titrated based on the member's IGF-1 level.
- **VYKAT XR**
    - **Interim Criteria (*if applicable*):**
    - *Vykat™ XR (Diazoxide Choline) Approval Criteria:*
    1. *An FDA approved diagnosis of Prader-Willi syndrome (PWS) confirmed by chromosome analysis (results of genetic testing must be submitted); and*
    2. *Member must be 4 years of age or older; and*
    3. *Prescriber must confirm member has moderate to severe hyperphagia related to PWS; and*

4. *Must be prescribed by a geneticist, endocrinologist, psychiatrist, or other specialist with expertise in the treatment of PWS; and*
5. *The member's caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g., locked food storage); and*
6. *Prescriber must confirm the member is able to successfully swallow the number of tablets necessary to achieve the target maintenance dose; and*
7. *Prescriber must confirm the member does not have hepatic impairment or renal impairment; and*
8. *Fasting plasma glucose and HbA1c must be evaluated prior to initiating treatment with Vykat™ XR; and*
    - *For members with hyperglycemia, the prescriber must confirm the member's blood glucose has been optimized prior to initiating treatment; and*
    - *Prescriber must agree to monitor blood glucose and HbA1c periodically during treatment; and*
9. *Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vykat™ XR, and agrees to modify the dose, if necessary; and*
10. *Member's recent weight (taken within the past month) must be provided to authorize the appropriate amount of drug required according to package labeling; and*
11. *Initial approvals will be for the duration of 6 months; and*
12. *Subsequent approvals (for the duration of 6 months) require all the following to be met:*
    - *Prescriber must verify the member is tolerating and responding well to the medication as demonstrated by an improvement in hyperphagic symptoms; and*
    - *Member has been adherent to therapy; and*
    - *Member's recent weight (taken within the past month) must be provided to ensure the requested dose is still appropriate for member's weight.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **<u>INSULIN-LIKE GROWTH FACTOR-1 (GF-1) AGENTS</u>**
    - **INCRELEX, IPLEX**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**

Standard Deviation Table (ONLY FOR IGF-1)

Age (years)	Lab Reference Range	Mean	SD	2.5 SD Below Mean**
1 – 2	30 – 122	76	23	≤18.5
3 – 4	54 – 178	116	31	≤38.5
5 – 6	60 – 228	144	42	≤39
7 – 8	113 – 261	187	37	≤94.5
9 – 10	123 – 275	199	38	≤104
11 – 12	139 – 395	267	64	≤107
13 – 14	152 – 540	346	97	≤103.5
15 – 16	257 – 601	429	86	≤214
17 – 18	236 - 524	380	72	≤200

**To be ≤ 2.5 SD below the mean, the level must be ≤ the value listed.

- **SEROSTIM**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Approval Length: Approvals will be for four weeks initially
  - Quantity Limit: 28 vials per 28 days
- **VOXZOGO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Epiphyses on average seal at age 15 years for girls and 16 years for boys. If we receive requests for Voxzogo beyond these ages, particularly if GV is <1.5cm/year, we should consider requesting clinical documentation of open epiphyses, such as an x-ray report stating the epiphyses are still open.
  - Approval Length: Initial: 6 months
  - Quantity Limit: 30 vials per 30 days
- **ZORBTIVE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Approval Length: 4 weeks of treatment

- **LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) & IUD AGENTS**
  - **GENERAL INFORMATION**
    - Only covered under the Medical Benefit. Do not approve for pharmacy.
    - Medical only and do not require prior authorization through medical:
      - Mirena (J7298)
      - Liletta (J7297)
      - Skyla (J7301)
      - Nexplanon (J7307)
      - Kyleena (J7296)
      - Paragard (J7300)
    - In the past, if for some reason the patient needed a new IUD early (e.g., IUD got dislodged), then a PA had to be entered to allow for a second device to be placed. The time frame limit has been removed and no longer applies.
- **TESTOSTERONE AGENTS**
  - **GENERAL INFORMATION**

- Please approve for boys aged 14 - 16 with one testosterone level below normal and a Tanner Score of 1 or 2 (1 is no development and 4 is fully developed). Approve for 6 months. If pt is responding well, approve for another 12 months. Most will only require 1.5 years, some may require longer depending on the underlying cause.
- In boys with diagnosis of delayed puberty, it may be appropriate to forgo the requirement for two 8:00am testosterone labs under 300ng/dL. For some kids 8:00am labs may be hard to obtain due to transportation arrangements. So one lab and not necessarily before 8:00am may be sufficient. The physician can tell by physical evaluation, and sometimes may initiate a testosterone injection first, due to the availability and low cost of the testosterone injections. If pt does not respond, a lab may be warranted for further evaluation. Main things to check for:
- Appropriate diagnosis of delayed puberty and age around 14-16.
- Appropriate Tanner Score if included.
- Appropriate medication and dosing (nothing out of the ordinary).
- Tanner Staging is an objective classification system that providers use to document and track the development and sequence of secondary sex characteristics of children during puberty. This is not a lab value, but is a scale of physical development. https://www.ncbi.nlm.nih.gov/books/NBK470280/
- We cover micronized testosterone (compound claim) for hypospadias, but a PA must be submitted. Usually it is little kids that need the product right around when they are having a surgery to correct the condition and it will just be a short-term approval.
- Allow for one-time testosterone prepubertal priming for boys prior to growth hormone stimulation testing.
- Jatenzo, Kyzatrex, Tlando, and Xyosted are contraindicated in men with hypogonadal conditions, such as “age-related hypogonadism”, that are not associated with structural or genetic etiologies. All other testosterone products contain “Limitations of Use” or other general statements regarding “age-related hypogonadism”, stating safety and efficacy have not been established for that indication. Testosterone products can increase blood pressure that can increase the risk of major adverse cardiovascular events (MACE).
- PA requests for gender identity disorder (GID)/gender dysphoria
    - Minors (ages 0-17) - No PAs should be approved after 4/5/24 for minor members when using for GID or a related diagnosis. There are no exceptions (for new requests or for continuation requests for coverage after 4/5/24). The coverage update/restriction is not appealable, as it is due to state law and is not due to clinical criteria (no clinical determination is made).
    - Adults (ages 18+) – continue coverage for GID/gender dysphoria:
        - Masculinizing hormones (i.e., testosterone) will continue to require PA for adult female members and may be approved when appropriate
        - Feminizing hormones (e.g., estrogen, progesterone) will now require PA for adult male members and may be approved when appropriate

- NDC vs. SEX RESTRICTION (4023) override will need to be added to approved PAs

- **AZMIRO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Azmiro™ (testosterone cypionate) is an androgen indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.
  - Limitation(s) of Use: Safety and efficacy of Azmiro™ in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and effectiveness in pediatric patients below the age of 12 years have not been established.
  - How Supplied: 200mg/mL in a single-dose vial or single-dose prefilled syringe
  - Dosing and Administration:
    - Recommended dosage is 50mg to 400mg administered every 2-4 weeks as a deep intramuscular (IM) injection in the gluteal muscle
    - Dose and schedule should be individualized based on the patient's age, diagnosis, response to treatment, and the appearance of adverse reactions.
    - The prefilled syringe should be administered as an intramuscular injection by a health care professional only.
  - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=235b5625-570d-3fba-e063-6394a90aa2d1
  - Coverage: **Azmiro™ will be placed into the Special PA Tier** of the Testosterone Products Tier chart.
- **UNDECATREX**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Undecatrex™ (testosterone undecanoate) is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
  - Limitation(s) of Use: Safety and efficacy of Undecatrex™ in males less than 18 years old have not been established.
  - How Supplied: 100mg, 150mg, and 200mg oral capsules
  - Dosing and Administration:
  - Recommended starting dose is 200mg twice daily with food
  - Serum testosterone should be measured 7 days after initiation (or after dosage adjustment), and dose should be adjusted as necessary
  - Minimum recommended dose is 100mg once daily in the morning
  - Maximum recommended dose is 400mg twice daily
  - See the full Prescribing Information for specific dosage adjustment recommendations, based on serum testosterone concentrations

- Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=0828e67d-8b53-4297-aab8-196ded3dba1f&type=pdf
- Coverage: **Undecatrex™ will be placed into the Special PA Tier** of the Testosterone Products Tier chart.
- Quantity Limit: 120 capsules per 30 days

- **CRENESSITY**
  - **Interim Criteria (*if applicable*):**
  - *Crenessity™ (Crinecerfont) Approval Criteria:*

1. *An FDA approved indication as adjunctive treatment to glucocorticoid replacement to control androgens in members with classic congenital adrenal hyperplasia (CAH); and*
2. *Member has a confirmed diagnosis of CAH due to 21-hydroxylase deficiency (21OHD) as confirmed by 1 of the following (results of the selected test must be submitted with the request):*
   - *Elevated 17-hydroxyprogesterone (17OHP) level; or*
   - *Confirmed CYP21A2 genotype; or*
   - *Positive newborn screening with confirmatory second-tier testing; or*
   - *Cosyntropin stimulation; and*
3. *Member must be 4 years of age or older and weigh ≥10kg; and*
4. *Crenessity™ must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and*
5. *Prescriber must verify that member will continue glucocorticoid replacement therapy concomitantly with Crenessity™ and the member will be monitored for signs of acute adrenal insufficiency or adrenal crisis; and*
6. *A quantity limit of 60 tablets or 60mLs per 30 days will apply; and*
   - *For members who require increased doses above 100mg twice daily, a quantity limit override may be approved with documentation that the member is taking a strong or moderate CYP3A4 inducer (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Crenessity™; and*
7. *Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents that the member is responding well to therapy as indicated by a decrease in glucocorticoid daily dose from baseline or a decrease in serum androstenedione levels from baseline; and*
8. *Subsequent approvals will be for 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Per the 2018 Endocrine Society guidelines for Congenital Adrenal Hyperplasia (CAH) Due to Steroid 21-Hydroxylase Deficiency (21-OHD), a morning 17-OHP level or a 17-OHP following a cosyntropin stimulation test >1,000ng/dL (>30nmol/L) is typically indicative of a diagnosis of CAH due to 21-OHD. However, some patients with non-classic CAH could potentially have a 17-OHP level ≥ 1,000ng/dL but they would likely not present with adrenal insufficiency requiring glucocorticoid

treatment but most patients with 21-OHD will likely have 17-OHP levels >3,000ng/dL making the diagnosis clearer. Please note that the results of the testing are required to be submitted with requests and lab ranges can vary from source to source so please use the reference ranges of the lab results submitted to assess the members 17-OHP level. Additionally, other hormonal and clinical assessments would likely be taken into consideration when diagnosing a member with CAH due to 21-OHD so if office notes are provided, please evaluate them with the requests received.

- Crenessity™ (crinecerfont) is a corticotropin-releasing factor type 1 receptor antagonist indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).
- How Supplied:
  - Capsules: 25mg, 50mg, 100mg
  - Oral solution: 50mg/mL
- Dosage and Administration:
  - Adults: 100mg twice daily with a meal
  - Pediatrics (4 years of age or older):
    - Weight (kg) Dosage Regimen
      10kg to <20kg 25mg twice daily
      20kg to <55kg 50mg twice daily
      ≥55kg 100mg twice daily
- Crenessity™ should be taken with glucocorticoid replacement therapy for adrenal insufficiency associated with CAH. Androstenedione levels may be assessed beginning 4 weeks after Crenessity™ initiation to inform reduction in glucocorticoid dosage as clinically indicated. The glucocorticoid dosage should not be reduced below that required for replacement therapy.
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218808s000,218820s000lbl.pdf
- Coverage: Crenessity™ will be covered with a hard PA with the criteria listed.
- Quantity Limit: 60 tablets or 60mLs per 30 days

GASTROINTESTINAL

- **PANCREATIC ENZYMES**
  - **PERTZYE, VIOKACE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - if a prescriber indicates the member is currently stable on one of the non-preferred products and states member is responding well to therapy and provides justification for continued use of the non-preferred product we should consider these for approval. The criteria requires either a trial of Creon and Zenpep OR a reason why these products are not appropriate. Creon and Zenpep are very similar so if they

have failed one we should not make them try the other. Also, Pertzye has bicarbonate in it which may be a little more effective in certain patients, and could be a reason for approval, especially after failure of Creon or Zenpep.
    - Pancreaze 21,000/54,700/83,900 unit capsules (NDC 62541040510): OHCA added coverage for one specific member, and in general, this NDC should not be approved for other members. Members should use the covered pancreatic enzyme products (Creon, Zenpep, Pertzye, Viokace) or have a reason why those are not appropriate.
- **ANTI-EMETIC AGENTS**
  - **CESAMET, MARINOL, SYNDROS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - SPECIAL CONSIDERATION: Per request from Dr. Condren and approved through OHCA. Children with a diagnosis of Cystic Fibrosis (CF) who are unable to gain or sustain weight may be approved for Marinol for 3 months if the petition has a diagnosis of CF, indicates inability to gain weight, and lists other failed therapies. For continued consideration, the petition would need to include documentation that the member is sustaining/gaining weight on Marinol therapy.
    - Syndros NDCs were inactivated due to the lack of a federal drug rebate agreement with its current manufacturer. However, OHCA has recently added coverage through EPSDT for pediatric members (age 0-20 years) with a medical necessity. Please consider approval for FDA approved diagnoses or for a diagnosis of cystic fibrosis (CF) if the member is unable to gain or sustain weight. PA requests for members older than 6 years of age should also document why dronabinol oral capsules cannot be used.
    - Requests for CF should be approved, if appropriate, for 3 months and then consider continued approval (x6 months) if the prescriber documents that the member is sustaining/gaining weight on Syndros. NDC 78613020130.
  - **PALONOSETRON**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - GCN for generic Aloxi® is 20228 there are quite a few covered NDC's. If they would like to know which products are covered they should provide an NDC and we can confirm or deny. We should not be giving out NDCs.
    - Aloxi® generic is currently available without a PA and a QL of 20/28.
  - **SUSTOL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Sustol® is the subcutaneous formulation of Kytril® (granisetron) IV. Since they both have to be administered by a healthcare provider we will ask if they can use the IV formulation, but you should be open-minded if they can't use the IV formulation.
- **ANTI-ULCER AGENTS**
  - **OMPERAZOLE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

- For pediatric members, PPI tier structure applies unless contraindicated or unless they require a unique dosage form not in the lower tiers. Keep in mind that many pharmacies are no longer compounding omeprazole suspension since there are commercially available products. If the member has H2 trials and is too young for an ODT we can consider Nexium granules or Prilosec suspension (2.5mg packets for oral suspension) as options (we do not cover First Omeprazole Suspension).
- First Omeprazole is not covered. First Omeprazole is not an FDA approved medication. First Omeprazole does not have a federal drug rebate agreement. This means we would not get any reimbursement from the federal government and the state would have to pay for 100% of the medication. While we do cover some (very few) products that do not have a federal drug rebate agreement, the state will not cover products that don't have an agreement when there are other similar choices that are already covered. We can't tell them to compound omeprazole and bicarbonate since there is a commercially available medication, however if they choose to use the capsules or the powder to compound it is covered. The best way to handle these requests is to make sure they meet Tier trials (did they try the H2 and could they use the Tier-1 Nexium granules? There is also the option of Prevacid ODT if they have tried the other options.)
- Quantity Limit Overrides
  - Omeprazole 10 mg: #60 for 30 days
  - Omeprazole 20 mg: #120 for 30 days
- All other PPI's: #30 for 30 days
- In order to request a quantity limit override, a quantity limit override request form must be sent in. The above quantity limits should only be overridden if detailed clinical information is supplied which convinces the pharmacist reviewing the request that the high dose is justified. If a high dose is approved, it should generally be approved for a maximum of 3 months. If a high dose is requested again after the first 3 month approval period, evidence of a dose reduction and more detailed information about the patient's condition should usually be requested before the high dose is approved again.

- **PYLERA**
  - **Interim Criteria (*if applicable*):**
  - *Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:*

1. *An FDA approved indication for the treatment of members with Helicobacter pylori (H. pylori) infection and active or previous duodenal ulcer disease; and*
2. *A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy (e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor, tetracycline) must be provided; and*
3. ~~*A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H2) antagonist], must be provided; and*~~
4. ~~*A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for H. pylori*~~

~~*infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and*~~

5. *A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for H. pylori infection (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and*
6. *A quantity limit of 120 capsules per 10 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Please consider approving tetracycline caps for H. pylori if the member requires a tetracycline regimen vs. other regimens (is more cost effective to approve tetracycline separately than approving an H. pylori convenience pack.
- Due to rising rates of resistance in the United States, clarithromycin-based regimens are no longer a preferred option for the treatment of Helicobacter pylori (H. pylori) infection, and optimized bismuth quadruple therapy (BQT) is now considered the preferred treatment option. Additionally, H2-receptor antagonists are no longer recommended to be used in H. pylori treatment regimens.

- **TALICIA**
  - **Interim Criteria (if applicable):**
  - *Talicia® (Omeprazole/Amoxicillin/Rifabutin) Approval Criteria:*

1. *An FDA approved diagnosis; and*
2. *A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for H. pylori infection (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and*
3. *A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy (e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor, tetracycline) must be provided; and*
4. ~~*A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for H. pylori infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, metronidazole, and tetracycline), which are available without prior authorization, must be provided; and*~~
5. *A quantity limit of 168 capsules per 14 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Due to rising rates of resistance in the United States, clarithromycin-based regimens are no longer a preferred option for the treatment of Helicobacter pylori (H. pylori) infection, and optimized bismuth quadruple therapy (BQT) is now considered the preferred treatment option. Additionally, H2-receptor antagonists are no longer recommended to be used in H. pylori treatment regimens.

- **TAGAMET**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Verruca vulgaris (common wart): compendia supported with evidence of IIa (greater than IIb) for peds so acceptable for approval

- **VOQUEZNA**
    - **Interim Criteria (*if applicable*):**
    - *Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate) and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/Clarithromycin) Approval Criteria:*

1. *An FDA approved indication for the treatment of Helicobacter pylori (H. pylori) infection; and*
2. *Member must be 18 years of age or older; and*
3. *A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy (e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor, tetracycline) must be provided; and*
4. ~~*A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for H. pylori infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and*~~
5. *A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for H. pylori infection (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and*
6. *A quantity limit of 112 tablets/capsules per 14 days will apply.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - We may see requests for the individual vonoprazan 20mg tablets to be used for H. pylori which would be preferred over the dual or triple packs due to cost. If a request is received for the individual vonoprazan 20mg tablets for H. pylori, please assess why they can't use other individual guideline recommended therapies. (Similar to what we do for tetracycline).
    - Due to rising rates of resistance in the United States, clarithromycin-based regimens are no longer a preferred option for the treatment of Helicobacter pylori (H. pylori) infection, and optimized bismuth quadruple therapy (BQT) is now considered the preferred treatment option. Additionally, H2-receptor antagonists are no longer recommended to be used in H. pylori treatment regimens.

- **<u>CONSTIPATION & DIARRHEA AGENTS</u>**
    - **GENERAL INFORMATION**
        - Please consider other types of colon screening if results are negative and within the recommended timeframe per USPSTF and ACG guidelines. For any non-colonoscopy screening that is positive, the recommended next step is a colonoscopy. Please note: SoonerCare does not cover all types of screening listed in the USPSTF and ACG guidelines.

Screening Intervals

Recommended intervals for colorectal cancer screening tests include

- High-sensitivity gFOBT or FIT every year
- sDNA-FIT every 1 to 3 years
- CT colonography every 5 years
- Flexible sigmoidoscopy every 5 years
- Flexible sigmoidoscopy every 10 years + FIT every year
- Colonoscopy screening every 10 years

- **AMITIZA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - We do cover Amitiza for opioid-induced constipation caused by opioids used for cancer pain even though the indication is chronic non-cancer pain. This was a request from the DUR board.
    - Approval Length Initial: 12 weeks
    - (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **LINZESS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Initial: 12 weeks (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **MOVANTIK**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - We do cover Movantik for opioid-induced constipation caused by opioids used for cancer pain even though the indication is chronic non-cancer pain. This was a request from the DUR board.
    - Approval Length Initial: 12 weeks
    - (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **RELISTOR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - We do cover Relistor for opioid-induced constipation caused by opioids used for cancer pain even though the indication is chronic non- cancer pain. This was a request from the DUR board.
    - Approval Length Initial: 12 weeks (except for terminal disease diagnosis – 16 weeks)

    - (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **SYMPROIC**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Initial: 12 weeks
    - (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **TRULANCE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Initial: 12 weeks
    - (Please note: Members with an oncology-related diagnosis are exempt from continuation criteria and may be approved for 1 year)
- **XERMELO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Carcinoid syndrome diarrhea is also known as metastatic neuroendocrine tumor - related diarrhea, please consider approval if they use this diagnosis (and meet the other criteria); SSA therapy available without a PA include Sandostatin (octreotide) and Somatuline (lanreotide)

- **<u>CLOSTRIDIUM DIFFICILE (C. DIFF) AGENTS</u>**
    - **REBYOTA**
        - **Interim Criteria (*if applicable*):**
        - *Rebyota™ (Fecal Microbiota, Live-jslm) Approval Criteria:*

        1. *An FDA approved indication for the prevention of recurrence of Clostridium difficile infection (CDI) in members 18 years of age or older; and*
        2. *Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and*
        3. *The most recent CDI episode must be confirmed by a positive stool test for C. difficile toxin; and*
        4. *The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days); and*
        5. *The prescriber must verify that administration of Rebyota™ will occur 24 to 72 hours following completion of antibiotic course for CDI treatment; and*
        6. *Rebyota™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and*
        7. *The member must not be using Rebyota™ in combination with Vowst™ (fecal microbiota spores, live-brpk); and*
        8. *Initial approvals will be for 1 treatment course. A second treatment course may be considered following a confirmed treatment failure within 8 weeks*.

        - **Additional Internal Notes (*for consideration toward approval*):**

- Based on the Jan 2025 discontinuation of Zinplava, Rebyota and Vowst's approval criteria were updated

- **VOWST**
  - **Interim Criteria (*if applicable*):**
  - *Vowst™ (Fecal Microbiota Spores, Live-brpk) Approval Criteria:*

1. *An FDA approved indication for the prevention of recurrence of Clostridium difficile infection (CDI) in members 18 years of age or older; and*
2. *Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and*
3. *The most recent CDI episode must be confirmed by a positive stool test for C. difficile toxin; and*
4. *The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of antibiotic therapy; and*
5. *The prescriber must verify that administration of Vowst™ will occur 2 to 4 days following completion of antibiotic course for CDI treatment; and*
6. *The member must agree to bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst™; and*
7. *Vowst™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with the expertise in the treatment of CDI; and*
8. *A patient specific, clinically specific reason (beyond convenience) why the member cannot use Rebyota™ (fecal microbiota, live-jslm) must be provided; and*
9. *The member must not be using Vowst™ in combination with Rebyota™ (fecal microbiota, live-jslm); and*
10. *A quantity limit of 12 capsules for 3 days for 1 treatment course will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Based on the Jan 2025 discontinuation of Zinplava, Rebyota and Vowst's approval criteria were updated

- **<u>CHRON'S DISEASE & ULVERATIVE COLITIS AGENTS</u>**
  - **ORTIKOS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Formulation Comparison:
    - Entocort EC (budesonide ER capsule) is FDA approved for Crohn's disease and works in the terminal ilium and the full effect needed for ulcerative colitis is actually in the colon.
    - Uceris (budesonide ER tablet) is FDA approved for ulcerative colitis and has target delivery to the colon for full effect (is not indicated for Crohn's).
    - ACG 2018 Guidelines (https://www.doi.org/10.1038/ajg.2018.27) recommend ileal release budesonide for induction of symptomatic remission in patients with mild-to-moderate Crohn's disease (this includes Entocort EC and Ortikos which are controlled ileal release formulations). Systemic side effects are less common with budesonide compared with conventional glucocorticoids such as prednisone.
    - Quantity Limits: 30 capsules per 30 days

- **ROWASA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Rowasa (mesalamine) rectal suspension enemas are covered without a prior authorization (GCN: 47270); however, the kit that contains wipes (GCN: 99847) is significantly more expensive and requires a PA.
    - Approval Length: 6 weeks
- **UCERIS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Anusol-HC (GCN 28850) is a rectally administered cream that is available without prior authorization.
    - Uceris is FDA approved for ulcerative colitis and has target delivery to the colon for full effect. Entocort is approved for Crohns disease and works in the terminal ilium and the full effect needed for ulcerative colitis is actually in the colon.
    - Approval Length:
    - Tablets: 8 weeks
    - Foam: 6 weeks
    - Quantity Limit:
    - Tablets: 30/30
    - Foam: 133.6g/42
- **GATTEX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - We can be flexible with requirement for parenteral nutrition; if they have had parenteral nutrition for the past 12 months that would work. Also, for the requirement for prior use of supportive therapies such anti- motility agents, proton pump inhibitors, bile acid sequestrants, and octreotide - if a specialist is requesting and they meet other criteria these trials are not required. We should not make them try them all, if they have a trial of one, that works as well (if non-specialist).
    - Approval Length: Initial - 3 months

GENETIC DISORDERS

- **SKYSONA**
    - **Interim Criteria (*if applicable*):**
    - *Skysona® (Elivaldogene Autotemcel) Approval Criteria:*

1. *An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and*
2. *Diagnosis must be confirmed by all of the following:*
    - *Molecular genetic testing confirming a mutation in the ABCD1 gene (results of genetic testing must be submitted); and*
        - *Members must not have a full deletion of the ABCD1 gene; and*

- *Lab results indicating elevated very long-chain fatty acids (VLCFAs); and*
- *Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:*
  - *Loes score between 0.5 and 9 on the 34-point scale; and*
  - *Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and*
- *Neurological Function Score (NFS) of ≤1; and*

3. *Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and*
4. *Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and*
5. *Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and*
6. *Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and*
7. *Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and*
8. *Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the package labeling; and*
9. *Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Skysona®); and*
10. *Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and*
11. *Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and*
12. *Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and*
13. *Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at least every 3 months and through assessments for evidence for clonal expansion or predominance at least twice in the first year after treatment with Skysona®, then annually thereafter for at least 15 years, and as warranted; and*
14. *Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and*
15. *Approvals will be for 1 dose per member per lifetime.*

- **HARLIKU**
  - **Interim Criteria (*if applicable*):**
  - *Harliku™ (Nitisinone) Approval Criteria:*

1. *An FDA approved indication to reduce urine homogentisic acid (HGA) in patients with alkaptonuria (AKU); and*

    - *The diagnosis of AKU must be confirmed by 1 of the following (results of the selected test must be submitted with the request):*
        - *Genetic testing identifying biallelic pathogenic variants in the homogentisate 1,2-dioxygenase (HGD) gene; or*
        - *Urine test for HGA showing 1-8 grams of HGA excreted in 24 hours; and*
2. *Harliku™ must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with the expertise in the treatment of AKU; and*
3. *The prescriber must confirm the member has received a baseline ophthalmologic examination prior to initiating Harliku™ treatment; and*
4. *The prescriber must confirm the member has been counseled to report any unexplained ocular symptoms to their health care provider; and*
5. *A patient specific, clinically significant reason why the member cannot use Nityr® (nitisinone) 2mg tablets must be provided; and*
6. *A quantity limit of 30 tablets for 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Nityr® (nitisinone) was originally FDA approved in 2017 for hereditary tyrosinemia type 1 (HT-1) and is available as a 2mg tablet as well but is significantly less expensive than Harliku™. It is also available without a PA at this time.

- **GAMIFANT**
    - **Interim Criteria (*if applicable*):**
    - *<u>Gamifant® (Emapalumab-lzsg) Approval Criteria [Hemophagocytic Lymphohistiocytosis (HLH)/ Macrophage Activation Syndrome (MAS) in Still's Disease Diagnosis]:</u>*

1. *An FDA approved indication for the treatment of adult and pediatric members with HLH/MAS in Still's Disease; and*
2. *Member must have a confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis (sJIA) or adult-onset Still's disease (AOSD); and*
3. *Member must have active MAS confirmed by ferritin >684ng/mL and at least 2 of the following:*
    - *Platelet count ≤181 x 109/L; or*
    - *Aspartate aminotransferase (AST) >48U/L; or*
    - *Triglycerides >156mg/dL; or*
    - *Fibrinogen levels ≤360mg/dL; and*
4. *Member meets 1 of the following:*
    - *Member has had an inadequate response or intolerance to high-dose intravenous (IV) glucocorticoids; or*
    - *Member has recurrent MAS; and*
5. *Must be prescribed by, or in consultation with, a rheumatologist, immunologist, or other specialist with expertise in the treatment of HLH/MAS; and*
6. *Prescriber must verify member has received or will receive prophylaxis for herpes zoster, Pneumocystis jirovecii, and fungal infection(s), if appropriate; and*
7. *Prescriber must verify member will be monitored for tuberculosis (TB), herpes zoster, adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) as clinically indicated; and*

8. *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
9. *Approvals will be for the duration of 6 months with reauthorization granted if the prescriber documents the member is responding well to treatment, no unacceptable toxicity has occurred, and the member requires continued treatment for HLH/MAS.*

- *<u>Gamifant® (Emapalumab-lzsg) Approval Criteria [Primary Hemophagocytic Lymphohistiocytosis (HLH) Disgnosis]:</u>*

1. *An FDA approved indication for the treatment of adult and pediatric members with primary HLH with refractory, recurrent, or progressive disease or who are intolerant to conventional HLH therapy; and*
2. *Diagnosis of primary HLH must be confirmed by 1 of the following:*
    - *Genetic testing confirming mutation of a gene known to cause primary HLH (e.g., PRF, UNC13D, STX11); or*
    - *Family history consistent with primary HLH; or*
    - *Member meets 5 of the following 8 diagnostic criteria:*
        - *Fever; or*
        - *Splenomegaly; or*
        - *Cytopenias affecting at least 2 of 3 lineages in the peripheral blood (hemoglobin <9g/dL, platelets <100 x 109/L, neutrophils <1 x 109/L); or*
        - *Hypertriglyceridemia (fasting triglycerides >3mmol/L or ≥265mg/dL) and/or hypofibrinogenemia (≤1.5g/L); or*
        - *Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy; or*
        - *Low or absent natural killer (NK)-cell activity; or*
        - *Hyperferritinemia (ferritin ≥500mcg/L); or*
        - *High levels of soluble interleukin-2 receptor (soluble CD25 ≥2,400U/mL); and*
3. *Gamifant® must be prescribed by, or in consultation with, a physician who specializes in the treatment of immune deficiency disorders; and*
4. *Member must have at least 1 of the following:*
    - *Failure of at least 1 conventional HLH treatment (e.g., etoposide, dexamethasone, cyclosporine); or*
    - *Documentation of progressive disease despite conventional HLH treatment; or*
    - *A patient-specific, clinically significant reason why conventional HLH treatment is not appropriate for the member must be provided; and*
5. *Prescriber must verify dexamethasone dosed at least 5mg/m2/day will be used concomitantly with Gamifant®; and*
6. *Prescriber must verify member has received or will receive prophylaxis for herpes zoster, Pneumocystis jirovecii, and fungal infection(s); and*
7. *Prescriber must verify member will be monitored for tuberculosis (TB), adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and as clinically indicated; and*

8. *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
9. *Approvals will be for the duration of 6 months with reauthorization granted if the prescriber documents the member is responding well to treatment, no unacceptable toxicity has occurred, and the member has not received hematopoietic stem cell transplantation (HSCT).*

- **Additional Internal Notes (*for consideration toward approval*):**

- **LIVMARLI**
  - **Interim Criteria (*if applicable*):**
  - ***Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:***

1. *An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and*
    - *Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the JAG1 or NOTCH2 genes (results of genetic testing must be submitted); and*
2. *Member must be 3 months of age or older; and*
3. *Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and*
4. *Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:*
    - *Cholestyramine; or*
    - *Rifampin; or*
    - *Sertraline; or*
    - *Naltrexone; and*
5. *Member must have evidence of cholestasis demonstrated by ≥1 of the following:*
    - *Total serum bile acid >3x upper limit of normal (ULN) for age; or*
    - *Conjugated bilirubin >1mg/dL; or*
    - *Fat soluble vitamin deficiency otherwise unexplainable; or*
    - *Gamma-glutamyl transferase (GGT) >3x ULN for age; or*
    - *Intractable pruritus explainable only by liver disease; and*
6. *Members with a history of liver transplantation will not generally be approved for Livmarli®; and*
7. *Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and*
8. *Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and*
9. *Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and*

10. *Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and*
11. *Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and*
12. *Requests must be for an appropriate formulation for the member's weight, including:*
    - *Solution: The request must be for the 9.5mg/mL solution; or*
    - *Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-43kg must have already completed dosing titration using the oral solution; and*
13. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.*

- ***Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:***

1. *An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and*
    - *Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B genes (results of genetic testing must be submitted); and*
2. *Member must be 12 months of age or older; and*
3. *Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and*
4. *Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:*
    - *Cholestyramine; or*
    - *Rifampin; or*
    - *Sertraline; or*
    - *Naltrexone; and*
5. *Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and*
6. *Prescriber must verify member does not have known pathologic variants of the ABCB11 gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and*
7. *Members with a history of liver transplantation will generally not be approved for Livmarli®; and*
8. *Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and*
9. *Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and*

10. *Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and*
11. *Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and*
12. *Requests must be for an appropriate formulation for the member's weight, including:*
    - *Solution: The request must be for the 19mg/mL solution; or*
    - *Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-32kg must have already completed dosing titration using the oral solution; and*
13. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Please verify that the requested dose and formulation are appropriate for the member's weight. Depending on the member's weight, they may be required to initiate treatment using the oral solution for dosage titration, but then they could switch to the oral tablet once they reach a higher stable dose.
- However, if a member is switching from the oral solution to the tablets, please ensure that they are not wasting the oral solution. Depending on the quantity of solution dispensed, they will need to continue using the solution until it is gone in order not to waste this very expensive medication. Continued use of the oral solution is appropriate and indicated for all ages and weight ranges, so there should be no reason they cannot continue to use the solution until it is gone. The bottles can be used for up to 100 days after opening.
- As an example, if a member with ALGS weighs 25kg, they should start by using 0.5mL of the oral solution daily for the first 7 days. If they filled the entire 30mL bottle initially, it would waste 26.5mL if we approved the tablets starting on day 8. Please be careful when approving either formulation to verify that the requested dosing, quantity, and day supply are correct.

- **JYNARQUE**
  - **Interim Criteria (*if applicable*):**
  - *Jynarque® (Tolvaptan) Approval Criteria:*
  1. *An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and*
  2. *Member must be 18 years of age or older; and*
  3. *Member must not have any contraindications to taking Jynarque® including the following:*
     - *Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and*
     - *History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and*
     - *Uncorrected abnormal blood sodium concentrations; and*

    - *Unable to sense or respond to thirst; and*
    - *Hypovolemia; and*
    - *Hypersensitivity to tolvaptan or any of its components; and*
    - *Uncorrected urinary outflow obstruction; and*
    - *Anuria; and*
4. *Member must not be taking any of the following medications concomitantly with Jynarque®:*
    - *Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and*
    - *Strong CYP3A inducers (e.g., rifampin); and*
    - *V2-receptor agonists (e.g., desmopressin); and*
5. *Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and*
6. *Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and*
7. *Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and*
8. *Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Jynarque and Samsca are both tolvaptan products that have different indications and are both now available in generic formulations. Jynarque (and its generics) are currently only available through a REMS program and Samsca (and its generics) do not have a REMS program as it is not recommended to be given for more than 30 days.

- **RIVFLOZA**
    - **Interim Criteria (*if applicable*):**
    - *Rivfloza® (Nedosiran) Approval Criteria:*

1. *An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:*
    - *Molecular genetic testing identifying biallelic pathogenic variants in the AGXT gene (results of genetic testing must be submitted); or*
    - *Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and*
2. *Member must be 9 2 years of age or older; and*
3. *Rivfloza® must be prescribed by a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1); and*
4. *Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m2 prior to starting Rivfloza® and must agree to monitor renal function regularly during treatment; and*

5. *Prescriber must confirm the member has not undergone a liver or kidney transplant; and*
6. *Member must not have evidence of systemic oxalosis; and*
7. *Prescriber must verify that Rivfloza® will be administered by a health care professional or, if appropriate, the member or caregiver have been trained on the subcutaneous administration and proper storage of Rivfloza®; and*
8. *Rivfloza® will not be approved for concomitant use with Oxlumo® (lumasiran); and*
9. *The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
10. *Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **VYJUVEK**
  - **Interim Criteria (*if applicable*):**
  - *Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:*

1. *An FDA approved indication for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB); and*
2. *Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (COL7A1) gene (results of genetic testing must be submitted); and*
3. *Vyjuvek® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and*
4. *Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering location (i.e. member's home, clinic) via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and*
5. *Vyjuvek® must be administered by a health care professional (HCP) or member/caregiver trained in the administration of Vyjuvek. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health, member's home); and*
    - *If member or caregiver is administering Vyjuvek®, the prescriber must attest that they have been trained on the dosing, administration, and storage of Vyjuvek®; and*
6. *Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and*
7. *Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings until the next dressing change following administration; and*

8. *Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and*
9. *Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and*
10. *Vyjuvek® will not be approved for concomitant use with Filsuvez® (birch triterpenes 10% topical gel) or for use on wounds treated with Zevaskyn™ (prademagene zamikeracel); and*
11. *A maximum approval quantity of 1 carton (2.5mL) per week will apply; and*
12. *Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds; and*
    - *Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan; and*
    - *Vyjuvek® must continue to be administered by an HCP or a trained member/caregiver. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health, member's home).*

- **LUXTURNA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - This is part of the High-Investment Drug Carve Out.
  - Spark Therapeutics may cover the cost of the genetic test used to identify the RPE65 gene. These results are acceptable as long as it is clear they are coming from a CLIA approved lab.
- **<u>ALPHA-PROTEINASE INHIBITORS</u>**
  - **ARALAST NP, GLASSIA, ZEMAIRA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please give special consideration to members with genetic confirmation of Alpha1 antitrypsin deficiency (AATD) prior to documented emphysema with airflow obstruction, particularly Pi(null, null) type. All other criteria for these products will continue to apply.
    - The alpha1 proteinase inhibitors are similar to the hemophilia factor replacements. Each vial contains approximately 1000 mg. The vial may contain slightly more or less (each vial is labeled with the exact number of mg in the vial) depending on the lot. They are billed by the mg. When approving requests for these products, will need to authorize the appropriate amount of units based on the number of mg to be used for each dose, not the number of vials being used.
  - **PROLASTIN-C LIQUID, PROLASTIN-C**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

- Prolastin C is billed based on mg
- Please give special consideration to members with genetic confirmation of Alpha1 antitrypsin deficiency (AATD) prior to documented emphysema with airflow obstruction, particularly Pi(null, null) type. All other criteria for these products will continue to apply.

- **<u>ANEMIA AGENTS</u>**
  - **SIKLOS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The National Heart, Lung, and Blood Institute (NHLBI) guidelines recommend use of hydroxyurea in infants, children, and adolescents with SCD regardless of symptoms; please keep this in mind when evaluating requests for this medication.
    - Hydroxyurea is a cytotoxic drug. Applicable special handling and disposal procedures should be followed. Hydroxyurea capsules should be swallowed whole. Therefore, if member is unable to swallow capsules or requires a dose that is not commercially available in the oral capsule formulation, they would not be required to provide reason they could not open or otherwise manipulate the capsules and requests for the oral tablet formulation (Siklos) should be considered for approval if other criteria is met. Siklos tablets can be dispersed immediately before use in a small quantity of water in a teaspoon for those patients unable to swallow tablets.
- **<u>DUCHENNE MUSCULAR DYSTROPHY AGENTS</u>**
  - **ELEVIDYS**
    - **Interim Criteria (*if applicable*):**
    - *Elevidys® (Delandistrogene Moxeparvovec-rokl) Approval Criteria:*

1. *An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene (results of genetic testing must be submitted); and*
2. *Member must be at least 4 years of age; and*
3. *Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:*
   - *North Star Ambulatory Assessment (NSAA); or*
   - *6-minute walk test (6MWT); or*
   - *10-meter walk test (10mWT); or*
   - *Ascend 4 Steps; or*
   - *Time to Rise (TTR); or*
   - *100-meter timed test; and*
4. *Elevidys® must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and*
5. *Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and*

6. *Member must not have any deletion in exon 8 and/or exon 9 in the DMD gene; and*
7. *If the member has a deletion in the DMD gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and*
8. *Member must not have any active infections and if the member does have an active infection, the prescriber must verify Elevidys® infusion will be postponed until infection has resolved; and*
9. *Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys® and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and*
10. *Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys® administration and will be monitored weekly for the first 3 months following Elevidys® infusion then as clinically indicated; and*
11. *Prescriber must verify troponin-I will be monitored before the Elevidys® infusion and weekly for the first month following infusion then as clinically indicated; and*
12. *Prescriber must verify that platelet counts will be monitored before the Elevidys® infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and*
13. *Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys® infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys® approval); and*
14. *Member's current weight (kg) taken within the past 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and*
15. *Approvals will be for 1 dose per member per lifetime*.
    - **Additional Internal Notes (*for consideration toward approval*):**

- **AMONDYS 45, EXONDYS 51, VILTEPSO, VYONDYS 53**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - For continued approval of DMD meds, if the member no longer shows improvement or maintains baseline with their functional test, please evaluate on a case-by-case basis and consider continued approval based on the prescriber's evaluation that the medication is effective and/or is slowing progression.
- **DUVYZAT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - For continued approval of DMD meds, if the member no longer shows improvement or maintains baseline with their functional test, please evaluate on a case-by-case basis and consider ontinued approval based on the prescriber's evaluation that the medication is effective and/or is slowing progression.

- **EMFLAZA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - For continued approval of DMD meds, if the member no longer shows improvement or maintains baseline with their functional test, please evaluate on a case-by-case basis and consider continued approval based on the prescriber's evaluation that the medication is effective and/or is slowing progression.
    - If they state significant weight gain associated with prednisone: significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height.
- **DAYBUE**
    - **Interim Criteria (*if applicable*):**
    - *Daybue™ (Trofinetide) Approval Criteria:*

1. *A diagnosis of typical Rett syndrome confirmed by all of the following:*
    - *Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:*
        - *A period of regression followed by recovery or stabilization; and*
        - *Partial or complete loss of acquired purposeful hand skills; and*
        - *Partial or complete loss of acquired spoken language; and*
        - *Gait abnormalities (impaired/dyspraxic or absence of ability); and*
        - *Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and*
        - *Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and*
        - *Lack of grossly abnormal psychomotor development in the first 6 months of life; and*
    - *Genetic testing documenting a disease-causing mutation in the MECP2 gene; and*
2. *Member must be 2 years of age or older; and*
3. *Daybue™ must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and*
4. *Prescriber must agree to counsel members and caregivers on the risks of diarrhea, and weight loss, and vomiting (including aspiration and aspiration pneumonia) associated with Daybue™, and will monitor appropriately for these adverse effects; and*
5. *Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue™, including the use of a calibrated device for measuring each dose; and*

6. *Prescriber must verify the member does not have moderate or severe renal impairment; and*
    - *If the member has moderate renal impairment, the prescriber must agree to reduce the dose as required in the package labeling; and*
7. *Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and*
8. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and*
9. *A quantity limit of 3,600mL per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Daybue™ (trofinetide) was FDA approved for an updated label to add additional information regarding dosage adjustments in patients with moderate renal impairment. Additionally, a new warning was added regarding the risk of vomiting, including aspiration and aspiration pneumonia, in patients treated with Daybue™.
- Approval Length
- Initial: 3 months
- Subsequent: 1 year
- *Quantity Limit: 3600mL per 30 days*

- **IMCIVREE**
    - **Interim Criteria (*if applicable*):**
    - *Imcivree® (Setmelanotide) Approval Criteria:*

1. *An FDA approved indication of chronic weight management in adult and pediatric members 6 2 years of age and older with obesity due to 1 of following:*
    - *Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or*
    - *Bardet-Biedl syndrome (BBS); and*
2. *For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and*
3. *For BBS, diagnosis must be confirmed by the following:*
    - *Molecular genetic testing to confirm homozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and*
    - *Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:*
        - *Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or*

- *Three of the primary features previously listed in 3.b.i. plus two secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and*

4. *Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign or other types of obesity not related to POMC, PCSK1, or LEPR deficiency or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and*
5. *Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and*
6. *Member's baseline weight and body mass index (BMI) must be provided; and*
7. *Baseline BMI must be ≥30kg/m2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and*
8. *Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and*
9. *Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and*
10. *Prescriber must verify member does not have end stage renal disease [estimated glomerular filtration rate (eGFR) <15mL/min/1.73m2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m2); and*
11. *Prescriber must verify female member is not pregnant or breastfeeding; and*
12. *Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and*
13. *For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or*
14. *For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and*
15. *A quantity limit of 9mL per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Imcivree® (setmelanotide) was FDA approved for an age expansion in pediatric patients 2 years of age or older for all indications.
- Dosing: Recommended dosage in pediatric patients 2 years to younger than 6 years of age:

        - Starting dose: 0.5mg (0.05mL) injected subcutaneously (sub-Q) once daily for 2 weeks
        - Maintenance dose is determined by body weight; see Prescribing Information for details.
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213793s007lbl.pdf

- **LYSOMAL STORAGE DISEASE AGENTS**
    - **BRINEURA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - For continued approval, if prescriber indicates member has demonstrated clinical improvement, this could be considered acceptable for reauthorization. (Patients with CLN2 have limited treatment options.)
        - Approval Length: Initial – 6 months
    - **CERDELGA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Approval Length: Initial - 6 months
        - Quantity Limit:
        - For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will
        - apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply.
    - **LUMIZYME**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Lumizyme (Alglucosidase Alfa): J0221
        - Approval Length: Late-onset form - Initial: 6 months; Reauth: 1 year
        - Quantity Limit: Weight based
    - **SOHONOS**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - In patients with fibrodysplasia ossificans progressiva (FOP), flare-ups are sporadic and unpredictable, but most patients experience about 2 flare-ups per year, on average. When a flare-up occurs, the Sohonos™ dosing should change to the flare-up dosing. Please consult the full Prescribing Information if you are approving a request for flare-up dosing to ensure the appropriate doses are approved for weeks 1-4 and weeks 5-12 according to the member's age or weight. The request should indicate if it is for chronic daily dosing or flare-up dosing. Depending on the dose, some patients may initiate the flare- up dosing by taking multiples of their current daily dose, so an early refill could be needed. However, it should be at least 12 weeks until they return to the chronic daily dose, so an early fill should not be needed in most cases.
        - Please discontinue the PA for the previous strength when a new strength is approved. The member should only be receiving 1 dose of Sohonos™ at a time.

- This medication is extremely expensive, so please be sure the flare-up dosing approved is for the appropriate dose and duration. The flare-up dosing can be re-started or extended depending on the member's clinical response.

- **MIPLYFFA**
  - **Interim Criteria (if applicable):**
  - *Miplyffa™ (Arimoclomol) Approval Criteria:*

1. *An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the NPC1 or NPC2 genes (results of genetic testing must be submitted); and*
2. *Member must have the presence of at least mild disease-related neurological symptoms; and*
3. *Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and*
4. *Must be used in combination with Zavesca® (miglustat); and*
    - *Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and*
5. *A patient-specific, clinically significant reason why the member cannot use Aqneursa™ (levacetylleucine) must be provided; and*
6. *Will not be approved for concomitant use with Aqneursa™; and*
7. *Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
8. *Prescriber must verify that females of reproductive potential have been counseled on the potential risks of embryofetal harm when administered during pregnancy; and*
9. *Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Miplyffa™ (arimoclomol) is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.
  - How Supplied: 47mg, 62mg, 93mg, and 124mg oral capsules
  - Dosing and Administration: Miplyffa™ should be administered orally, in combination with miglustat, with the following recommended doses based on actual body weight:
  - 8 to 15kg: 47mg 3 times a day
  - >15kg to 30kg: 62mg 3 times a day
  - >30kg to 55kg: 93mg 3 times a day
  - >55kg: 124mg 3 times a day

- See the full Prescribing Information for additional administration instructions for patients who have difficulty swallowing capsules or when the use of a feeding tube (nasogastric or gastric tube) is needed.
- Prescribing Information:
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214927s000lbl.pdf
- Coverage: Miplyffa™ will be covered with a hard PA

- **ZAVESCA**
  - **Interim Criteria (*if applicable*):**
  - *Zavesca® (Miglustat) Approval Criteria [Niemann-Pick Disease Type C (NPC) Diagnosis]:*

1. *A diagnosis of NPC confirmed by molecular genetic testing confirming biallelic pathogenic variants in the NPC1 or NPC2 genes (results of genetic testing must be submitted); and*
2. *Member must have the presence of at least mild disease-related neurological symptoms; and*
3. *Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and*
4. *Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and*
5. *For members younger than 12 years of age, the member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug; and*
6. *A quantity limit of 180 capsules per 30 days will apply; and*
7. *Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Zavesca® (miglustat) is a glucosylceramide synthase inhibitor that is FDA approved as monotherapy for treatment of adult patients with mild/moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option.
  - Please note: Miglustat can also be used for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC), although this has not been approved by the FDA. Miplyffa™ (arimoclomol) is FDA approved, when used in combination with miglustat, for the treatment of neurological manifestations of NPC in patients 2 years of age and older, which would require off-label use of miglustat. Aqneursa™ (levacetylleucine) was also studied in combination with miglustat in a majority in study participants, although the indication does not specifically require it to be used in combination with miglustat. Zavesca® has been approved for NPC in Europe, and expert consensus guidelines for NPC also recommend the use of miglustat.

- How Supplied: 100mg oral capsules
- Dosing and Administration for NPC (based on European Labeling):
  - Patients 12 years of age and older: Recommended dose is 200mg 3 times a day
  - Patients younger than 12 years of age: Recommended dose should be adjusted based on body surface area (BSA) as follows:

BSA (m2)	Recommended Dose
>1.25	200mg 3 times a day
>0.88-1.25	200mg twice a day
>0.73-0.88	100mg 3 times a day
>0.47-0.73	100mg twice a day
≤0.47	100mg once a day

- Prescribing Information (FDA): https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021348s016lbl.pdf
- Prescribing Information (European):
- https://www.ema.europa.eu/en/documents/product-information/zavesca-epar-product-information_en.pdf
- Zavesca is recommended for off-label use in patients with Niemann-Pick disease type C (NPC) by expert consensus guidelines (https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0785-7), and is approved for use in Europe for NPC. Zavesca could potentially be requested as monotherapy based on these expert consensus guidelines, or in combination with either of the 2 FDA approved treatment options for NPC, Aqneursa (levacetylleucine) or Miplyffa (arimoclomol). Please keep this in mind if they are requesting Zavesca in combination with either of these medications.
- Zavesca is brand preferred. The cost difference between the brand and generic formulations is very significant, so we should expect them to use brand name Zavesca unless they have a very good reason why the brand name product cannot be used. There is also a branded generic (Yargesa) available which is very expensive and should not be approved in place of brand name Zavesca.

- **SPINAL MUSCULAR ATROPHY AGENTS**
  - **EVRYSDI**
    - **Interim Criteria (*if applicable*):**
    - *Evrysdi® (Risdiplam) Approval Criteria:*

1. *An FDA approved diagnosis of spinal muscular atrophy (SMA); and*
2. *Molecular genetic testing to confirm biallelic pathogenic variants in the survival motor neuron 1 (SMN1) gene (results of genetic testing must be submitted); and*
3. *Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and*
4. *Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and*

5. *For the tablet formulation, the member must be 2 years of age and older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and*
6. *Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and*
7. *Pharmacy must confirm Evrysdi® oral solution will be constituted by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the Evrysdi® Prescribing Information; and*
8. *Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and*
9. *Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and*
10. *Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and*
11. *Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and*
12. *Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and*
13. *Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and*
14. *A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Revised Upper Limb Module (RULM) Test]; and*
15. *Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and*
16. *Member's recent weight must be provided to ensure accurate dosing in accordance with Evrysdi® Prescribing Information; and*
17. *For the oral suspension, a quantity limit of 240mL per 36 days will apply. and for the tablets, a quantity limit of 30 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- If the member is receiving Spinraza (nusinersen) through a patient assistance program from the drug company and the prescriber wants to continue this

therapy along with Evrysdi (risdiplam), this is not a reason for denial; however, SoonerCare will not cover both Spinraza and Evrysdi concomitantly.

- **SPINRAZA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes**
    - This is part of the High-Investment Drug Carve Out
    - Please note: If a member's assessment scores have declined since baseline, may need to ask for further detailed information from prescriber to support continued approval. Examples of other parameters that may be taken into consideration include respiratory function tests [e.g., forced vital capacity (FVC), etc.]; number of respiratory infections in the preceding year/timeframe; number of hospitalizations in the preceding year/timeframe; patient weight; rate of decline.
    - To SoonerCare a member is considered permanently ventilated if they require use of a ventilator more than 16 hours ventilation/day for > 21 days continuously in the absence of an acute reversible event.
    - Some patients may be permanently ventilated (on ventilation for more than 16 hours) and the prescriber may just be submitting in order to get a denial from us and get coverage from the drug company. They will likely not fill out the motor function scales as there is not really a point to doing it since they are just seeking a denial. If they don't qualify based on ventilation status, go ahead and deny even if they didn't fill out the motor function information on the PA.
    - If the prescriber states on the form they are planning to do the labs just prior to dose administration that is fine. We just want to make sure they do them. Dr. Katz has confirmed that he will do the lab testing right before administration to save money on doing them twice. Also many of these have submitted additional paperwork with the genetic testing attached. Please review the genetic testing documents and if there, do not ask for it again just because it is not specifically on the form. We do need the baseline exam (CHOP, HFSME, etc) before we can approve.
    - Quantity limit of 5mL per 1 day to ensure pharmacy does not send more than one vial at a time. OHCA has also added a high-dose edit if pharmacy tries to get more than one vial at a time. Pharmacy can only dispense one vial at time. If it is an adult member, we can possibly override this if they are going to hit their 6 RX limit but for pediatric members this override should not be given
    - Approval Length:
    - Initial - 6 months
    - Reauthorization: 1 year
    - Quantity Limit: 5mL per 1 day (can approve quantities for the entire PA but the pharmacy will only be able to dispense one dose at a time)
- **ZOLGENSMA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - This is part of the High-Investment Drug Carve Out

    - Currently Zolgensma may only be dispensed by a specialty pharmacy (Accredo and Orsini)
    - All requests for Zolgensma should be sent to RPH and RPH should send for OHCA consult by their Medical Director – notify Jill if a request is received for Zolgensma; we have a 24 hour turn around time on Zolgensma requests so the filter should be checked for these each evening. The prescribers have been instructed that if there is primary insurance we need to know their coverage determination. This does not affect our coverage determination; OHCA is asking for it in case we need documentation later. We use our PA criteria to determine coverage separate from the primary determination.

- **KEBILIDI**
    - **Interim Criteria (*if applicable*):**
    - *Kebilidi™ (Eladocagene Exuparvovec-tneq) Approval Criteria:*

1. *An FDA approved diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency; and*
2. *Diagnosis must be confirmed by:*
    - *Genetic testing confirming biallelic pathogenic or likely pathogenic mutations in the DDC gene (results of genetic testing must be submitted); and*
    - *Functional confirmation with measured diagnostic variations in AADC enzyme activity in plasma and/or levels of neurotransmitters in cerebrospinal fluid (CSF) (results of testing must be submitted); and*
3. *Member must be 16 months of age or older; and*
4. *Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to Kebilidi™ administration; and*
5. *Must be prescribed by a neurologist, neurosurgeon, or a specialist with expertise in the treatment of AADC deficiency; and*
6. *Prescriber must verify the member has confirmed skull maturity as assessed by neuroimaging; and*
7. *Must be administered by intraputaminal infusion in a medical center that is capable of stereotactic neurosurgery in addition to the preparation and infusion of Kebilidi™; and*
8. *Must be shipped to the facility where the member is scheduled to receive treatment, and the facility must be capable of adhering to the storage, handling, and preparation requirements as described in the package labeling; and*
9. *Must only be administered using an FDA-authorized cannula for intraparenchymal infusion (e.g., ClearPoint® SmartFlow® Neuro Cannula); and*
10. *Approvals will be for 1 treatment per member per lifetime.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Kebilidi™ (eladocagene exuparvovec-tneq) is an adeno-associated virus (AAV) vector-based gene therapy that received accelerated FDA-approval in November 2024 as a targeted therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. AADC deficiency is an ultra-rare genetic disorder caused by pathogenic variants in the DDC gene. This results in less AADC which, in turn, leads to decreased synthesis of monoamine neurotransmitters (e.g., dopamine, epinephrine, norepinephrine, serotonin). This deficiency causes a wide

array of neurological symptoms that typically manifest during the first months of life and include movement disorders, autonomic dysfunction, and developmental and cognitive delays. These debilitating symptoms can lead to life-threatening complications. Treatment options have been limited to symptom management only until the approval of Kebilidi™.

- How Supplied: 2mL single-dose vial containing an extractable suspension volume of 0.5mL with a concentration of 2.8x1011 vector genomes (vg)/0.5mL (nominal concentration: 5.6x1011vg/mL) for intraputaminal administration
- Dosage and Administration:
    - Single-dose intraputaminal infusion
    - The recommended total dose is 1.8x1011vg (0.32mL) as (4) 0.08mL (0.45x1011vg) infusions (anterior and posterior of each putamen) at 0.003mL/min for a total of 27 minutes per site
    - Administration should be during a single stereotactic surgery using a cannula that is FDA -authorized for intraparenchymal infusion
- Prescribing Information: https://www.fda.gov/media/183530/download?attachment
- Coverage: Kebilidi™ will be covered with a hard PA with the criteria listed.
- Quantity Limit: 1 treatment per member per lifetime

GENITOURINARY SYSTEM

- **BENIGN PROSTATIC HYPERPLASIA (BPH) AGENTS**
    - **ENTADFI**
    - **Interim Criteria (*if applicable*):**
    - *Entadfi™ (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:*

1. *An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and*
2. *A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and*
3. *A patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and*
4. *A quantity limit of 30 capsules per 30 days will apply.*
5. *Maximum treatment duration of 26 weeks will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- **TEZRULY**
- **Interim Criteria (*if applicable*):**
- *Tezruly™ (Terazosin Oral Solution) Approval Criteria:*

1. *An FDA approved diagnosis of benign prostatic hyperplasia (BPH) or hypertension (HTN); and*
2. *A patient specific, clinically significant reason why the member cannot use terazosin capsules must be provided; and*
3. *For a diagnosis of BPH, a patient specific, clinically significant reason why the member cannot use Rapaflo® (silodosin), which may be opened and sprinkled on applesauce for patients with difficulties swallowing, must be provided; and*

4. *A quantity limit of 600mL per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Per the package labeling for Rapaflo (silodosin), "Patients who have difficulty swallowing pills and capsules may carefully open the silodosin capsule and sprinkle the powder inside on a tablespoonful of applesauce. The applesauce should be swallowed immediately (within 5 minutes) without chewing and followed with an 8 oz glass of cool water to ensure complete swallowing of the powder." None of the other BPH products state that they can be opened or crushed. Please consider approving Tier-2 Rapaflo if they say they have difficulties swallowing.

- **<u>BLADDER CONTROL AGENTS</u>**
- **GENERAL INFORMATION**
  - If member has had a trial with oxybutynin ER, a trial with oxybutynin IR is not required to move to a tier-2 medication. Please consider approval of Myrbetriq requests in members who cannot use anticholinergics or who have post void residual volume or incomplete bladder emptying.
- **PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN) Agents**
  - **FILSPARI**
  - **Interim Criteria (*if applicable*):**
  - *Filspari® (Sparsentan) Approval Criteria:*

1. *An FDA approved indication to reduce proteinuria slow kidney decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and*
2. *The diagnosis of primary IgAN must be confirmed by the following:*
   - *Kidney biopsy; and*
   - *Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and*
3. *Member must be 18 years of age or older; and*
4. *Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and*
5. *Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day, despite 3 months of maximal supportive care; and*
6. *Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and*
7. *Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari®; and*
8. *Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and*
9. *Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and*
10. *If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and*

11. *Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and*
12. *A quantity limit of 30 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Filspari® (sparsentan) received full FDA approval to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of disease progression. Originally, Filspari® was given accelerated approval for adults who were at risk of rapid disease progression. Additionally, KDIGO released new draft guidelines for the management of IgAN in August 2024. There were 2 changes made since the last interim criteria was sent out on 10/11/24: The indication in criteria #1 should be to "slow kidney decline" after the new full FDA approval and then criteria #6 should be proteinuria "≥" not ">" based on the new cutoff in the KDIGO guidelines.
    - Prescribing Information: https://filspari.com/igan/filspari-prescribing-information.pdf
    - KDIGO Guidelines: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf
- **VANRAFIA**
- **Interim Criteria (*if applicable*):**
- *Vanrafia™ (Atrasentan) Approval Criteria:*
    1. *An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and*
    2. *The diagnosis of primary IgAN must be confirmed by the following:*
        - *Kidney biopsy; and*
        - *Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and*
    3. *Member must be 18 years of age or older; and*
    4. *Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and*
    5. *Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day, despite 3 months of maximal supportive care; and*
    6. *Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and*
    7. *Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Vanrafia™; and*
    8. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.*
- **Additional Internal Notes (*for consideration toward approval*):** n/a
- **TARPEYO**
- **Interim Criteria (*if applicable*):**
- *Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:*

1. *An FDA approved indication to reduce proteinuria the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and*
2. *The diagnosis of primary IgAN must be confirmed by the following:*
    - *Kidney biopsy; and*
    - *Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and*
3. *Member must be 18 years of age or older; and*
4. *Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and*
5. *Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and*
6. *Member must be on a stable dose of a maximally-tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and*
7. *Approval duration will be for 9 months. The safety and efficacy of Tarpeyo® have not been established beyond 9 months of treatment. For continued authorization consideration after 9 months of treatment, a patient-specific, clinically significant reason why a longer treatment duration is appropriate for the member must be provided; and*
8. *A quantity limit of 120 capsules per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Tarpeyo® [budesonide delayed release (DR) capsule] received full FDA approval to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of disease progression. Originally, Tarpeyo® was given accelerated approval to reduce proteinuria in adults who were at risk of rapid disease progression. Additionally, KDIGO released new draft guidelines for the management of IgAN in August 2024.
- Prescribing Information: https://www.tarpeyohcp.com/prescribinginformation.pdf
- KDIGO Guidelines: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf

HEMOPHILIA

- **HEMOPHILIA AGENTS**
    - **QFITLIA**
        - **Interim Criteria (*if applicable*):**
        - *Qfitlia™ (Fitusiran) Approval Criteria:*

1. *A diagnosis of severe hemophilia A or B, with or without factor inhibitors; and*
2. *Member must be 12 years of age or older; and*
3. *Member must not have a history of or be at high risk for thromboembolic events; and*

4. *Member must not have clinically significant liver disease; and*
5. *Member must not have active hepatitis C; and*
6. *Member must not have an acute or chronic hepatitis B infection; and*
7. *Members with human immunodeficiency virus (HIV) must be controlled with antiviral therapy as shown by CD4+ counts ≤200cells/mm3 or viral load ≥20 copies/mL; and*
8. *In a member with a history of symptomatic gallbladder disease, a reason why the member cannot use other available treatments must be provided; and*
9. *Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and*
10. *Prescriber must agree the member will not be continuing other prophylactic therapies for longer than 7 days after initiation of fitusiran; and*
11. *Prescriber must agree to perform an FDA-cleared test for antithrombin activity at weeks 4, 12, 20, and 24 and adjust the dosing as outlined in the package labeling; and*
12. *Prescriber must agree to perform baseline liver tests prior to initiation of fitusiran and monthly for at least 6 months and after any dose increase; and*
13. *Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of fitusiran; and*
14. *Prescriber must verify that the member has been counseled on the use of factor replacement therapy or bypassing agent as outlined in the prescribing information for breakthrough bleeding episodes; and*
15. *Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.*

- **Additional Internal Notes (*for consideration toward approval*):** n/a

- **ADYNOVATE, AFSTYLA, ALPROLIX, ALTUVIIO, ELOCATE, ESPERCOT, IDELVION, JIVI, REBINYN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - One dose approved for half-life testing.
- **COAGADEX**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - One dose approved for half-life testing.
- **CORIFACT, TRETTEN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - One dose approved for half-life testing.
- **HEMLIBRA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - The recommended dosing for Hemlibra requires a loading dose given weekly for the first 4 weeks, followed by maintenance dosing.

- Please refer to the Hemlibra website for further information which contains:
- A dosing guide - https://www.hemlibra.com/content/dam/gene/hemlibra/pdfs/hcp/EMI0712170054%20vFinal%202.0_ PI.pdf
- And a dosing calculator - https://www.hemlibra.com/hcp/dosing-administration/dosing- calculator.html#calculator
- Please note: Not indicated for acquired hemophilia. Hemlibra is FDA approved for hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors

- **HYMPAVZI**
  - **Interim Criteria (*if applicable*):**
  - *Hympavzi™ (Marstacimab-hncq) Approval Criteria:*
    1. *A diagnosis of severe hemophilia A (FVIII <1%) without inhibitors or moderately severe to severe hemophilia B (FIX activity <2%); and*
    2. *Member must be 12 years of age or older and weigh at least 35kg; and*
    3. *Member must not have a current inhibitor or documented history of an inhibitor; and*
    4. *For females of reproductive potential:*
       a. *Member must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and*
       b. *Member must be willing to use effective contraception during and after treatment for at least 2 months after the last dose; and*
    5. *For members receiving appropriate factor replacement prophylaxis:*
       a. *Experiencing repeated breakthrough bleeding episodes despite compliance with current prophylaxis regimen; or*
       b. *Clinically significant reason current prophylaxis treatment is no longer appropriate; or*
    6. *For members using factor replacement on demand only:*
       a. *Experienced ≥6 acute bleeding episodes within the last 6 months; and*
       b. *Clinically significant reason factor replacement prophylaxis is not appropriate; and*
    7. *Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200u/L; and*
    8. *Member must not be receiving other non-factor replacement therapies for hemophilia such as emicizumab concurrently; and*
    9. *Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and*
    10. *Prescriber must agree to appropriate training for subcutaneous injections; and*
    11. *Prescriber must counsel member on the use of factor replacement therapy at the lowest possible dose for breakthrough bleeding episodes; and*

12. *Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness; and*
13. *Approvals will be for the 300mg loading dose followed by 150mg weekly doses. Approvals may be granted for dose escalation to 300mg weekly when the following are met:*
    a. *Member weighs ≥50kg; and*
    b. *There have been ≥2 spontaneous bleeding episodes which were treated with factor replacement therapy in the last 6 months despite compliance; and*
    c. *Absence of inhibitor development.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Hympavzi™ (marstacimab-hncq) is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:
- Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors; or
- Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
- How Supplied: 150mg/mL single-dose prefilled syringe or pen
- Dosing and Administration:
    - Loading Dose: 300mg [using (2) 150mg injections]
    - Maintenance Dose: 150mg every week starting 1 week after the loading dose
    - Dose Adjustment During Treatment: Dose adjustment to 300mg weekly can be considered in patients weighing ≥50kg when control of bleeding events is judged to be inadequate by the health care provider.
    - Safety and efficacy of Hympavzi™ at doses above 300mg weekly have not been established.
    - Should be administered by subcutaneous (sub-Q) injection on the same day each week at any time of day.
    - If more than 1 injection is required to deliver a complete dose, each injection should be administered at a different injection site.
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761369s000lbl.pdf
- Coverage: Hympavzi™ will be covered with a hard PA with the criteria listed.

- **NOVOSEVEN RT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - NovoSeven RT is billed by the mcg.
- **OBIZUR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - One dose approved for half-life testing.

- **ALHEMO**
  - **Interim Criteria (*if applicable*):**
  - *Alhemo® (Concizumab-mtci) Approval Criteria:*

1. *A diagnosis of 1 of the following:*
    - *Hemophilia A or B with inhibitors; or*
    - *Severe hemophilia A (factor VIII ≤1%) without inhibitors; or*
    - *Moderately severe or severe hemophilia B (factor XI ≤2%); and*
2. *Member must be 12 years of age or older; and*
3. *Member's recent weight (taken within the past 3 months) must be provided and must be ≥25kg; and*
4. *Member must not be undergoing immune tolerance induction (ITI); and*
5. *Members without an inhibitor must have a clinically significant reason why current prophylaxis therapy is not appropriate; and*
6. *Member must not have a history of or be at high risk for thromboembolic events; and*
7. *Female members of reproductive potential must meet the following:*
    - *Must not be pregnant; or*
        - *If member is pregnant or becomes pregnant during treatment, the risk to the fetus must be weighed against the benefit to the mother; and*
    - *Must agree to use effective birth control during treatment and for at least 7 weeks after the last dose; and*
8. *Prescriber must agree the member will not be continuing on other prophylactic therapies; and*
9. *Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and*
10. *Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Alhemo®; and*
11. *Prescriber must verify that the member has been counseled on the potential risk of thrombosis; and*
12. *Prescriber must verify the member has been counseled on the use of bypassing agents or factor concentrate at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed; and*
13. *Requests must be for an FDA approved dosing regimen as outlined in the package labeling; and*
14. *Initial approvals will be for 3 months for the loading dose of 1mg/kg on day 1 and 0.2mg/kg daily until individualization of the maintenance dose has been achieved. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.*

  - **Additional Internal Notes (*for consideration toward approval*):**

HEPATIC DISORDERS

- **CHOLESTATIC LIVER DISEASE AGENTS**
  - **BYLVAY**
    - **Interim Criteria (*if applicable*):**
    - *Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:*

1. *An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and*
    - *Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the JAG1 or NOTCH2 genes (results of genetic testing must be submitted); and*
2. *Member must be 12 months of age or older; and*
3. *Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and*
4. *Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:*
    - *Cholestyramine; or*
    - *Rifampin; or*
    - *Sertraline; or*
    - *Naltrexone; and*
5. *Member must have elevated serum bile acid concentration >3x >1x the upper limit of normal (ULN) for age at baseline; and*
6. *Members with a history of liver transplantation will generally not be approved for Bylvay®; and*
7. *Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and*
8. *Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and*
9. *Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and*
10. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.*

    - **Additional Internal Notes (*for consideration toward approval*):**
  - **IQIRVO**
    - **Interim Criteria (*if applicable*):**
    - *Iqirvo® (Elafibranor) Approval Criteria:*

1. *An FDA approved diagnosis of primary biliary cholangitis (PBC); and*

2. *Member must be 18 years of age or older; and*
3. *Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and*
4. *Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and*
5. *Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and*
    - *Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and*
6. *Iqirvo® must be taken in combination with UDCA; or*
    - *For Iqirvo® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and*
7. *Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and*
8. *Prescriber must agree to monitor all of the following:*
    - *Muscle pain or myopathy at baseline and periodically during treatment; and*
    - *Fracture risk and bone health; and*
    - *Liver function tests at baseline and thereafter; and*
9. *Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy, must agree to use effective non-hormonal contraception (or add a barrier method when using hormonal contraception), and must not be breastfeeding during treatment and for 3 weeks following the last dose of Iqirvo®; and*
10. *A quantity limit of 30 tablets per 30 days will apply; and*
11. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **LIVDELZI**
    - **Interim Criteria (*if applicable*):**
    - *Livdelzi® (Seladelpar) Approval Criteria:*

1. *An FDA approved diagnosis of primary biliary cholangitis (PBC); and*
2. *Member must be 18 years of age or older; and*
3. *Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and*
4. *Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a*

supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and

5. *Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and*
    - *Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and*
6. *Livdelzi® must be taken in combination with UDCA; or*
    - *For Livdelzi® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and*
7. *Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and*
8. *Prescriber must agree to monitor all of the following:*
    - *Fracture risk and bone health; and*
    - *Liver function tests at baseline and thereafter; and*
9. *Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and*
10. *A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and*
11. *A quantity limit of 30 capsules per 30 days will apply; and*
12. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **CTEXLI**
    - **Interim Criteria (*if applicable*):**
    - *Ctexli™ (Chenodiol) Approval Criteria:*

1. *An FDA approved diagnosis of cerebrotendinous xanthomatosis (CTX); and*
    - *Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the CYP27A1 gene (results of genetic testing must be submitted); and*
2. *Member must be 16 years of age or older; and*
3. *Must be prescribed by a neurologist, geneticist, or other specialist with expertise in the treatment of CTX (or an advanced care practitioner with a supervising physician who is a neurologist, geneticist, or other specialist with expertise in the treatment of CTX); and*
4. *Prescriber must agree to obtain baseline liver transaminase, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST), and total bilirubin levels prior to initiating treatment; and*

5. *Prescriber must agree to monitor liver transaminase and total bilirubin levels yearly and as clinically indicated and will interrupt or discontinue treatment with Ctexli™, if appropriate, per package labeling; and*
6. *Member must not be using bile acid sequestering agents (e.g., cholestyramine, colestipol) or aluminum-based antacids concomitantly with Ctexli™; and*
7. *Initial approvals will be for a duration of 3 months. After 3 months of treatment, subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in cholestanol or bile alcohol levels or documentation of other clinical improvements; and*
8. *A quantity limit of 90 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- How Supplied: 250mg oral tablets
- Dosing and Administration:
  - 250mg orally 3 times daily
  - Before initiating treatment, baseline alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin levels should be obtained in all patients.
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219488s000lbl.pdf
- Coverage: Ctexli™ will be covered with a hard PA with the criteria listed.
  - Quantity Limit: 90 tablets per 30 days

- **HEPATITIS C AGENTS**
  - **GENERAL INFORMATION**
    - Guidelines can be found at the following link: http://www.hcvguidelines.org/
    - Our preferred regimens also consider cost, rebated medications, and FDA approved indications. The package inserts actually conflict occasionally with the guidelines. Just because a prescriber submits a copy of the guidelines does not mean we do exactly what it says. There are reasons for our preferred regimens. You may have to pull up the package insert as well.
    - If a patient is treatment-experienced and requesting hepatitis C therapy you need to reference the HCV guidelines. It is too complicated to create a table with all the different regimens so the best place to look is the guidelines. Mavyret cannot be used in cases where a patient has failed an NS5A inhibitor AND a NS3/4A protease inhibitor. It can only be used if they have failed one or the other so this narrows down its appropriateness in treatment experienced patients. If a patient has failed multiple regimens Vosevi is likely the most appropriate choice but you should reference the HCV guidelines to determine this (see link above).
    - Fibrosis score explanation: www.hepatitis.va.gov/provider/reviews/liver-biopsy.asp

      Fibrosis score:
      F0 = no fibrosis
      F1 = portal fibrosis without septa
      F2 = portal fibrosis with few septa
      F3 = numerous septa without cirrhosis

F4 = cirrhosis

- How to convert hepatitis C testing types: http://www.hepatitisc.uw.edu/go/evaluation-staging- monitoring/evaluation-staging/core-concept/all#liver-biopsy-histologic-assessment-liver
- Viral Load Conversion:
  - Viral load in its normal form (example: 75,000IU/ML) and its log form (example: 4.875 logIU/mL). You can also calculate this with your calculator.
  - If you are given the viral load in log form (4.875) put the number into your calculator and then hit the "10x" button. It should convert it to 74,989
  - If you are given the viral load in regular form (75,000) and are trying to figure out the log form you put the number into your calculator and then hit the "log" button. It should convert it to 4.875
- Prescriber Specialty:
  - Check the NPPES NPI Registry to verify specialty
  - IHS (INDIAN HEALTH SERVICES PHARMACY) facilities: Claremore IHS (INDIAN HEALTH SERVICES PHARMACY) (NPI 1023168051) and Lawton IHS (INDIAN HEALTH SERVICES PHARMACY) (NPI 1316097298) are exempt from the specialist requirement for hepatitis C medications.
  - For prescribers who are not one of the defined specialties but want to be considered as a specialist for DAAs for HCV, please request a record of their CME related to infection disease/hepatitis C completed within the last 3 years. Once received, please email the information to Jill (jill.ratterman@okhca.org) for review by an OHCA medical director.
- Decompensated Hepatic Disease:
  - For members with decompensated hepatic disease, they should be referred to a medical practitioner with expertise in that condition (ideally in a liver transplant center) per HCV guidelines. In general, a gastroenterologist, infectious disease, or hepatic specialist would not meet this requirement unless they are practicing in a liver transplant center.
- Hepatitis A & B vaccines:
  - Viral Hepatitis Serology training: https://www.cdc.gov/hepatitis/resources/professionals/training/serology/training.htm
  - Hep A: https://www.hepatitis.va.gov/hav/screening-tests-interpretation.asp
  - Hep B: https://www.cdc.gov/hepatitis/hbv/pdfs/SerologicChartv8.pdf
  - Hep B: https://www.hepb.org/prevention-and-diagnosis/diagnosis/hbv-blood-tests/
- Noncompliance (Filling the medication >3 days late)
  - Implications are not yet known of non-compliance with DAA's, they must prove that they can be compliant on a medication (taking it daily with no missed doses) for >6 months before another treatment regimen will be approved. This will continue to evolve- they may have to use a regimen with another therapy due to the potential for resistance.
- Drug/Alcohol Use:

        - Patients with substance use disorders are protected by the Americans with Disabilities Act of 1990 (ADA).
        - PA requests for DAAs for the treatment of hepatitis C should not be denied based on prior or current drug or alcohol use.
    - Project ECHO:
        - Beginning 7/1/19, prescribers in Oklahoma who are not specifically gastroenterology, infectious disease, or transplant specialists will be allowed to submit requests for Hepatitis C treatment if they have consulted with specialists through a program called Project Echo. Project Echo provides an opportunity for prescribers in more rural areas or with limited access to specialists to participate in a weekly conference call with a team of Hepatitis C specialists. The Hepatitis C specialists make recommendations for that patient that the local prescriber can use to treat the patient's Hepatitis C. Project Echo specialists only work with de-identified data, therefore all communication will need to be done with the local prescriber.
        - If a request is received for one of these patients, the name of specialist recommending hepatitis C treatment should state "Project Echo" and the request should include a copy of the Hepatitis C TeleEcho Clinic Recommendations page in addition to the 3 hepatitis C forms we currently require. The 3 regular hepatitis C forms should be completed and we need to verify that the member has completed all of the recommendations from the Project Echo prescribers. This may require that the pharmacist ask specific the prescriber questions regarding each recommendation. Please do not send back a blanket question about the recommendations being addressed.
        - If the member is cirrhotic (F4) and decompensated, that person should be referred to medical practitioner with expertise in that condition. The Project Echo process is not sufficient to meet this criteria.
        - When you approve one of these requests, please include "Project Echo" in the Internal Comments to make it easier for us to track these members.
        - Mavyret (glecaprevir/pibrentasvir) is the preferred direct-acting antiviral (DAA) for the treatment of chronic hepatitis C virus (HCV). Use of an alternative for the treatment of HCV requires patient-specific, clinically significant reasoning why the preferred DAA is not appropriate for the member. Mavyret (glecaprevir/pibrentasvir) oral pellets are covered for pediatric patients 3 to 11 years of age requiring that dosage form. The criteria for each medication may include U.S. Food and Drug Administration (FDA) approved regimens or American Association for the Study of Liver Diseases (AASLD) guideline recommended regimens that are not included in the SoonerCare preferred regimens table. Preferred regimens for each genotype can be found in the preferred regimens table. Additional regimens other than those listed in the preferred regimens table may be considered based on patient-specific clinical situations.

- INTERNAL: This table is for treatment-naïve regimens, members with treatment-experience are still covered but you must consult the guidelines or prescribing information when doing those. Patient specific situations may exist where you will also need to consult the guidelines or prescribing information. ALWAYS consult the criteria. Members who qualify for 8 weeks of Harvoni should only get 8 weeks of Harvoni. We shouldn't approve 12 just because the table says 8 or 12 weeks. If they only qualify for 8 weeks that is all we will approve. Remember also we are not approving new starts to 24 weeks of Harvoni anymore (unless they have failed a sofosbuvir based regimen in the past and are cirrhotic). The table is supposed to make referencing the guidelines easier, but there are specific circumstances when a certain regimen should be approved and that is what the criteria is for. It is important to note that the 8-week Harvoni regimen is not specific in the guidelines but is in the package insert. We use this regimen as it is FDA approved, less costly, and highly effective.

Genotype	Patient Factors	Preferred Regimen(s)
	Genotype 1	
1	Treatment-naïve, non-cirrhotic	Mavyret for 8 weeks
1	Treatment-naïve, cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)
	Genotype 2	
2	Treatment-naïve, non-cirrhotic	Mavyret for 8 weeks
2	Treatment-naïve, cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)
	Genotype 3	
3	Treatment-naïve, non-cirrhotic	Mavyret for 8 weeks
3	Treatment-naïve, cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)
	Genotype 4	
4	Treatment-naïve, non-cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)
4	Treatment-naïve, cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)
	Genotype 5 or 6	
5 or 6	Treatment-naïve, non-cirrhotic	Mavyret for 8 weeks
5 or 6	Treatment-naïve, cirrhotic	Mavyret for 8 weeks (only if compensated, Child-Pugh A)

- **EPCLUSA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Can be used in decompensated cirrhosis patients.
  - Due to rebate agreements, we are no longer requiring Y93H testing for patients who are genotype 3 and cirrhotic.
  - Due to similar net costs, brand or generic Epclusa may be approved if the member has a patient-specific, clinically significant reason why they require Epclusa over Mavyret (and they meet all other PA criteria).
- **HARVONI**

- **Interim Criteria (*if applicable*): n/a**
- **Additional Internal Notes (*for consideration toward approval*):**
- If members have Genotype 1 and are non-cirrhotic (i.e., fibrosis score of F0 to F3), we need a viral load within 3 months of when members are requesting to start therapy. This is because the member may be eligible for only 8 weeks of therapy and in order to determine this, we need a viral load within 3 months. This is regardless of whether the prescriber is requesting 12 weeks of therapy. Please refer to AASLD/IDSA guidelines for special populations, including children, African Americans, etc.
- Harvoni® for 8 weeks versus 12 weeks: We have had a request to extend from 8 weeks versus 12 weeks for Harvoni® in an African American patient. The updated guidelines state the following in regards to 8 weeks versus 12 weeks: 8 weeks of daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg); for patients who are non-black, HIV-uninfected, and whose HCV RNA level is <6 million IU/mL. When you look into the clinical studies cited in the guidelines , African American patients who are specifically treatment naïve, noncirrhotic, and have a pre-treatment viral load <6million had similar SVR results (see bulleted list and images). Therefore we are not going to change our criteria just based on the guideline recommendation for African American patients. We will evaluate these on a case-by-case basis. There is evidence that the following patients are more likely to fail an 8 week regimen: males, older age (>55 years), obesity, African American, or HIV positive. If they have multiple risk factors in this list, we may consider approval of 12 weeks.
- Remember we are not approving 24 weeks of Harvoni anymore (unless they have failed a sofosbuvir-based regimen in the past and are cirrhotic).

- **MAVYRET**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Due to a new VBA with OHCA and AbbVie, effective 7/28/2022 Mavyret tablets and pellets (NDCs noted below) are SoonerCare's preferred DAA and are available without PA. Use of a non-preferred DAA will require a patient-specific, clinically significant reason why the member cannot use Mavyret.
  - Requests for the non-preferred NDC for Mavyret should be incompleted to ask the pharmacy to use the preferred NDC. If you receive a request for the non-preferred NDC due to supply issues with the preferred NDC, please let me know.
  - Preferred NDCs (no PA required, no age restriction): 00074-2625-28 Mavyret 100/40mg tablets
  - 00074-2600-28 Mavyret 50/20mg oral pellets
  - Non-preferred NDC (PA required):
  - 00074-2625-84 Mavyret 100/40mg tablets
  - The FDA approved changes to the Mavyret labeling with dosing for liver or kidney transplant recipients. The dosage and administration section was revised to state that Mayvret is recommended for 12 weeks in liver or kidney transplant recipients. Please keep this in mind when reviewing requests for Mavyret.

- Approval of the 8-week carton (in place of the 4-week carton) requires a patient-specific, clinically significant reason why they need the 8-week carton in place of the 4-week carton (the 8-week carton should pretty much never be approved).

- **DEFITELIO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Medical Only
  - Please give specialists special consideration, make sure dosing is appropriate (please note maximum duration of therapy); Defitelio® is contraindicated with systemic anticoagulants, or if the patient is receiving fibrinolytic therapy.
  - Approval Length: Initial One month
  - Quantity Limit: Weight based
- **OCALIVA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Ocaliva is indicated for diagnosis of primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension. In May 2021 the FDA issued a drug safety communication to restrict the use of Ocaliva in PBC patients with advanced cirrhosis due to risk of serious liver injury. The FDA found some PBC patients with cirrhosis who took Ocaliva, especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant.
  - https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious- liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary- cholangitis
  - https://www.interceptpharma.com/wp-content/uploads/2021/05/US-Package_Insert-26May2021-VV-REG-037160.pdf
- **REZDIFFRA**
  - **Interim Criteria (*if applicable*):**
  - *Rezdiffra™ (Resmetirom) Approval Criteria:*

1. *An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and*
2. *Member must be 18 years of age or older; and*
3. *Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following:*
   - *FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/min; or*
   - *Liver biopsy showing stage F2 or F3 fibrosis with NASH; and*
4. *Member must not have known liver cirrhosis (e.g., stage F4); and*
5. *Must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and*
6. *Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:*
   - *Type 2 diabetes; and*
   - *Dyslipidemia; and*

    - *Hypertension; and*
7. *Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra™; and*
8. *If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra™, prescriber must agree to reduce the dose as required in the package labeling; and*
9. *If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and*
10. *Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and*
11. *Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and*
12. *A quantity limit of 30 tablets per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Limitation(s) of Use: Avoid use of Rezdiffra™ in patients with decompensated cirrhosis.
- How Supplied: 60mg, 80mg, and 100mg oral tablets
- Dosing and Administration: May be administered with or without food with the dose based on actual body weight as follows:
    - <100kg: 80mg once daily
    - ≥100kg: 100mg once daily
    - Lower doses are required if used concomitantly with a moderate CYP2C8 inhibitor (e.g., clopidogrel), and use is not recommended concomitantly with strong CYP2C8 inhibitors (e.g., gemofibrozil) or OATP1B1/OATP1B3 inhibitors.
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217785s000lbl.pdf
- Coverage: Rezdiffra™ will be covered with a hard PA with the criteria listed below.
- Quantity Limit: 30 tablets per 30 days
- Please Note: The Enhanced Liver Fibrosis (ELF) test is not currently covered through SoonerCare but would be appropriate to review if a member has that type of testing available when they request Rezdiffra. The ELF test is a blood test to evaluate liver fibrosis and it is included in the American Association for the Study of Liver Diseases (AASLD)'s algorithm for evaluating patients with NAFLD/NASH and was included in the clinical trial for Rezdiffra. Most members will likely have Fibroscan testing, which

is a specific type of ultrasound for evaluating steatosis and fibrosis of the liver, and the Fibroscan testing is covered by SoonerCare. Additionally, a liver biopsy would be acceptable, but most patients will not have a liver biopsy done. Biopsies are typically reserved for special situations where other testing is indeterminate or there is diagnostic uncertainty.

HIV MEDICATIONS

IRON THERAPY

- **IRON AGENTS**
  - **GENERAL INFORMATION**
    - All IV iron products are covered as Medical Only
    - Separate payment for IV Iron Therapy is not allowed when members are on dialysis, as it is bundled into the dialysis payment.
    - Before initiating IV iron, oral elemental iron therapy is usually initiated first. The usual starting dose is 3mg/kg/day of elemental iron and can be increased to a maximum dose of 6mg/kg/day of elemental iron. The maximum absolute dose of elemental iron is 150-300mg per day in 2-3 doses. A trial of oral elemental iron therapy should be documented. Documentation should support patient's response was refractory to oral iron, patient is unable to take oral iron and why, or non-compliance with oral iron therapy.
    - Short bowel syndrome (SBS): If the request is for a member with SBS or from a pediatric GI specialist, please consider approval of IV iron without a trial of oral iron if they have given us a clinical reason why a trial of oral iron is not appropriate for the member. Patients with SBS may have absorption and motility issues that lead to poor tolerance of enteral formulations, or they may be TPN dependent. We should not require them to fail oral iron if they've provided us with a clinical reason why oral iron would not be appropriate for the member. Additionally, please consider approving non-preferred formulations of IV iron (e.g., Injectafer) for members with SBS if they have provided clinical information about why the requested product is needed.
  - **FERAHEME**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Q0138 is for non-ESRD use
    - Q0139 is covered without a PA when a member is on dialysis, and therefore is not separately billable. Allowance for Feraheme in this patient population is included in the dialysis bundle payment.
  - **FERRLECIT**
    - **Interim Criteria (*if applicable*): n/a**

- **Additional Internal Notes (*for consideration toward approval*):**
- Only Covered when a member is on dialysis, and therefore is not separately billable. Allowance for Ferrlecit is included in the dialysis bundled payment.

METABOLIC DISORDERS

- **PHENYLKETONURIA AGENTS**
  - **SEPHIENCE**
    - **Interim Criteria (*if applicable*):**
    - *Sephience™ (Sepiapterin) Approval Criteria:*

1. *An FDA approved diagnosis of phenylketonuria (PKU); and*
2. *Documentation of active management with a phenylalanine restricted diet; and*
3. *Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and*
4. *Concomitant use with Kuvan® (sapropterin) or Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq; and*
5. *Sephience™ must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with the expertise in the treatment of PKU; and*
6. *A patient specific, clinically significant reason why the member cannot use generic Kuvan® must be provided; and*
7. *Initial approvals will be for 2 weeks. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and*
   - *Members less than 2 years of age will be approved for a longer dosage titration per the package labeling up to the maximum daily dosage of 60mg/kg/day. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; or*
   - *If the member was initiated at 60mg/kg/day, then no additional approvals will be granted after a trial period of 2 weeks if the member did not respond to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and*
8. *Subsequent approvals will be for the duration of one year; and*
9. *Reauthorization requires the following:*
   - *Documentation of active management with a phenylalanine restricted diet; and*
   - *Verification from the prescriber of continued response to therapy.*

    - **Additional Internal Notes (*for consideration toward approval*):**
  - **PALYNZIQ**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

    - Members with phenylketonuria may be monitored by the health department and prescribers may not have recent labs. Please keep this in mind when assessing these patients. Palynziq has a risk for anaphylaxis and prescribers titrate the dose very slowly, this may mean the member needs to stay on Kuvan until they achieve a therapeutic dose of Palynziq.
- **STRENSIQ**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Molecular genetic testing can support a diagnosis of hypophosphatasia. Molecular genetic testing can detect mutations in the ALPL gene known to cause the disorder, but it is only available as a diagnostic service at specialized laboratories. The test is often expensive and often not necessary to confirm a diagnosis of HPP. Please consider approval if they submit a genetic test showing mutations in the ALPL gene known to cause HPP and the member has low ALP.
    - For determining low age-adjusted alkaline phosphatase (ALP) levels, this website can be used for reference https://hypophosphatasia.com/hcp/accurately-diagnose/low-alp- can-differentiate-hpp. This site includes a chart and calculator for age and gender adjusted ALP; however, ALP activity is laboratory-specific so this source is for reference only and may be used if laboratory- specific normal reference values are not provided with the prior authorization request.
    - For determining elevated pyridoxal 5'-phosphate (PLP) levels, the normal reference values are 5 to 50mcg/L. PLP greater than 100mcg/L is suggestive of hypophosphatasia; however, our criteria does not specify an exact number above normal so a value above the reference range would meet the criteria for elevated PLP levels.
- **UREA CYCLE DISORDER (UCD) AGENTS**
    - **OLPRUVA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - A 30-day supply of Olpruva is provided in a kit containing 90 dosage envelopes
        - Available in 2g, 3g, 4g, 5g, 6g, and 6.67g dosage envelopes
        - The dosage envelopes include 1-2 envelopes of drug pellets + 1 Mix-Aid packet
        - The QL is 90/30 for each NDC, based on the dosage envelopes (WAC corresponds to 90 dosage envelopes per 30 days, not the package size).
        - Max dose = 20g sodium phenylbutyrate; filling the 6.67g kit per day

OCULAR/OTIC

- **GLAUCOMA AGENTS**
    - **TIMOPTIC-XE**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**

    - Timoptic-XE® (timolol gel) for infantile hemangioma diagnosis: please consider approval for children under five years of age. The gel formulation doesn't run off the skin as easily as the solution and has less of a risk of systemic absorption relative to the solution. http://onlinelibrary.wiley.com/doi/10.1111/j.1525-1470.2011.01664.x/full http://pediatrics.aappublications.org/content/early/2016/08/11/peds.2016- 0355
    - See Overrides (Early Refill, Brand-Only, Quantity Limit, 3rd Brand) for information regarding early refills for prescription eye drops.
- **DURYSTA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Quantity Limit - 1 Durysta 10mcg implant per eye per lifetime
- **INTRAVITERAL IMPLANTS**
- **ENCELTO**
    - **Interim Criteria (*if applicable*):**
    - *Encelto™ (Revakinagene Taroretcel-lwey) Approval Criteria: (MEDICAL ONLY)*

1. *An FDA approved diagnosis of idiopathic macular telangiectasia (MacTel) type 2; and*
2. *Member must be 18 years of age or older; and*
3. *Encelto™ must be prescribed and administered by a qualified ophthalmologist under aseptic conditions; and*
4. *Member must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00mm2 measured by spectral domain-optical coherence tomography (SD-OCT); and*
5. *Member must have a best corrected visual acuity (BCVA) of 20/80 or better; and*
6. *Member must not have neovascular MacTel type 2; and*
7. *Member must not have ocular or periocular infections; and*
8. *Member must not have known hypersensitivity to Endothelial Serum Free Media (Endo-SFM); and*
9. *If the member is taking an antithrombotic medication (i.e., oral anticoagulants, aspirin, and nonsteroidal anti-inflammatory drugs) they have been counseled to temporarily discontinue therapy with their antithrombotic medication prior to Encelto™ implantation due to the risk of vitreous hemorrhage; and*
10. *Prescriber must verify the member will be monitored for vision loss, infectious endophthalmitis, retinal tear and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation after Encelto™ implantation and treated, if appropriate; and*
11. *A quantity limit of 1 implant per eye per lifetime will apply.*

    - **Additional Internal Notes (*for consideration toward approval*):**
- **ILUVIEN**
    - **Interim Criteria (*if applicable*):**
    - *Iluvien (Fluocinolone Intravitreal Implant) Approval Criteria:*

1. *An FDA approved diagnosis of 1 of the following:*

        - *The treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; and or*
        - *The treatment of chronic non-infectious uveitis affecting the posterior segment of the eye; and*
    2. *Iluvien must be administered by an ophthalmologist; and*
    3. *Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and*
    4. *A patient-specific, clinically significant reason why the member requires Iluvien in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and*
    5. *A quantity limit of 1 implant per eye every 36 months will apply.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **OZURDEX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The dx of "non- infectious uveitis affecting the posterior segment of the eye" includes the dx of intermediate uveitis/posterior cyclitis, posterior uveitis (various chorioretinitis ICD codes), and panuveitis. Use your clinical judgment and consider approval without a reason why ophthalmic corticosteroid solutions or suspensions wouldn't be appropriate for the member if the member has already tried/failed ophthalmic corticosteroid injections and/or other implants or if the prescriber documents patient-specific info regarding the severity of the dx.
- **RETISERT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Medical Only – J7311
    - Yutiq is essentially an injectable Retisert (Retisert needs a trip to the operating room, while Yutiq is injected into the office) and Yutiq is 0.18mg fluocinolone while Retisert is 0.59mg. Patients who are front loaded with Ozurdex and then given Yutiq can do really well and likely be at smaller risk of IOP issues than Retisert. Retisert has a very high incidence of IOP issues.
    - Use your clinical judgment and consider approval without a reason why ophthalmic corticosteroid solutions or suspensions wouldn't be appropriate for the member if the member has already tried/failed ophthalmic corticosteroid injections and/or other implants or if the prescriber documents patient-specific info regarding the severity of the dx.
    - Retisert (Fluocinolone acetonide 0.59 mg, Long -acting implant, Code J7311)
    - Is an intravitreal implant that can deliver the corticosteroid fluocinolone acetonide [fluocinolone acetonide implant, Retisert] to posterior eye tissue for up to 3 years. In July 2000, it received Orphan Drug designation from the FDA for posterior uveitis (i.e., chronic non-infectious uveitis of the posterior segment) not responding sufficiently to less invasive treatments (e.g. local, systemic and/or periocular steroids or antimetabolites).

    - Effectiveness has not been established for:
        - Anterior uveitis
        - Intermediate (pars planitis) uveitis
        - Macular edema/central retinal vein occlusion
        - Serpiginous choroditis
        - Sympathetic ophthalmia
        - Vogt-Koyanagi-Harada disease
- **XIPERE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - For any PAs approved for Xipere (medical PA for J3299), add a line for CPT code 67516 (1 unit per dose per eye). CPT code 67516 covers the procedure (INJECTION OF MEDICATION INTO SPACE ABOVE CHOROID MEMBRANE OF EYE).
- **YUTIQ**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Medical Only
    - Yutiq is essentially an injectable Retisert (Retisert needs a trip to the operating room, while Yutiq is injected into the office) and Yutiq is 0.18mg fluocinolone while Retisert is 0.59mg. Patients who are front loaded with Ozurdex and then given Yutiq can do really well and likely be at smaller risk of IOP issues than Retisert. Retisert has a very high incidence of IOP issues.
    - The implant theoretically releases fluocinolone up to 36 months; however, clinically, in some patients, the implant seems to lose effect at 12- 18 months. If you receive a request for retreatment with Yutiq at 12 months (or sooner than 36 months) and it seems appropriate, please consider approval.
- **<u>OTIC ANTI-INFECTIVE AGENTS</u>**
    - **GENERAL INFORMATION**
        - Dexamethasone 0.1% ophthalmic solution is available without prior authorization for members who require concomitant steroid therapy.
    - **OTIPRIO**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Medical Only
        - Otiprio is the only single-dose otic drop FDA approved for intratympanic administration. Other treatments commonly used during tympanostomy tube placement include ofloxacin or ciprofloxacin administered into the ear intraoperatively and then twice daily for five days following the procedure.
    - **ACETASOL HC/VOSOL HC**
        - **Interim Criteria (*if applicable*):**

1. *Acetasol HC and VoSol HC (Acetic Acid/Hydrocortisone) Approval Criteria:*
2. *Diagnosis of acute otitis externa; and*
3. *Recent trials (within the last six months) with all other commonly used topical otic anti-infectives that have failed to resolve infection; or*

4. *Allergy to all available products and failure of acetic acid alone.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **AGE-RELATED MACULAR DEGENERATION (AMD) AGENTS**
    - **AHZANTIVE, OPUVIZ, YESAFILI**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
    - **SUSVIMO**
        - **Interim Criteria (*if applicable*):**
        - *Susvimo® (Ranibizumab Intravitreal Implant) Approval Criteria:*
        1. *An FDA approved diagnosis of 1 of the following:*
            - *Neovascular (wet) age-related macular degeneration (AMD) in adults; or*
            - *Diabetic macular edema (DME); and*
        2. *Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and*
        3. *Member must not have ocular or periocular infections or active intraocular inflammation; and*
        4. *Susvimo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and*
        5. *Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and*
        6. *A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea® (aflibercept)] must be provided; and*
        7. *A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.*
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
    - **PAVBLU**
        - **Interim Criteria (*if applicable*):**
        - ***Ahzantive™ (Aflibercept-mrbb), Enzeevu™ (aflibercept-abzv), Opuviz™ (Aflibercept-yszy), Pavblu™ (Aflibercept-ayyh), and Yesafili™ (Aflibercept-jbvf) Approval Criteria:***
        1. *An FDA approved diagnosis; and*
        2. *A patient-specific, clinically significant reason why the member cannot use Eylea®/Eylea® HD (aflibercept) must be provided. Biosimilars and/or reference*

products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

- **Additional Internal Notes (*for consideration toward approval*):**
- Pavblu™ (aflibercept-ayyh) is a new Eylea® (aflibercept) biosimilar that has been approved by the FDA for neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy (DR) which is 4 of the 5 FDA approved indications for Eylea®.
- Coverage: Pavblu™ (aflibercept-ayyh) will be covered as **MEDICAL ONLY** with a hard PA with criteria similar to Ahzantive™ (aflibercept-mrbb), Enzeevu™ (aflibercept-abzv), Opuviz™ (aflibercept-yszy) and Yesafili™ (aflibercept-jbvf), listed above.
- Prescribing Information: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/pavblu/pavblu_fpi_english.pdf

- **IZERVAY**
  - **Interim Criteria (*if applicable*):**
  - *Izervay™ (Avacincaptad Pegol) Approval Criteria:*

1. *An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and*
2. *Member must not have ocular or periocular infections or active intraocular inflammation; and*
3. *Izervay™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and*
4. *Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and*
5. *A patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and*
6. *A quantity limit of (1) 0.1mL single-dose vial per eye once monthly for up to 12 months will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- **<u>OPHTHALMIC CORTICOSTEROIDS</u>**
  - **DEXTENZA**
    - **Interim Criteria (if applicable):**
    - *Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria [Ocular Inflammation and Pain following Ophthalmic Surgery Diagnosis]:*

1. *An FDA approved indication of the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric members; and*
2. *Dextenza® must be prescribed and administered immediately following ophthalmic surgery by an ophthalmologist, or a physician experienced in intracanalicular administration; and*
3. *Date of ophthalmic surgery must be provided; and*
4. *A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and*

5. *A quantity limit of 1 insert per eye every 30 days will apply.*

- *Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria [Ocular Itching Associated with Allergic Conjunctivitis Diagnosis]:*

1. *An FDA approved indication of the treatment of ocular itching associated with allergic conjunctivitis; and*
2. *Member must be 2 years of age or older; and*
3. *Dextenza® must be prescribed and administered by an ophthalmologist, or a physician experienced in intracanalicular administration; and*
4. *For pediatric members, the prescriber must attest the member does not require sedation; and*
5. *A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used for allergic conjunctivitis are not appropriate for the member must be provided; and*
6. *A quantity limit of 1 insert per eye every 30 days will apply.*

- **Additional Internal Notes:**

- **<u>OPHTHALMIC ALLERGY AGENTS</u>**
  - **GENERAL INFORMATION**
    - OTC products are not covered for adult members (age ≥21 years).
    - See Overrides (Early Refill, Brand-Only, Quantity Limit, 3rd Brand) for information regarding early refills for prescription eye drops.
    - Lastacaft has been removed from Tier-3 due to being OTC with no drug rebate agreement.
    - Approval Length: 3 months
- **<u>OPHTHALMIC DRY EYE DISEASE AGENTS</u>**
  - **TRYPTYR**
    - **Interim Criteria (if applicable):**
    - *Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Approval Criteria:*

1. *An FDA approved indication to treat the signs and symptoms of dry eye disease (DED); and*
2. *Member must be 18 years of age or older; and*
3. *Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and*
4. *Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and*
5. *A patient-specific, clinically significant reason why the member cannot use Restatis® (cyclosporin ophthalmic emulsion) single-use vials, which are available without a prior authorization, and Xiidra® (lifitegrast ophthalmic solution) must be provided; and*
6. *A quantity limit of 60 single-use vials (1 box) per 30 days will apply.*

- **Additional Internal Notes:**

- **<u>OPHTHALMIC ANTIBIOTIC AGENTS</u>**
  - **GENERAL INFORMATION**

    - These are set up in DUR plus to auto PA if they are written by optometrists/ophthalmologists.
    - See Overrides (Early Refill, Brand-Only, Quantity Limit, 3rd Brand) for information regarding early refills for prescription eye drops.
- **QUIXIN**
    - **Interim Criteria (if applicable): n/a**
    - **Additional Internal Notes:**
    - As of 5/9/25 a new NDC of generic Quixin® has been launched and will be added back to the Tier chart as a Tier-2 medication.
- **TOBRADEX**
    - **Interim Criteria (if applicable): n/a**
    - **Additional Internal Notes:**
    - Tobradex ointment may be considered for members when used for tracheostomy issues.

ONCOLOGIC THERAPIES

- **GRANULOCYTE COLONY STIMULATING FACTORS (G-CSF)**
    - **NEULASTA, NYVEPRIA, STIMUFEND, UDENYCA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Fylnetra's package labeling indicates that a member or a caregiver could be trained on administering Fylnetra. Ziextenzo's package labeling does not specify who can give the product, and their website advertises that it can be self-administered as long as a HCP provides training. So, if a provider indicates the member needs Neulasta OnPro due to issues with traveling to the provider's office, please clarify if the member or caregiver could be trained to use the preferred products. Also, please remember Neulasta OnPro when billed as a medical claim does not require a prior authorization, so this could be an option too.
        - Neulasta (pre-filled syringe) and Neulasta OnPro (on-body injector) are assigned the same HCPCS code (J2506). J2506 does not require PA. Neulasta OnPro is a medical-only benefit and is covered without PA. Neulasta billed by the NDC (pharmacy billing) is not preferred and requires PA.
    - **NIVESTYM, NYPOZI, RELEUKO**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Biosimilar to Neupogen (filgrastim). Filgrastim and pegfilgrastim are not to be given together. They are the same medication with different half-lives. Prophylactic use of both treatments is not appropriate. There may be some clinical cases when the member gets febrile neutropenia despite having been dosed with Neulasta and they might require immediate treatment with Neupogen. However, this should be rare and is no longer a prophylactic instance.
- **STEM CELL MOBILIZERS**

- **APHEXDA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Approving for 2 months for 2 cycles should be okay to begin with, similar to Mozobil
- **MOZOBIL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Mozobil J2562 (1 J code unit = 1 mg) approval for 2 months (I think we should approve 2 cycles to start off with and if it becomes necessary increase to 3 cycles for initial approval.)
    - Dosing and Regimen: 0.24 mg/kg (up to 40 mg) daily x 4 days
    - Calculation: 70kg patient x 0.24mg/kg = 16.8 mg per day (comes as 24 mg SUV) provider will use#1 - 24 mg vial per dayx4 days=96 mg 2 cycles=192mg
    - J code units: 192 units
- **<u>ONCOLOGY AGENTS</u>**
    - **GENERAL INFORMATION**
        - <u>DO NOT DENY requests for cancer medications for not meeting criteria without sending them to the oncology pharmacists.</u> The guidelines are continuously being updated and the coverage of these medications is evolving based on studies coming out literally every day. Additionally, the criteria have been interpreted differently on a few occasions by us and them, so to ensure that they want us to deny we should refer. If you need to deny based on member not being eligible or being a dual eligible that is fine, but if it is solely based on clinical criteria, please send to the oncology pharmacists for review.
        - When a prior authorization is implemented for an oncology medication that was not previously prior authorized (e.g., Herceptin), members currently on the medication are approved for continuation of therapy to avoid interruption of the member's treatment. When the pre-approved prior authorization expires or a new request is received (due to a dose change, billing change, etc.), please approve the medication for continuation of treatment. The member will not be held to the new/current prior authorization criteria once they have been approved for continuation of therapy.
        - Prescriber specialty: The medication-specific forms for the oncology medications include a line for the prescriber to indicate his/her specialty. Please be sure to check this line when reviewing prior authorizations. If this line is left blank, please verify the prescriber specialty is appropriate (e.g., oncologist) by looking up the prescriber on the state medical board(s) or NPI search. If upon verification, the prescriber does not appear appropriate, please ask for clarification from the prescriber. If the prescriber specialty is listed and does not appear appropriate, please verify it on one of the above- mentioned sites or ask for clarification from the prescriber.
        - IHS (INDIAN HEALTH SERVICES PHARMACY) refers a lot of their cancer patients out and when they do they will check Medicaid eligibility. If eligible they will update it/enroll them. This means they may have already given them the drug by the time they do all the paperwork. So we may receive some requests from a non-IHS (INDIAN HEALTH SERVICES PHARMACY) provider that say "eligibility issue; back

date (IHS (INDIAN HEALTH SERVICES PHARMACY))" They still must meet our criteria but we can consider back date for these members. Please check and see if they had any eligibility updates and document it in PA Viewer. Most likely coming from the following clinic: Oklahoma Cancer Specialists and Research Institute in Tulsa

- KP or KQ units: Some requests for oncology medical drugs may require the addition of KP or KQ units to the PA. Per OHCA we are not supposed to tell them they need these, but if they call and request them, we can add them to the PA. They would need to be added similarly to JW units and each needs their own line item. This is a normal process and if they have an approved PA, we can add them as they request them.
- A9699: Unclassified radiopharmaceuticals; PA requests should be reviewed by an oncology pharmacist.
- Peer-to-peer review: If a prescriber requests a Peer-to-peer review of a denied prior authorization, email the prescriber contact information, a copy of the prior authorization form and available chart notes to the oncology pharmacists for them to reach out to the prescriber.
- **Additional Criteria for <u>ANY</u> Oncology Agent:**

1. *Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and*
2. *Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and*
3. *The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:*
    a. *Any request for an oncology medication which does not meet approval criteria; or*
    b. *Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or*
    c. *Any level-1 appeal request for an oncology medication; or*
    d. *Any peer-to-peer request for an oncology medication*.

- **CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY**
- The FDA recently announced that it has eliminated the Risk Evaluation and Mitigation Strategies (REMS) for currently approved BCMA- and CD19-directed autologous CAR T-cell immunotherapies. Interim criteria for all agents with impacted policies below:
    - *<u>Abecma (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:</u>*

1. *Diagnosis of relapsed or refractory multiple myeloma (RRMM):*
    1. *Member has received ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and*
        - *Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and*
        - *Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and*

2. *Member must have measurable disease, including at least 1 of the following:*
    - *Serum M-protein ≥0.5g/dL; or*
    - *Urine M-protein ≥200mg/24hr; or*
    - *Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or*
    - *Bone marrow plasma cells >30% of total bone marrow cells; and*
3. *Member must not have any central nervous system involvement with multiple myeloma*.

2. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and;*
3. *Approvals will be for 1 dose per member per lifetime*.

- *<u>Breyanzi (Lisocabtagene Maraleucel) Approval Criteria [Large B Cell Lymphoma Diagnosis]</u>:*

1. *Diagnosis of large B-cell lymphoma; and*
    1. *One of the following:*
        - *Refractory disease to frontline chemoimmunotherapy; or*
        - *Relapse within 12 months of frontline chemoimmunotherapy; or*
        - *Relapse within 12 months of frontline chemoimmunotherapy and member is not eligible for hematopoetic stem cell transplantation (HSCT) due to comorbidity or age; or*
        - *Relapse or refractory disease after 2 or more lines of systemic therapy; and*
2. *Member does not have primary central nervous system (CNS) lymphoma; and*
3. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
4. *A patient-specific, clinically significant reason why Kymriah (tisagenlecleucel) or Yescarta (axicabtagene) is not appropriate for the member must be provided*.
5. *Approvals will be for 1 dose per member per lifetime*.

- *<u>Breyanzi (Lisocabtagene Maraleucel) Approval Criteria [Follicular Lymphoma Diagnosis]</u>:*

1. *Diagnosis of FL; and*
2. *Relapsed or refractory disease after 2 or more lines of systemic therapy; and*
3. *Member does not have primary central nervous system (CNS) lymphoma; and*
4. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities; and*
5. *A patient-specific, clinically significant reason why Kymriah (tisagenlecleucel) or Yescarta (axicabtagene ciloleucel) are not appropriate for the member must be provided; and*
6. *Approvals will be for 1 dose per member per lifetime*.

- *Breyanzi (Lisocabtagene Maraleucel) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:*

1. *Diagnosis of CLL/SLL; and*
2. *Relapsed or refractory disease after 2 or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B cell lymphoma-2 (BCL-2) inhibitor; and*
3. *Member does not have primary central nervous system (CNS) lymphoma; and*
4. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
5. *Approvals will be for 1 dose per member per lifetime.*

- *Breyanzi (Lisocabtagene Maraleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:*

1. *Diagnosis of MCL; and*
2. *Relapsed or refractory disease after 2 or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor; and*
3. *Member does not have primary central nervous system (CNS) lymphoma; and*
4. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
5. *A patient-specific, clinically significant reason why Tecartus (brexucabtagene autoleucel) is not appropriate for the member must be provided; and*
6. *Approvals will be for 1 dose per member per lifetime.*

- *Carvykti (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:*
- *Diagnosis of relapsed or refractory multiple myeloma (RRMM):*

1. *Member has received ≥1 prior line of therapy, including an immunomodulatory agent and a proteasome inhibitor; and*
    1. *Member must be refractory to lenalidomide; and*
        - *Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and*
        - *Member must have measurable disease, including at least 1 of the following:*
    2. *Serum M-protein ≥0.5g/dL; or*
        - *Urine M-protein ≥200mg/24hr; or*
        - *Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or*
        - *Bone marrow plasma cells >30% of total bone marrow cells; and*
    3. *Member must not have any central nervous system involvement with multiple myeloma; and*
2. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
3. *Approvals will be for 1 dose per member per lifetime.*

- *<u>Kymriah (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]</u>:*

1. *Members must meet all of the following:*
    1. *B-cell precursor ALL; and*
    2. *Member must be 25 years of age or younger; and*
    3. *Refractory or in second or later relapse:*
        - *Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or*
        - *Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and*
    4. *Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and*
2. *Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and*
3. *Approvals will be for 1 dose per member per lifetime.*

- *<u>Kymriah (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]</u>:*

1. *Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and*
2. *Relapsed/refractory disease; and*
3. *Member must be 18 years of age or older; and*
4. *Member must not have primary central nervous system lymphoma; and*
5. *Member must have had ≥2 lines of therapy; and*
6. *Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and*
7. *Approvals will be for 1 dose per member per lifetime.*

- *<u>Tecartus (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]</u>:*

1. *Diagnosis of acute lymphoblastic leukemia (ALL); and*
2. *Relapsed or refractory disease; and*
3. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
4. *Approvals will be for 1 dose per member per lifetime.*

- *<u>Tecartus (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]</u>:*

1. *Diagnosis of mantle cell lymphoma; and*
2. *Relapsed or refractory disease; and*

3. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
4. *Approvals will be for 1 dose per member per lifetime.*

- *<u>Yescarta (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:</u>*

1. *Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and*
2. *Member must be 18 years of age or older; and*
3. *Relapsed or refractory disease used in 1 of the following settings; and*
    1. *After 2 or more lines of therapy; or*
    2. *After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and*
4. *Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), and neurologic toxicities, and*
5. *For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma.*
6. *Approvals will be for 1 dose per member per lifetime.*

- **LIBTAYO**
    - **Interim Criteria (*if applicable*):**
    - *Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (CSCC) Diagnosis]:*

1. *Diagnosis of metastatic or locally advanced CSCC; and*
2. *Member must meet 1 of the following:*
    - *Disease is very-high risk; and*
        - *Used as neoadjuvant treatment when surgery alone may be insufficient; or*
        - *Used as adjuvant treatment following surgery or radiation in patients at high risk of recurrence; or*
    - *Disease is primary or recurrent; and*
        - *Used for systemic therapy alone when curative surgery and curative radiation are not feasible.*

- **KOSELUGO**
    - **Interim Criteria (*if applicable*):**
    - *Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:*

1. *Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas; and*
2. *Members must be 1 year of age or older; and*
3. *Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling; and*

4. *For the 5mg and 7.5mg oral granule formulation, the request must indicate that the member is unable to swallow whole capsules.*

- **BEIZRAY**
  - **Interim Criteria (*if applicable*):**
  - *Beizray™ Kit (Docetaxel/Albumin) Approval Criteria:*

1. *An FDA approved diagnosis; and*
2. *A patient-specific, clinically significant reason why the member cannot use generic docetaxel formulations, which are available without a prior authorization, must be provided.*

- **ZEPZELCA**
  - **Interim Criteria (*if applicable*):**
  - *Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:*

1. *A diagnosis of SCLC; and*
2. *Used in 1 of the following settings:*
   - *Disease is metastatic; and*
     - *Used as subsequent therapy following disease progression on or after platinum-based chemotherapy; or*
   - *Disease is extensive-stage; and*
     - *Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and*
     - *Maintenance treatment is given in combination with atezolizumab or atezolizumab/hyaluronidase; and*
3. *Member must be 18 years of age or older.*

- **TECENTRIQ/TECENTRIQ HYBREZA**
  - **Interim Criteria (*if applicable*):**
  - *Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/Hyaluronidase-tqjs) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:*

1. *A diagnosis of SCLC; and*
2. *Extensive-stage disease; and*
3. *Used in 1 of the following settings:*
   - *Used as primary treatment in combination with carboplatin and etoposide; or*
   - *Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and*
     - *Maintenance treatment is given in combination with lurbinectedin; and*
4. *Member must be 18 years of age or older.*

- **INLURIYO**
  - **Interim Criteria (*if applicable*):**
  - *Inluriyo™ (Imlunestrant) Approval Criteria [Breast Cancer Diagnosis]:*

1. *Diagnosis of advanced or metastatic breast cancer; and*

2. *Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and*
3. *Tumor is positive for estrogen receptor-1 (ESR-1) mutation; and*
4. *Disease has progressed following at least 1 line of endocrine therapy; and*
5. *Member must be 18 years of age or older.*

- **HERNEXEOS**
  - **Interim Criteria (*if applicable*):**
  - *Hernexeos® (Zongertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:*

1. *Diagnosis of non-squamous NSCLC; and*
2. *Disease is unresectable or metastatic; and*
3. *Disease is positive for HER2 (ERBB2) tyrosine kinase domain activating mutation; and*
4. *Member has received prior systemic therapy; and*
5. *Member must be 18 years of age or older.*

- **MODEYSO**
  - **Interim Criteria (*if applicable*):**
  - *Modeyso™ (Dordaviprone) Approval Criteria [Glioma Diagnosis]:*

1. *Diagnosis of diffuse midline glioma; and*
2. *Member must be 1 year of age or older; and*
3. *Presence of H3 K27M mutation; and*
4. *Member has progressed on at least 1 prior therapy.*

- **LYNOZYFIC – MEDICAL ONLY**
  - **Interim Criteria (*if applicable*):**
  - *Lynozyfic™ (Linvoseltamab-gcpt) Approval Criteria [Multiple Myeloma Diagnosis]:*

1. *Diagnosis of relapsed or refractory multiple myeloma; and*
2. *Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and*
3. *Member is 18 years of age or older; and*
4. *Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Medical Only. Lynozyfic does not have a specific HCPCS code at this time. Please note, we cannot approve a PA for Lynozyfic for a miscellaneous HCPCS code. Once Lynozyfic gets a specific HCPCS code, it will require PA with the approval criteria provided.

- **IBTROZI**
  - **Interim Criteria (*if applicable*):**
  - *Ibtrozi™ (Taletrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:*

1. *Diagnosis of NSCLC; and*
2. *Disease is locally advanced or metastatic; and*
3. *Disease is positive for ROS1 rearrangements; and*

4. *Members is 18 years of age or older.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The rebate agreement for Ibtrozi starts on 10/1/2025; therefore, this medication will not be covered until then.
- **INLEXZO**
    - **Interim Criteria (*if applicable*):**
    - *Inlexzo™ (Gemcitabine Intravesical System) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:*

1. *Diagnosis of NMIBC with carcinoma in situ (CIS), with or without papillary tumors; and*
2. *Disease is unresponsive to Bacillus Calmette-Guérin (BCG) treatment; and*
3. *Member must be 18 years of age or older; and*
4. *Used for intravesical administration only; and*
5. *Initial approvals will be for 6 months for 8 doses administered every 3 weeks; and*
6. *Subsequent approvals will be for 6 months for 2 doses administered every 12 weeks; and*
7. *Approval will be limited to a maximum total of 14 doses.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - MEDICAL BENEFIT ONLY
    - Inlexzo is only FDA approved for a maximum of 14 doses. If requests are received for additional treatment(s) beyond 14 doses, they would need to be submitted for oncology consult for review.
- **MONJUVI**
    - **Interim Criteria (*if applicable*):**
    - *Monjuvi® (Tafasitamab-cxix) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:*

1. *Diagnosis of classic FL; and*
2. *Member must be 18 years of age or older; and*
3. *Used as second line or later line of therapy (no response, relapsed, or progressive disease); and*
4. *Used in combination with lenalidomide and rituximab; and*
5. *Member has received at least 1 prior systemic therapy including an anti-CD20 monoclonal antibody.*

    - **Additional Internal Notes (*for consideration toward approval*):**
- **ZUSDURI**
    - **Interim Criteria (*if applicable*):**
    - *Zusduri™ (Mitomycin Intravesical Solution) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:*

1. *Diagnosis of NMIBC; and*
2. *Disease is low-grade, intermediate-risk; and*
3. *Disease is recurrent; and*
4. *Administered by intravesical instillation only; and*
5. *Member must be 18 years of age or older; and*
6. *Approval will be limited to a total of 6 weekly instillations*

    - **Additional Internal Notes (*for consideration toward approval*):**

- MEDICAL ONLY – Cannot be approved for miscellaneous HCPCS codes.
- Zusduri is only FDA approved for a total of 6 weekly instillations. If requests are received for additional treatment(s), they would need to be submitted for oncology consult for review.

- **KEYTRUDA**
  - **Interim Criteria (*if applicable*):**
  - *Keytruda® (Pembrolizumab) Approval Criteria [Head and Neck Cancer Diagnosis]:*

1. *Diagnosis of head and neck cancer; and*
2. *Squamous cell histology; and*
3. *Used in first-line or recurrent setting for resectable locally advanced disease; and*
   - *As neoadjuvant and adjuvant addition to standard care (surgery and adjuvant radiotherapy with or without concomitant chemotherapy); and*
   - *Tumor expresses PD-L1 [Combined Positive Score (CPS) ≥1]; or*
4. *Used in metastatic or unresectable disease, as first-line or subsequent-line therapy, in combination with chemotherapy; and*
   - *Pembrolizumab was not previously used; and*
   - *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or*
5. *As subsequent therapy as a single agent; and*
   - *Disease is PD-L1 positive recurrent or metastatic disease; or*
   - *Disease is tumor-mutational burden-high (TMB-H) tumors (≥10 mut/Mb); or*
   - *Disease has progressed on or after prior platinum therapy.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **NUBEQA**
  - **Interim Criteria (*if applicable*):**
  - *Nubeqa® (Darolutamide) Approval Criteria [Metastatic Castration-Sensitive Prostate Cancer (mCSPC) Diagnosis]:*

1. *Diagnosis of mCSPC; and*
2. *Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and*
3. *Used in combination with docetaxel or as a single agent.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **WELIREG**
  - **Interim Criteria (*if applicable*):**
  - *Welireg® (Belzutifan) Approval Criteria [Pheochromocytoma or Paraganglioma (PPGL) Diagnosis]:*

1. *Diagnosis of locally advanced, unresectable, or metastatic PPGL; and*
2. *Member must be 12 years of age or older; and*
3. *As a single agent.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **ZYNYZ**
  - **Interim Criteria (*if applicable*):**
  - *Zynyz® (Retifanlimab-dlwr) Approval Criteria [Squamous Cell Carcinoma of the Anal Canal (SCAC) Diagnosis]:*

1. *Diagnosis of SCAC; and*
2. *Used as first-line treatment in combination with carboplatin and paclitaxel; and*
    - *Inoperable locally recurrent or metastatic disease; and*
    - *A maximum treatment duration of 12 months will apply; or*
3. *Used as a single agent; and*
    - *Locally recurrent or metastatic disease; and*
    - *Used as subsequent or second-line therapy if progression or intolerance to platinum-based chemotherapy; and*
    - *Member has received no prior immunotherapy; and*
    - *A maximum treatment duration of 24 months will apply; and*
4. *Member must be 18 years of age or older.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **EMRELIS**
    - **Interim Criteria (*if applicable*):**
    - *Emrelis™ (Telisotuzumab Vedotin-tllv) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:*

1. *Diagnosis of recurrent, advanced, or metastatic non-squamous NSCLC; and*
2. *Disease with high c-Met/MET protein overexpression, defined as ≥50% of tumor cells with strong staining [immunohistochemistry (IHC) 3+]; and*
3. *Epidermal growth factor receptor (EGFR) wild-type; and*
4. *Member has received prior systemic therapy; and*
5. *ECOG performance status of 0-2; and*
6. *Used as a single agent; and*
7. *Member must be 18 years of age or older.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **AVMAPKI/FAKZYNJA CO-PACK**
    - **Interim Criteria (*if applicable*):**
    - *Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Approval Criteria [Ovarian Cancer Diagnosis]:*

1. *Diagnosis of low-grade serious ovarian cancer; and*
2. *Disease is recurrent; and*
3. *Member has KRAS-mutation; and*
4. *Member has received prior systemic therapy; and*
5. *Member is 18 years of age or older.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219616s000lbl.pdf
- Coverage: Avmapki™ Fakzynja™ Co-Pack will be covered with a hard PA with the criteria listed below.
    - Quantity Limit(s): 66 capsules/tablets per 28 days

- **AUCATZYL**
    - **Interim Criteria (*if applicable*):**
    - *Aucatzyl® (Obecabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:*

1. *Diagnosis of B-cell precursor ALL; and*
2. *Disease is relapsed or refractory; and*
3. *Member has not received any prior CD19-directed CART product; and*
4. *Approvals will be for 1 split dose infusion per member per lifetime.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Medical Coverage Only
    - The rebate agreement for Aucatzyl starts on 4/1/2025; therefore, this medication will not be covered until then.

- **AMTAGVI**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Amtagvi™ is currently not a covered product due to no federal drug rebate agreement with the manufacturer. The above criteria will only apply if the manufacturer obtains a federal drug rebate. If a request is received for Amtagvi, please notify a pharmacist. If covered, Amtagvi will have similar requirements to CAR-T therapies and Omisirge due to the high cost, such as submitting it for oncology consult and OHCA medical review prior to approval.
- **ANKTIVA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The dosing for Anktiva is complicated. Please be careful when approving requests to ensure the appropriate number of doses and duration is approved (considering both the induction and maintenance dosing). Here is an example of how it may be approved:
    - Induction (6-week approval duration):
        - First approval: 6 induction doses
        - Second approval: 6 induction doses (if complete response not achieved at month 3)
    - Maintenance (6-month approval duration):
        - First approval: 6 doses (months 4 and 7)
        - Second approval: 6 doses (months 10 and 13)
        - Third approval: 3 doses (month 19)
        - Fourth approval: 3 doses (month 25)
        - Fifth approval: 3 doses (month 31)
        - Sixth approval: 3 doses (month 37)
    - Note: For a member who requires 2 induction courses, a maximum total of 36 doses could be received (over 37 months).
- **ASPARLAS, ONCASPAR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Currently, Servier Pharmaceuticals, the manufacturer of both Asparlas and Oncaspar, is not allowing Oncaspar to be ordered for any patient who is 1 month (31 days) to 21.5 years of age. If the patient is within that age range, they are directed to order Asparlas which is FDA approved for use only in patients 1 month to 21 years of

age. Oncaspar is still FDA approved for use in pediatric patients, so this change in the ability to order Oncaspar does not represent any action the FDA has taken and does not appear to be based on any clinical considerations regarding the efficacy and/or safety of Oncaspar.
    - Because of this, we are not planning to update the approval criteria for Asparlas and Oncaspar, which is based on the FDA approved labels and the documented efficacy and safety data for both products.
    - However, in order not to delay treatment, if a request is received for Asparlas for a member who is 1 month to 21 years of age, please do not require a reason why they cannot use Oncaspar at this time. If all other criteria are met, please consider approval of Asparlas. Additionally, for members previously on Oncaspar who are 1 month to 21.5 years of age, they may be required to switch to Asparlas after their current treatment cycle ends. Please keep that in mind if a patient was previously approved for Oncaspar and they are now requesting Asparlas due to the member's age.
    - We will provide more information as it becomes available and if any additional updates are needed.
- **AQNEURSA**
    - **Interim Criteria (*if applicable*):**
    - *Aqneursa™ (Levacetylleucine) Approval Criteria:*

1. *An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the NPC1 or NPC2 genes (results of genetic testing must be submitted); and*
2. *Member must have the presence of at least mild disease-related neurological symptoms; and*
3. *Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and*
4. *Will not be approved for concomitant use with Miplyffa™ (arimoclomol); and*
5. *Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and*
6. *Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 7 days after the last dose of Aqneursa™; and*
7. *Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Aqneursa™ (levacetylleucine) is a modified amino acid indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15kg.
    - How Supplied: Unit-dose packets containing 1g levacetylleucine strawberry flavored granules

- Dosing and Administration - Administered orally up to 3 times daily based on actual body weight:

Body Weight	Morning Dose	Afternoon Dose	Evening Dose
15kg to <25kg	1g	No dose	1g
25kg to <35kg	1g	1g	1g
35kg or more	2g	1g	1g

  - If the 2g dose is needed, 2 packets must be prepared individually.
  - The contents of 1 packet should be emptied into a container with 40mL of water, orange juice, or almond milk. Hot liquid should not be used. The medication should be stirred to form a suspension.
  - The suspension should be swallowed immediately (within 30 minutes).
  - The above steps should be repeated with a second packet if a dose of 2g is needed.
  - See the full Prescribing Information for additional instructions if administration through a gastrostomy tube (G-tube) is needed.
  - Prescribing Information:
  - https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219132s000lbl.pdf
  - Coverage: Aqneursa™ will be covered with a hard PA
- **BIZENGRI**
  - **Interim Criteria (*if applicable*): MEDICAL ONLY**
  - *Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:*
    1. *Diagnosis of advanced, unresectable or metastatic NSCLC; and*
    2. *Neuregulin 1 (NRG1) gene fusion-positive; and*
    3. *Disease progression on or after prior systemic therapy; and*
    4. *Used as single agent.*
  - *Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Pancreatic Cancer Diagnosis]:*
    1. *Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma; and*
    2. *Neuregulin 1 (NRG1) gene fusion-positive; and*
    3. *Disease progression on or after prior systemic therapy; and*
    4. *Used as single agent.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Bizengri® (zenocutuzumab-zbco) a bispecific HER2- and HER3-directed antibody indicated for the treatment of:
    - Adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy; or
    - Adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.
    - These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

- How Supplied: 375mg/18.75mL (20mg/mL) solution in a single-dose vial (SDV)
- Dosing and Administration:
  - Recommended dose is 750mg as an intravenous (IV) infusion every 2 weeks
  - Should be continued until disease progression or unacceptable toxicity
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761352s001lbl.pdf
- Coverage: Bizengri® will be covered as **Medical Only** with a hard PA with the criteria listed above.

- **BLINCYTO**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Blincyto has a complex dosing schedule and changes every week depending on cycle. You should just be authorizing the maximum dose which is one vial per day (35mcg or 35 units). Hopefully they will give you length of therapy but if not you can approve the default 6 months, so they are able to get what
  - they need without us readjusting the PA every other day.
- **BOSULIF**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Bosulif® is available in the following formulations and strengths:
  - Tablets: 100mg, 400mg, and 500mg (must be swallowed whole)
  - Capsules: 50mg and 100mg (may be opened, and the contents mixed with applesauce or yogurt)
  - The quantity limit for the 50mg capsule is set as #30/30 to discourage the use of multiple 50mg capsules to achieve larger doses, when possible, based on net cost. If a pediatric member needs an in-between dose, such as 250mg, it would be preferable for them to use (2) of the 100mg capsules and (1) of the 50mg capsules rather than (5) of the 50mg capsules. It would also be preferable to ask an older member to use the 500mg tablet, if possible, instead of multiples of the capsules. If a clinical reason is given for needing the capsules (for a member who cannot swallow tablets, for example), please consider that for approval.
  - Quantity Limits:
  - 500mg: One a day
  - 100mg: Up to 2 a day
- **BRAFTOVI**
  - **Interim Criteria (*if applicable*):**
  - *Braftovi (encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:*

1. *Diagnosis of advanced or metastatic colorectal cancer (CRC); and*
   - *BRAF V600E mutation positive; and*
   - *Used in combination with cetuximab or panitumumab; and*
   - *Disease must have progressed following adjuvant therapy within 12 months; or*
   - *Used following progression of any line of metastatic therapy; or*
2. *Diagnosis of metastatic CRC; and*

        - *BRAF V600E mutation positive; and*
        - *Used in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin).*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Braftovi® (encorafenib) was granted accelerated approval for a new indication, in combination with cetuximab and mFOLFOX6, for patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by an FDA-approved test.
- **DARZALEX, DARZALEX FASPRO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The oncology pharmacists have indicated that Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) are used interchangeably and can continue to be used interchangeably.
- **EXKIVITY**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If a request is received for Exkivity for a member who is new to treatment, the request would need to be submitted for oncology consult to determine the appropriateness of approving the medication as a new start despite the pending withdrawal of the medication from the market.
- **HERCEPTIN, HERZUMA, KANJINTI, OGIVRI, ONTRUZANT, TRAZIMERA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Members who are already stable on a biosimilar or the reference product may be approved for continuation even if our preferred products change based on net cost. We do not require members to switch to a different biosimilar if they've already been stable on a different biosimilar or reference product.
    - Effective November 11, 2024, Herzuma® (trastuzumab-pkrb) will no longer be a preferred trastuzumab product. SoonerCare members currently on therapy with Herzuma® will be approved for continuation of therapy. Requests for new starts will need to use a preferred trastuzumab product.
    - The preferred trastuzumab products include:
        - Kanjinti® (trastuzumab-anns); and
        - Trazimera® (trastuzumab-qyyp)
    - The specific prior authorization (PA) requirements for Herzuma® and other trastuzumab products can be found in the "Oncologic Therapies" therapeutic category on the OHCA website at www.oklahoma.gov/ohca/pa. The trastuzumab product PA form, PHARM-133, is located on the OHCA website at www.oklahoma.gov/ohca/rxforms.
    - Members currently stable on Herzuma should already have an approved PA in place. Those PAs will be reviewed for continuation once their current PA expires and should be approved at that time for another 6 months as long as there is no evidence of disease progression or adverse drug reactions (per the Oncology Medications

Additional Criteria). We don't require members to switch products if they are already stable on a biosimilar (or the reference product), so essentially Herzuma PAs would be approved indefinitely (every 6 months), as long as the member is still on therapy (and there is no evidence of disease progression or adverse drug reactions).

- **HYFTOR**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Angiofibromas are benign lesions; however, PA requests that are not approvable or are questionable should be sent to oncology consult for review.
  - Coverage is restricted to ages 6-20 years, but with the option to add an age restriction override (4025) for members ≥21 years if there's documentation of a medical issue secondary to facial angiofibroma (e.g., nasal or eye obstruction, bleeding).
- **IBRANCE**
  - **Interim Criteria (*if applicable*):**
  - *Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:*

1. *Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and*
2. *Used in combination with:*
   - *An aromatase inhibitor in female members; or*
   - *Fulvestrant in women with disease progression following endocrine therapy; or*
   - *An aromatase inhibitor or fulvestrant in male patients; or*
   - *Inavolisib and fulvestrant in patients with disease progression following endocrine therapy.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Ibrance® (palbociclib) may now be used in combination with Itovebi™ (inavolisib) based on the recent FDA approved dosing for Itovebi
- **IMFINZI**
  - **Interim Criteria (*if applicable*):**
  - *Imfinzi® (Durvalumab) Approval Criteria [Limited-Stage Small Cell Lung Cancer (LS-SCLC) Diagnosis]:*

1. *Diagnosis of LS-SCLC; and*
2. *Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; and*
3. *Used as single agent.*

  - *Imfinzi® (Durvalumab) Approval Criteria [Bladder Cancer Diagnosis]:*

1. *Diagnosis of muscle invasive bladder cancer; and*
2. *Used in combination with gemcitabine and cisplatin as neoadjuvant treatment for 4 cycles; and*
3. *Followed by single-agent adjuvant treatment following radical cystectomy for up to 8 additional cycles.*

  - **Additional Internal Notes (*for consideration toward approval*):**

- **PLUVICTO**
    - **Interim Criteria (*if applicable*):**
    - *Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan) Approval Criteria [Prostate Cancer Diagnosis]:*
    1. *Diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC); and*
    2. *Member must have been treated with androgen receptor pathway inhibitor (ARPI) therapy; and*
    3. *Member must meet 1 of the following:*
        - *Considered appropriate to delay taxane-based chemotherapy; or*
        - *Has received prior taxane-based chemotherapy.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **RYONCIL**
    - **Interim Criteria (*if applicable*):**
    - *Ryoncil® (Remestemcel-L-rknd) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Diagnosis]:*
    1. *A diagnosis of aGVHD; and*
    2. *The aGVHD is steroid refractory; and*
    3. *Member is 2 months of age to younger than 18 years of age; and*
    4. *Member is an allogeneic hematopoietic stem cell transplant (HSCT) recipient; and*
    5. *Initial approvals will be for a maximum of 8 infusions; and*
    6. *Subsequent approvals for additional infusions will require repeat authorization and clinical documentation must be submitted to support the need for additional infusions.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The rebate agreement for Ryoncil starts on 7/1/2025; therefore, this medication will not be covered until then. If we receive requests prior to 7/1/2025, please respond with messages #2523, or #2524.
    - Due to the high cost, Ryoncil must be reviewed by an oncology pharmacist (all requests). They have asked that we send all chart notes with these requests as well. Requests should be sent via the Oncology Consult site for review, even if approvable based on the PA criteria. If additional infusions are requested after the initial 8 infusions, updated clinical documentation is required and will need to be submitted again for oncology consult review to evaluate the need for additional infusions based on the member's response to initial treatment.
    - Notify Jill at OHCA if a request is received for this medication. If a request for Ryoncil is approved by the oncology pharmacists, please email Jill and send the PA for OHCA medical review. Please attach all the documents submitted from the prescriber and any correspondence from the oncology pharmacists available in the PA viewer (i.e., consult response(s), approval).
- **IMDELLTRA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Medical Only. Imdelltra does not have a specific HCPCS code at this time.

- Please note, we cannot approve a PA for Imdelltra for a miscellaneous HCPCS code. Once Imdelltra gets a specific HCPCS code, it will require PA with the approval criteria provided.

- **ISTODAX, ROMIDEPSIN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Romidepsin 27.5mg/5.5ml vial (solution) was approved by the FDA 3/13/2020. It is not an authorized generic of Istodax, so it will be designated as brand in ICE. Romidepsin 10mg/2ml (powder for reconstitution) was previously added to ICE and is an authorized generic of Istodax.
- **ITOVEBI**
  - **Interim Criteria (*if applicable*):**
  - *Itovebi™ (Inavolisib) Approval Criteria [Breast Cancer Diagnosis]:*
  1. *Diagnosis of locally advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and*
  2. *PIK3CA-mutated; and*
  3. *Used in combination with palbociclib and fulvestrant; and*
  4. *Following recurrence on or after completing adjuvant endocrine therapy.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Itovebi™ (inavolisib) is a kinase inhibitor indicated in combination with palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.
  - How Supplied: 3mg and 9mg oral tablets
  - Dosing and Administration:
  - The recommended dose is 9mg orally once daily, with or without food, until disease progression or unacceptable toxicity.
  - Itovebi should be administered in combination with palbociclib and fulvestrant.
  - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219249s000lbl.pdf
  - Coverage: Itovebi™ will be covered with a hard PA with the criteria listed below.
- **JAKAFI**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - PA requests for the FDA-approved indications (graft-versus-host disease, myelofibrosis, or polycythemia vera) not meeting criteria, or requests for any other oncology-related indications should be sent for oncology consult.
  - PA requests for any non-oncology indications should not be submitted for oncology consult. Please request any information needed to support the use of Jakafi for the requested indication (journal articles, etc.) and review the request on a case-by-case basis based on the information submitted.

- Jakafi 5mg is set up in ICE without PA with a QL of 6 tablets per 3 days as a way to not delay treatment for acute GVHD. Approvals of the 5mg tablets for chronic use will require an NDC vs. days supply (4026) override in order for the claims to process for 60 tablets per 30 days.

- **JYLAMVO**
  - **Interim Criteria (*if applicable*):**
  - *Jylamvo™ (Methotrexate Oral Solution) Approval Criteria:*

1. *An FDA approved diagnosis of 1 of the following:*
   - *Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or*
   - *Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or*
   - *Polyarticular juvenile idiopathic arthritis (pJIA); or*
   - *Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or*
   - *Rheumatoid arthritis; or*
   - *Severe psoriasis; and*
2. *Member must be 18 years of age or older unless the diagnosis is ALL or pJIA; and*
3. *A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided*.

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Jylamvo™ (methotrexate oral solution) was FDA approved for an expanded label to include the treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen and for the treatment of polyarticular juvenile idiopathic arthritis (pJIA). The other indications for Jylamvo™ are still only FDA approved in adults.

- **KEPIVANCE**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Any requests for Kepivance will need to be submitted to oncology consult to review the preparative regimen and the reference provided. The reference can be either a PMCID, DOI, or physical copy of the paper as long as the oncology pharmacists can review it. The oncology pharmacists will determine if the preparative regimen is appropriate and if it would be predicted to cause the level of mucositis required for Kepivance.
  - Clinical trials for Kepivance included patients with hematologic malignancies such as non-Hodgkin's lymphoma (NHL), Hodgkin's disease, acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), chronic myeloid leukemia (CML), chronic lymphocytic leukemia (CLL), or multiple myeloma.

- **LUTATHERA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Please approve Lutathera for the full duration [every 8 weeks for 4 doses (1unit = 1 mCi; 200mCi x 4 doses = 800mCi for 224 days)] to ensure the member does not

experience delays in this treatment. Please send any requests outside of the FDA approved regimen to the oncology pharmacists for consult.

- **OJEMDA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Ojemda is dosed once weekly. It is available as 100mg oral tablets or a 25mg/mL oral suspension. The suspension comes as a single-use bottle which contains up to 300mg. If the member's dose is >300mg, they would need to fill 2 bottles per dose. This makes the suspension twice as expensive as the tablets for any dose >300mg.
  - Members with a BSA of 0.30-0.83m2 should only use the oral suspension but should only need 1 bottle (12mL) per dose.
  - Members with a BSA of 0.84-0.89m2 should only use the oral suspension and will need to fill 2 bottles (24mL) per dose.
  - Members with a BSA ≥0.90m2 can use either the tablets or the suspension according to package labeling. We would prefer them to use the tablets for any member who is able to use the tablets. However, please review the information submitted for a reason why the suspension is needed. If a member is not able to swallow tablets, the suspension should be approved. We do not want to delay treatment if they give a reason why the suspension is needed.
  - Please note: If they are using the tablets, those are available in blister cards containing multiple 100mg tablets to achieve a 400mg, 500mg, or 600mg dose. The approved quantity should reflect the full number of tablets needed. For example, if the dose is 400mg, they would need 4 tablets per dose once weekly, so the approved quantity should be #16 for a 28-day supply.
- **OPDIVO**
  - **Interim Criteria (*if applicable*): *MEDICAL BENEFIT ONLY***
  - ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:***

1. *Member has had complete resection of melanoma; and*
2. *Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and*
3. *Member is 12 years of age or older for Opdivo®; and or*
   - *Member is 18 years of age or older for Opdivo Qvantig™; and*
4. *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
5. *Used as a single agent; and*
6. *Opdivo Qvantig™ must not be used in combination with ipilimumab; and*
7. *Maximum approval duration of 1 year.*

  - ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:***

1. *Diagnosis of unresectable or metastatic CRC; and*
2. *Tumor is microsatellite-instability high (MSI-H), or mismatch repair deficient (dMMR), or has polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., TMB >50mut/Mb]; and*

3. *Used as a single agent or in combination with ipilimumab; and*
4. *Member is 12 years of age or older for Opdivo®; or*
    - *Member is 18 years of age or older for Opdivo Qvantig™; and*
5. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:***

1. *Diagnosis of unresectable advanced or metastatic ESCC; and*
    - *Used in the first-line setting; and*
    - *Used in combination with 1 of the following:*
        - *Fluoropyrimidine- and platinum-based chemotherapy; or*
        - *Ipilimumab; or*
2. *Diagnosis of esophageal or GEJ cancer; and*
    - *Member has received preoperative chemoradiation; and*
    - *Member underwent R0 (complete) resection and has residual disease; and*
    - *As a single agent; or*
3. *Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and*
    - *Human epidermal receptor 2 (HER2)-negative disease; and*
        - *Used in first-line setting; and*
            - *Used in combination with oxaliplatin and fluorouracil or capecitabine; and*
            - *Adenocarcinoma pathology; or*
        - *Used in the second-line or greater setting; and*
            - *As a single agent; and*
            - *Squamous cell pathology; and*
4. *Member is 18 years of age or older for Opdivo Qvantig™; and*
5. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Gastric Cancer Diagnosis]:***

1. *Diagnosis of advanced or metastatic disease; and*
2. *Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and*
3. *Member is 18 years of age or older for Opdivo Qvantig™; and*
4. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Head and Neck Cancer Diagnosis]:***

1. *Diagnosis of recurrent or metastatic head and neck cancer; and*
2. *Squamous cell histology; and*
3. *Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and*

4. *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
5. *Member is 18 years of age or older for Opdivo Qvantig™; and*
6. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:***

1. *Diagnosis of HCC; and*
2. *Member must have unresectable disease and is not a transplant candidate, metastatic disease, or extensive liver tumor burden; and*
3. *Must meet 1 of the following:*
    - *Used as first-line systemic therapy, in combination with ipilimumab, if no previous anti-CTLA-4 combination therapy; or*
    - *Used as subsequent therapy, as a single agent, if not previously treated with another checkpoint inhibitor as subsequent therapy; and*
4. *Member is 18 years of age or older for Opdivo Qvantig™; and*
5. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:***

1. *Diagnosis of NSCLC; and*
2. *For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:*
    - *Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and*
    - *No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and*
    - *Expresses programmed death ligand 1 (PD-L1) ≥1%; or*
3. *For first-line therapy for resectable disease (>4cm or node positive), meeting the following:*
    - *Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or*
4. *For resectable disease (tumors ≥4cm or node positive), meeting the following:*
    - *Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery; and*
    - *No known EGFR mutations or ALK rearrangements; or*
5. *For second-line therapy for metastatic disease, meeting the following:*
    - *Tumor histology is 1 of the following:*
        - *Adenocarcinoma; or*
        - *Squamous cell; or*
        - *Large cell; and*
    - *Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and*

- *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
- *Used as a single agent; and*

6. *Member is 18 years of age or older for Opdivo Qvantig™; and*
7. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:***

1. *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
2. *Used in 1 of the following settings:*
    - *For nivolumab monotherapy:*
        - *Diagnosis of relapsed or surgically unresectable stage 4 disease; and*
        - *Failed prior therapy with 1 of the following medications:*
            - *Sunitinib; or*
            - *Sorafenib; or*
            - *Pazopanib; or*
            - *Axitinib; or*
    - *For nivolumab use in combination with ipilimumab:*
        - *Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or*
    - *For nivolumab use in combination with cabozantinib:*
        - *Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and*
        - *Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and*
3. *Member is 18 years of age or older for Opdivo Qvantig™; and*
4. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:***

1. *Must meet 1 of the following criteria:*
    - *Disease relapsed within 6 months of initial chemotherapy; or*
    - *Disease is progressive on initial chemotherapy; and*
2. *Used as a single agent; and*
3. *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
4. *Member is 18 years of age or older for Opdivo Qvantig™; and*
5. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:***

1. *Diagnosis of unresectable or metastatic melanoma; and*

2. *Member is 12 years of age or older for Opdivo®; or*
    - *Member is 18 years of age or older for Opdivo Qvantig™; and*
3. *Used as a single agent or in combination with ipilimumab:*
    - *As first-line therapy for untreated melanoma; or*
    - *As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and*
        - *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and*
4. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- ***Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:***

1. *Diagnosis of urothelial carcinoma; and*
    - *Member has undergone radical resection; and*
    - *Disease is at high risk of recurrence; or*
2. *Diagnosis of metastatic or unresectable locally advanced disease; and*
    - *Used as second-line or greater therapy; and*
    - *Previous failure of a platinum-containing regimen; and*
    - *Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or*
3. *Diagnosis of metastatic or unresectable urothelial carcinoma; and*
    - *Used as first-line therapy; and*
    - *In combination with cisplatin and gemcitabine; and*
4. *Member is 18 years of age or older for Opdivo Qvantig™; and*
5. *Opdivo Qvantig™ must not be used in combination with ipilimumab.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Opdivo and Opdivo Qvantig are medical only.

- **PEMAZYRE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The oncology pharmacists have requested that all requests for Pemazyre be submitted for oncology consult until further notice, even if they appear to meet the current criteria. The criteria may need to be tightened as more information on this medication is published.
- **PROVENGE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If approvable, should be approved for a total of 3 doses (3 units). It is a 1-time treatment course of 3 doses total and should not be repeated. If you receive a request for a second treatment course, it should be sent to the oncology pharmacists.
- **SCEMBLIX**
    - **Interim Criteria (*if applicable*):**

- *Scemblix® (asciminib) was granted accelerated approval for a new indication for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Scemblix® (Asciminib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:*

1. *Diagnosis of Philadelphia chromosome-positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase; and*
    - *Used in the first line setting; or*
    - *Previously treated with ≥2 or more tyrosine kinase inhibitors (TKIs); or*
    - *Frontline or subsequent therapy in patients with the T315I mutation.*

- **Additional Internal Notes (*for consideration toward approval*):**
- The oncology pharmacists have requested that we verify the dosing when reviewing PAs for Scemblix as the dosing is different depending on the indication.
- Philadelphia chromosome-positive CML in chronic phase: 80mg orally once daily or 40mg twice daily
- Philadelphia chromosome-positive CML in chronic phase with the T315I mutation: 200mg orally twice daily

- **TECELRA**
    - **Interim Criteria (*if applicable*):**
    - *Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:*

1. *Diagnosis of unresectable or metastatic synovial sarcoma; and*
2. *Member must be 18 years of age or older; and*
3. *Has received previous anthracycline or ifosfamide-containing chemotherapy; and*
4. *HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive; and*
5. *Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and*
6. *Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and*
7. *Approvals will be for 1 dose per member per lifetime.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Tecelra will be covered as Medical Only. It will also have similar PA requirements as the CAR-T therapies regarding sending it for oncology consult and OHCA medical consult for final review prior to approval.
- Requests should be sent for Oncology Consult for review, even if approvable based on the PA criteria. Due to the high cost, this medication must be reviewed by an oncology pharmacist (all requests). Please send all chart notes with these requests as well.
- This is part of the High-Investment Drug Carve Out.

- **TEVIMBRA**
    - **Interim Criteria (*if applicable*):**
    - ***Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:***

1. *Diagnosis of unresectable or metastatic ESCC; and*
2. *Used after disease progression on prior systemic chemotherapy; and*

3. *Member has not previously failed other programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitors; and*
4. *Used as a single agent*.

- ***Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:***

1. *Diagnosis of unresectable or metastatic gastric or GEJ adenocarcinoma; and*
2. *Used in the first-line setting in combination with platinum and fluoropyrimidine-based chemotherapy; and*
3. *Human epidermal receptor 2 (HER2)-negative disease; and*
4. *Tumor expresses programmed death ligand 1 (PD-L1) ≥1%*.

- **Additional Internal Notes (*for consideration toward approval*):**
- Tevimbra® (tislelizumab-jsgr) was approved for a new indication, in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (≥1). For the previously approved indication for the treatment of unresectable or metastatic esophageal squamous cell carcinoma (ESCC), Tevimbra® should be used as a single agent.

- **VYLOY**
  - **Interim Criteria (*if applicable*):**
  - *Vyloy® (Zolbetuximab-clzb) Medical Only Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:*

1. *Diagnosis of locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma; and*
   - *Human epidermal growth factor receptor 2 (HER2)-negative; and*
   - *Claudin (CLDN) 18.2 positive (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining); and*
   - *Used for first-line treatment; and*
   - *Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and*
2. *Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling*.

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Vyloy® (zolbetuximab-clzb) is a claudin (CLDN) 18.2-directed cytolytic antibody and is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are CLDN 18.2 positive as determined by an FDA-approved test.
  - How Supplied: 100mg lyophilized powder in a single-dose vial for intravenous (IV) infusion
  - Dosing and Administration:
    - Initial dose: 800mg/m2 IV

        - Subsequent doses:
            - 600mg/m2 IV every 3 weeks; or
            - 400mg/m2 IV every 2 weeks
    - Should be continued until disease progression or unacceptable toxicity
    - Should be administered in combination with fluoropyrimidine- and platinum-containing chemotherapy
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761365s000lbl.pdf
    - Coverage: Vyloy® will be covered as Medical Only with a hard PA with the criteria listed.
- **YERVOY**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please verify Opdivo (nivolumab) request is also approvable when reviewing requests for use in combination.
- **BORUZU**
    - **Interim Criteria (*if applicable*):**
    - *Boruzu® (Bortezomib) Approval Criteria:*

1. *An FDA approved diagnosis; and*
2. *A patient-specific, clinically significant reason the member cannot use generic Velcade® (bortezomib), which is available without a prior authorization, must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Boruzu® (bortezomib) is a proteasome inhibitor that contains a new formulation of bortezomib that does not have to be reconstituted. It is FDA approved for the same indications as Velcade® (bortezomib).
    - How Supplied: 3.5mg/1.4mL solution in a single-dose vial (SDV)
    - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b92628dd-fa09-4c3a-b6a3-66426025807c
    - Coverage: Boruzu® will be covered with a hard PA with the criteria listed.
- **DANZITEN and NILOTINIB TARTARATE**
    - **Interim Criteria (*if applicable*):**
    - *Danziten™ (Nilotinib) and Nilotinib Tartarate Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:*

1. *Diagnosis of CML; and*
2. *Member must have 1 of the following:*
    - *Newly diagnosed chronic, accelerated, or blast phase CML; or*
    - *Philadelphia Chromosome Positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy; or*
    - *Post-hematopoietic stem cell transplant; and*
3. *A patient-specific, clinically significant reason the member cannot use Tasigna® (nilotinib) must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**

- Danziten™ (Nilotinib) is a proteasome inhibitor that contains a new formulation of nilotinib that does not have to be taken on an empty stomach. It is FDA approved for 2 of the same adult indications as Tasigna® (nilotinib).
- How Supplied: 71mg and 95mg oral tablets
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219293s000lbl.pdf
- Coverage: Danziten™ will be covered with a hard PA with the criteria listed.

- **REVUFORJ**
  - **Interim Criteria (*if applicable*):**
  - *Revuforj® (Revumenib) Approval Criteria [Acute Leukemia Diagnosis]:*

1. *Diagnosis of acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL); and*
2. *Disease is relapsed or refractory; and*
3. *Leukemia is positive for a lysine methyltransferase 2A gene (KMT2A) translocation; and*
4. *Member is 1 year of age or older; and*
5. *Member's recent weight (kg) must be provided; and*
   - *For members weighing <40kg, the member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug.*

  - **Additional Internal Notes (*for consideration toward approval*):**
  - Revuforj® (revumenib) is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year of age and older.
  - How Supplied: 25mg, 110mg, and 160mg oral tablets
  - Dosing and Administration: Recommended dosage is based on patient weight and concomitant use of strong CYP3A4 inhibitors
    - Weight ≥40kg: 270mg twice daily (or 160mg twice daily if used with strong CYP3A4 inhibitors)
    - Weight <40kg: 160mg/m2 twice daily (or 95mg/m2 twice daily if used with strong CYP3A4 inhibitors)
    - See the full Prescribing Information for the recommended BSA-based tablet doses
    - If patients are unable to swallow the tablets whole, the tablets may be crushed and dispersed in water and taken within 2 hours of preparation
  - For patients without disease progression or unacceptable toxicity, treatment should continue for a minimum of 6 months to allow time for clinical response
  - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218944s000lbl.pdf
  - Coverage: Revuforj® will be covered with a hard PA with the criteria listed.

- **ZIIHERA**
  - **Interim Criteria (*if applicable*):**
  - *Ziihera® (Zanidatamab-hrii) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:*

1. *Diagnosis of unresectable or metastatic BTC; and*

2. *Human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry (IHC) 3+; and*
3. *Used for subsequent-line therapy; and*
4. *As a single agent*.

- **Additional Internal Notes (*for consideration toward approval*):**
- Ziihera® (zanidatamab-hrii) is bispecific human epidermal growth factor receptor 2 (HER2)-directed antibody indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive immunohistochemistry (IHC) 3+ biliary tract cancer (BTC), as detected by an FDA-approved test.
- This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- How Supplied: 300mg lyophilized powder in a SDV
- Dosing and Administration: Recommended dose is 20mg/kg as an IV infusion every 2 weeks until disease progression or unacceptable toxicity
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761416s000lbl.pdf
- Coverage: Ziihera® will be covered with a hard PA with the criteria listed.

- **CALQUENCE**
  - **Interim Criteria (*if applicable*):**
  - *Calquence® (Acalabrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:*

1. *Diagnosis of MCL; and*
   - *Used after at least 1 prior line of therapy; and*
   - *As a single agent; or*
2. *Diagnosis of previously untreated MCL; and*
   - *Used in combination with bendamustine and rituximab; and*
   - *Member is ineligible for autologous hematopoietic stem cell transplantation (HSCT).*

- **Additional Internal Notes (*for consideration toward approval*):**

- **DATROWAY**
  - **Interim Criteria (*if applicable*):**
  - **Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:**

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Disease is epidermal growth factor receptor (EGFR)-mutated; and
3. Member has received prior EGFR-directed therapy and platinum-based chemotherapy.

- ***Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Breast cancer Diagnosis]:***

1. *Diagnosis of unresectable or metastatic breast cancer; and*

2. *Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and*
3. *Member has received prior endocrine-based therapy and chemotherapy.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **LUMAKRAS**
    - **Interim Criteria (*if applicable*):**
    - *Lumakras® (Sotorasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:*
1. *Diagnosis of metastatic CRC; and*
2. *Presence of KRAS G12C mutation; and*
3. *Disease has progressed on prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and*
4. *Used in combination with panitumumab.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **ENHERTU**
    - **Interim Criteria (*if applicable*):**
    - *Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Breast Cancer Diagnosis]:*
1. *Adult members with unresectable or metastatic disease; and*
        - *For human epidermal growth factor receptor 2 (HER2)-positive disease, must meet the following:*
            - *Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and*
            - *Member has received ≥1 prior anti-HER2-based regimens; or*
        - *For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet 1 of the following:*
            - *Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; or*
            - *Disease is hormone receptor (HR)-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy; or*
        - *For HER-2 ultralow (IHC 0 with membrane staining) disease, must meet the following:*
            - *Disease is HR-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy.*
    - **Additional Internal Notes (*for consideration toward approval*):**
- **GRAFAPEX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Coverage: Grafapex™ will be covered as **Medical Only** with a hard PA with the criteria listeD.
- **ADCETRIS**

- **Interim Criteria (*if applicable*):**
- *Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:*

1. *As a single agent; and*
    - *CD30+ disease; and*
    - *For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates or non-candidates for chimeric antigen receptor (CAR) T-cell therapy; or*
2. *Used in combination with lenalidomide and a rituximab product; and*
    - *CD30+ disease; and*
    - *Relapsed or refractory disease after 2 or more lines of systemic therapy; and*
    - *Ineligible for autologous hematopoietic stem cell transplantation (HSCT) or CAR T-cell therapy; or*
3. *Used in combination with nivolumab; and*
    - *CD30+ disease; and*
    - *Relapsed or refractory primary mediastinal large B-cell lymphoma.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Based on current NCCN recommendations, removed #1c and added a new option for combination use with nivolumab in patients with relapsed or refractory primary mediastinal LBCL.

- **GOMEKLI**
    - **Interim Criteria (*if applicable*):**
    - *Gomekli™ (Mirdametinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:*

1. *Diagnosis of NF1; and*
2. *Member must be 2 years of age or older; and*
3. *Member has symptomatic plexiform neurofibromas not amenable to complete resection; and*
4. *Member's recent body surface area (BSA) must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219379Orig1s000lbl.pdf
    - Coverage: Gomekli™ will be covered with a hard PA with the criteria listed below.
    - Quantity Limit(s):
        - 1mg strength: 168 capsules or tablets per 28 days
        - 2mg strength: 84 capsules or tablets per 28 days
- **ROMVIMZA**
    - **Interim Criteria (*if applicable*):**
    - *Romvimza™ (Vimseltinib) Approval Criteria [Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:*

1. *Diagnosis of TGCT; and*
2. *Member is 18 years of age or older; and*
3. *Member is not a candidate for surgical resection.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219304s000lbl.pdf
- Coverage: Romvimza™ will be covered with a hard PA with the criteria listed below.
- Quantity Limit: 8 capsules per 28 days

- **CABOMETYX**
  - **Interim Criteria (*if applicable*):**
  - *Cabometyx® (Cabozantinib) Approval Criteria:*

1. *For cabozantinib monotherapy:*
   - *Diagnosis of advanced renal cell carcinoma (RCC); or*
   - *Diagnosis of advanced hepatocellular carcinoma (HCC); and*
     - *Member has previously received sorafenib; or*
   - *Diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) in adults and pediatric members 12 years of age and older; and*
     - *Disease has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy; and*
     - *Disease is radioactive iodine-refractory or member is ineligible for radioactive iodine; or*
   - *Diagnosis of locally advanced, unresectable or metastatic well-differentiated pancreatic neuroendocrine tumors (pNET) or extrapancreatic neuroendocrine tumors (epNET) in adults and pediatric members 12 years of age and older; and*
     - *As second line or subsequent therapy; or*
2. *For cabozantinib in combination with nivolumab:*
   - *Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and*
   - *Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **HALAVEN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Margenza (margetuximab-cmkb) is currently not a covered product through SoonerCare due to no federal drug rebate. The Halaven criteria for breast cancer allows for combination with margetuximab based on NCCN recommendations. If a request for Halaven indicates they will be using it in combination with margetuximab, they could be getting the margetuximab through a primary insurance or a patient assistance program. The combination is still clinically appropriate, but the margetuximab will not be paid by SoonerCare at this time.
- **JOBEVNE/ALYMSYS/AVZIVI/VEGZELMA**
  - **Interim Criteria (*if applicable*):**
  - *Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), Jobevne™ (Bevacizumab-nwgd), and Vegzelma® (Bevacizumab-adcd) Approval Criteria:*

1. *A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*
    - **Additional Internal Notes (*for consideration toward approval*):**

OPIOID-REVERSAL AGENTS

RESPIRATORY

- **LEUKOTRIENE MODULATORS**
    - **SINGULAIR**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Singulair Chewables: FDA approved for 24 months to 14 years old.
        - Singulair Granules: 6-23 months only.
- **MAINTENANCE ASTHMA & COPD AGENTS**
    - **FLOVENT HFA/FLUTICASONE HFA**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - 9/9/25: Due to the continued shortage of Asmanex products, the state has also temporarily removed the PA requirement for one NDC of generic Fluticasone HFA 110mcg (NDC 66993007996) for members 0-8 years of age.
            - If you get a request for the fluticasone 110 mcg for kids within that age range who cannot use Qvar appropriately please approve fluticasone 110 mcg without a PA.
        - 4/25/25: Due to a shortage of Asmanex 50 mcg, the state has temporarily removed the PA requirement for one NDC of generic Fluticasone HFA 44mcg (NDC 66993007896) for members ages 0-3 years of age.
            - If you get a request for the fluticasone 44 mcg for a 4-6 years of age who cannot do the breath actuation of Qvar, then it should be approved. While Qvar is indicated in ages 4 and up, some in those that age range may struggle with breath actuation and the product cannot be used with a spacer.
        - This will be in effect for 6 months (through 11/1/25)
        - Please approve generic Flovent® for a diagnosis of eosinophilic esophagitis (EoE) as a clinical exception without trials of a Tier-1 product.
            - Please approve Tier-2 generic Flovent® for a diagnosis of eosinophilic esophagitis (EoE) as a clinical exception. The other Tier-1 inhaled

corticosteroids are not appropriate for this diagnosis, and generic Flovent® is a cheaper alternative than Eohilia™. The criteria for Eohilia™ asks why they cannot use a swallowed respiratory corticosteroid (i.e., Flovent® or budesonide). Both require a prior authorization, and we should be approving both for the EoE diagnosis as a clinical exception.

- **NUCALA**
  - **Interim Criteria (*if applicable*):**
  - *Nucala (Mepolizumab) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:*

1. *An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and*
2. *Member must be 18 years of age or older; and*
3. *Member has moderate to very severe disease [i.e., GOLD 2, GOLD 3, or GOLD 4 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV1) of <80% predicted]; and*
4. *Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and*
5. *Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and*
6. *Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and*
7. *For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or*
8. *For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and*
9. *Nucala must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and*
10. *Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and*
11. *A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.*

  - **Additional Internal Notes (*for consideration toward approval*):**
- **ADVAIR, DULERA, SYMBICORT**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**

    - SmartPA for a Tier-1 LABA/ICS for members ages 2-11 years when prescribed by one of the listed specialists.
- **ANORO ELLIPTA, BEVESPI AEROSPHERE, DUAKLIR PRESSAIR, STIOLTO RESPIMAT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please consider approval of these products for members with 2 brand issues (use of separate LABA and LAMA would use up their 2 brand limit)
- **BREZTRI AEROSPHERE, TRELEGY ELLIPTA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please consider approval of Trelegy Ellipta for members with 6 Rx or 2 brand issues (use of separate LABA and LAMA would use up their 2 brand limit)
- **PULMICORT RESPULES, ASMANEX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Budesonide inhalation suspension: covered for a diagnosis of eosinophilic esophagitis (may need to add override 4025 NDC vs AGE RESTRICTION)
- **SEREVENT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Serevent has an age restriction of 12 (Micromedex says 4). Many years ago, the DUR board voted to have the age restriction on Serevent and Foradil so that we could make sure the kids were also on an inhaled corticosteroid concomitantly with the LABA.
- **XOLAIR**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - JW UNITS: 75mg Xolair® (omalizumab) vial is no longer available. This means they will have to use the 150mg vial for all doses. Since they may have considerable waste we need to start adding JW units to PA's where they will have to waste units. These will be similar to Botox.
    - If you receive a petition that is approvable for diagnosis of Chronic Idiopathic Urticaria: Approve initially x 3 months to see how member responds to Xolair and then ask for a new UAS score. The clinical trials in the package insert were done for 12 and 24 weeks, most CIU resolves within 1 year.
    - The NAEPP guidelines are at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm
- **OHTUVAYRE**
    - **Interim Criteria (*if applicable*):**
    - *Ohtuvayre™ (Ensifentrine) Approval Criteria:*

1. *An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and*
2. *Member must be 18 years of age or older; and*
3. *Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV1) ≥30% and <80%*

predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and

4. *Member is inadequately controlled on dual or triple combination long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months); and*
5. *Member must not be taking Daliresp® (roflumilast) concurrently with Ohtuvayre™; and*
6. *A quantity limit of 60 ampules (150mL) per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **RHAPSIDO**
  - **Interim Criteria (*if applicable*):**
  - *Rhapsido® (Remibrutinib) Approval Criteria*

1. *An FDA approved diagnosis of chronic spontaneous urticaria (CSU); and*
2. *Member must be 18 years of age or older; and*
3. *Other forms of urticaria must be ruled out; and*
4. *Other potential causes of urticaria must be ruled out; and*
5. *Member must have an Urticaria Activity Score (UAS) ≥16; and*
6. *Rhapsido® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and*
7. *Member must have a documented trial (or have a contraindication or documented intolerance) of all of the following therapies:*
   - *Second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and*
   - *Xolair® (omalizumab) for at least 12 weeks at recommended dosing; and*
   - *Dupixent® (dupilumab) for at least 12 weeks at recommended dosing; and*
8. *Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.*

- **DUPIXENT**
  - **Interim Criteria (*if applicable*):**
  - ***Dupixent® (Dupilumab Injection) Approval Criteria [Bullous Pemphigoid (BP) Diagnosis]:***

1. *An FDA approved diagnosis of BP; and*
2. *Member must be 18 years of age or older; and*
3. *Prescriber must verify that all other potential causes and/or diagnoses with a similar presentation to BP have been ruled out; and*
4. *Member must have both of the following:*
   - *Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24; and*
   - *Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥4; and*

5. *Dupixent® must be prescribed by a dermatologist, or the member must have been evaluated by a dermatologist for BP within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist); and*
6. *Member must be using Dupixent® in combination with a tapering course of oral corticosteroids as outlined in the package labeling (or have a contraindication or documented intolerance); and*
7. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):*
    - *1 medium potency to very-high potency Tier-1 topical corticosteroid; or*
    - *Oral corticosteroids; or*
    - *Immunosuppressive agents (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide); or*
    - *Oral antibiotic agents (e.g., doxycycline, dapsone); and*
8. *Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and*
9. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.*

- ***Dupixent® (Dupilumab injection) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:***

1. *An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and*
2. *Member must be 18 years of age or older; and*
3. *Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and*
4. *Member must have a blood eosinophil count of ≥300 cells/mcL; and*
5. *Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency room or urgent care) in the last 12 months; and*
6. *Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and*
7. *Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and*
8. *Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist*

within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and

9. *Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and*
10. *Quantities approved must not exceed FDA recommended dosing requirements.*

- **Dupixent® (Dupilumab injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:**

1. *An FDA approved indication for add-on maintenance treatment in adult patients with inadequately controlled CRSwNP; and*
2. *Member must be 12 ~~18~~ years of age or older; and*
3. *Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and*
4. *Member must meet 1 of the following:*
    - *Member has required prior sino-nasal surgery; or*
    - *Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and*
5. *Dupixent must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and*
6. *Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and*
7. *Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and*
8. *Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and*
9. *Prescriber must verify the member has been counseled on proper administration and storage of Dupixent; and*
10. *Requests for concurrent use of Dupixent with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and*
11. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and*
12. *A quantity limit of 2 syringes every 28 days will apply.*

- **Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma or Oral Corticosteroid-Dependent Asthma Diagnosis]:**

1. *An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and*

2. *Member must be 6 years of age or older; and*
3. *Member must meet 1 of the following:*
    - *Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); or ~~and~~*
    - *Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and*
4. *Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and*
5. *Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and*
6. *Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and*
7. *Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and*
8. *Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and*
9. *Quantities approved must not exceed FDA recommended dosing requirements.*

- ***Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Spontaneous Urticaria (CSU) Diagnosis]:***

1. *An FDA approved diagnosis of CSU; and*
2. *Member must be 12 years of age or older; and*
3. *Other forms of urticaria must be ruled out; and*
4. *Other potential causes of urticaria must be ruled out; and*
5. *Member must have an Urticaria Activity Score (UAS) ≥16; and*
6. *Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and*
7. *Member must have a documented trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and*
8. *A patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided; and*
9. *Requests for concurrent use of Dupixent with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to*

support the concurrent use. (Dupixent® has not been studied in combination with other biologic therapies); and

10. *Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline in UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.*

- **Additional Internal Notes (*for consideration toward approval*):**
- For initial approvals of Dupixent for atopic dermatitis, please approve a quantity limit override for the full 16 weeks of the initial approval. Received a new indication for add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- There is no data available on the use of Dupixent with other biologics including Xolair. Requests for both should be reviewed individually but they must have VERY good reason for using both. In general, these should not be approved. Additionally, please consider approval of Dupixent in members who are on systemic TCI's or mycophenolate (do not make them go back and try topical therapies if they are on systemic therapies) if they meet all other criteria.
- Quantity Limit Asthma: Initial fill will need a QLO to account for the loading dose
- Since Dupixent® is the only FDA approved medication for bullous pemphigoid and has an established safety profile in pediatrics, please use your clinical judgement and consider approval for members under the age of 18 years if prescribed by a specialist and they meet all other criteria.

- **FASENRA**
  - **Interim Criteria (*if applicable*):**
  - Fasenra® (benralizumab) received a new indication for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adults
    - Dosing for new EGPA indication: 30mg every 4 weeks
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761070s021lbl.pdf
  - *Fasenra® (Benralizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:*

1. *An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and*
2. *Member must be 6 12 years of age or older; and*
3. *Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and*
4. *Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and*

5. *Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and*
6. *Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and*
7. *For authorization of Fasenra® prefilled syringe, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or*
8. *For authorization of Fasenra® prefilled autoinjector pen, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and*
9. *Fasenra® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and*
10. *Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and*
11. *A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.*

- *Fasenra® (Benralizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) diagnosis]:*

1. *An FDA approved indication for the treatment of EGPA; and*
2. *Member meets 1 of the following:*
    - *Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] with in the past 12 months; or*
    - *Member must have refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months; and*
3. *Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and*
4. *Failure to achieve remission despite glucocorticoid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration; and*
5. *Fasenra® must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and*

6. *For authorization of Fasenra® prefilled syringe, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or*
7. *For authorization of Fasenra® prefilled autoinjector pen, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and*
8. *A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply.*
9. *Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant, and prescriber must verify the member is responding to Fasenra® as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dose regimen from baseline.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **FOMOTEROL NEBULIZER SOLUTION KIT**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Formoterol nebulizer solution kit was approved through an Abbreviated New Drug Application (ANDA). This new approval is for the formoterol fumarate inhalation solution that also includes an LC PLUS nebulizer co-packaged in 1 kit.
  - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3da9b6eb-67fa-4baf-9d6b-1ad327e63c55
  - Coverage: Formoterol nebulizer solution kit will be placed into Tier-2 of LABA/LAMA Tier chart

- **NASAL ALLERGY AGENTS**
  - **GENERAL INFORMATION**
    - Beconase AQ is no longer available and has been discontinued by the manufacturer. It is still active in ICE to allow pharmacies to use their available stock. Please do not require a trial of Beconase AQ for a tier-2 medication.
  - **XHANCE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Multiple randomized trials have found that fluticasone (200mcg twice daily), budesonide (200mcg twice daily), and mometasone (280mcg daily) are superior to placebo in reducing symptoms of nasal obstruction in patients with nasal polyposis. There are little data directly comparing different intranasal preparations.
- **ALLERGEN IMMUNOTHERAPY AGENTS**
  - **GENERAL INFORMATION:** https://oklahomaallergy.com/wp-content/uploads/522-POLLEN- SEASONS.pdf
  - **GRASTEK**
    - **Interim Criteria (*if applicable*): n/a**

- **Additional Internal Notes (*for consideration toward approval*):**

Medication Name	Season Type	Start of Season	End of Season	Approval Start Date	Approval End Date
Grastek®	Cool Season Grasses (Timothy)	Late February-March	May	November 15th	May 15th

- **ORALAIR**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**

Medication Name	Season Type	Start of Season	End of Season	Approval Start Date	Approval End Date
Oralair	Cool Season Grasses	Late February-March	May	October 15th	May 15th

  - Oralair does contain a warm season grass (sweet vernal); however, it is not present in Oklahoma, therefore we only authorize in the fall and do not have a spring authorization date.
- **RAGWITEK**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**

Medication Name	Season Type	Start of Season	End of Season	Approval Start Date	Approval End Date
Ragwitek™	Ragweed	Mid-August	Late November	May 15th	November 30th

- **ODACTRA**
  - **Interim Criteria (*if applicable*):**
  - *Odactra™ (House Dust Mite Allergen Extract) Approval Criteria:*

1. *Member must be 12 5 to 65 years of age; and*
2. *Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or in vitro testing for immunoglobulin E (IgE) antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites; and*
3. *Member must not have severe uncontrolled asthma; and*
4. *Member must have failed conservative attempts to control allergic rhinitis; and*

5. *Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):*
    - *Antihistamines: Trials of 2 different products for 14 days each; and*
    - *Intranasal corticosteroids: Trials of 2 different products for 21 days each; and*
6. *The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and*
7. *Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and*
8. *Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and*
9. *Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and*
10. *A quantity limit of 1 tablet daily will apply; and*
11. *Initial approvals will be for the duration of six months of therapy, at which time the prescriber must verify the patient is responding well to Odactra™ therapy. Additionally, compliance will be evaluated for continued approval.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **<u>CYSTIC FIBROSIS (CF) AGENTS</u>**
    - **JASCAYD**
        - **Interim Criteria (*if applicable*):**
        - *Jascayd® (Nerandomilast) Approval Criteria:*
        1. *An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and*
        2. *Member must be 18 years of age or older; and*
        3. *Medication must be prescribed by a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and*
        4. *Requests must indicate if Jascayd® will be used as monotherapy or in combination with nintedanib or pirfenidone; and*
            - *If combination therapy is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and*
        5. *A patient-specific, clinically significant reason why the member cannot use Ofev® (nintedanib) must be provided; and*
        6. *A quantity limit of 60 tablets per 30 days will apply.*
    - **BRINSUPRI**
        - **Interim Criteria (*if applicable*):**
        - *Brinsupri™ (Brensocatib) Approval Criteria:*
        1. *An FDA approved diagnosis of non-cystic fibrosis bronchiectasis (NCFB). Diagnosis must be confirmed by the following:*
            - *Chest computed tomography (CT) scan; and*

        - *Clinical history consistent with NCFB (e.g., cough, chronic sputum production and/or recurrent respiratory infections); and*
    2. *Member must be 12 years of age or older; and*
    3. *Member must not have cystic fibrosis; and*
    4. *Member must have experienced ≥2 exacerbations (e.g., required treatment with antibiotics and/or required hospitalization or emergency room visit) in the last 12 months; and*
    5. *Prescriber must verify that any underlying cause of NCFB is adequately treated, if applicable; and*
    6. *Brinsupri™ must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and*
    7. *Initial approvals will be for the duration of 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Brinsupri™ as demonstrated by a decrease in NFCB symptoms and/or exacerbations. Subsequent approvals will be for 1 year.*
- **KALYDECO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - If the patient's genotype is unknown, an FDA- cleared CF mutation test should be used to detect the presence of a CFTR mutation. Ivacaftor has been found to be effective in the following CFTR mutations: E56K, G178R, S549R, S977F, F1074L, 2789+5G→A, P67L, E193K, G551D, F1052V, D1152H, 3272-
    - 26A→G, R74W, L206W, G551S, K1060T, G1244E, 3849+10kbC→T, D110E, R347H, D579G, A1067T, S1251N, D110H, R352Q, 711+3A→G, G1069R, S1255P, R117C, A455E, E831X, R1070Q, D1270N, R117H, S549N, S945L, R1070W, G1349D. These can be found in the clinical pharmacology section of the package insert (section 12.1).
    - The 5.8mg and 13.4mg granules will have an age restriction of 0-1 year of age as they are only indicated in those 1 month to <4 months of age. Please refer to the Prescribing Information for appropriate dosing.
- **ORKAMBI**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Initial approval: 6 months.
    - At 6 months we check compliance and to see if the medication is working (improvement or stabilization in FEV1, improved BMI, fewer hospitalizations or exacerbations). Please be lenient when checking compliance as these members have limited treatment options.
    - Subsequent: 1 year
- **SYMDEKO**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**

- Vertex has conducted stability studies which demonstrated that crushing or splitting the tezacaftor/ivacaftor FDC tablet or the ivacaftor tablet has no detrimental effect. Therefore, crushing or splitting the tezacaftor/ivacaftor FDC tablet or ivacaftor tablet immediately prior to dosing should not impact the quality.

- **TRIKAFTA**
  - **Interim Criteria (*if applicable*):**
  - *Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:*

1. *An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 F508del mutation in the CF transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data; and*
2. *If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and*
3. *Member must be 2 years of age or older; and*
4. *Members using Trikafta® must be supervised by a pulmonary specialist; and*
5. *If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and*
6. *Prescriber must verify that member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and*
7. *Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Trikafta®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and*
8. *Prescriber must verify that the member does not have severe hepatic impairment; and*
9. *Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and*
10. *Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and*
11. *The following quantity limits will apply:*
    - *Oral tablets: a quantity limit of 3 tablets per day or 84 tablets per 28 days; or*
    - *Oral granules: a quantity limit of 2 packets per day or 56 packets per 28 days; and*
12. *For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and*
13. *Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and*

14. *Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor); and*
15. *Subsequent approvals will be for the duration of 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) was approved for a label expansion for the treatment of people with cystic fibrosis (CF) 2 years of age and older who have at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation that is responsive to Trikafta® based on clinical and/or in vitro data. This expansion will add 94 additional non-F508del CFTR mutations to the label. Additionally, the safety information on liver injury and failure has been updated from Warnings and Precautions to a Boxed Warning and now includes more frequent monitoring of liver function tests while on Trikafta®.
- Prescribing Information: https://pi.vrtx.com/files/uspi_elexacaftor_tezacaftor_ivacaftor.pdf

- **ALYFTREK**
  - **Interim Criteria (*if applicable*):**
  - *Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivacaftor) Approval Criteria:*

1. *An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 F508del mutation in the CF transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on clinical response and/or in vitro data; and*
2. *If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and*
3. *Member must be 6 years of age or older; and*
4. *Members using Alyftrek™ must be supervised by a pulmonary specialist; and*
5. *If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi®, Symdeko®, or Trikafta® use, the prescriber must indicate that information on the prior authorization request; and*
6. *Prescriber must verify that member has been counseled on proper administration of Alyftrek™ including taking with a fat-containing food; and*
7. *Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Alyftrek™, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and*

8. *Prescriber must verify that the member does not have severe hepatic impairment; and*
9. *Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and*
10. *Member must not be taking strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek™; and*
11. *The following quantity limits will apply:*
    - *Alyftrek™ 4/20/50mg tablets: a quantity limit of 3 tablets per day or 84 tablets per 28 days; or*
    - *Alyftrek™ 10/50/125mg tablets: a quantity limit of 2 tablets per day or 56 tablets per 28 days; and*
12. *Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and*
13. *Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/ tezacaftor/ivacaftor and ivacaftor); and*
14. *Subsequent approvals will be for the duration of 1 year.*

- **Additional Internal Notes (*for consideration toward approval*):**
- Alyftrek™ (vanzacaftor/tezacaftor/deutivacaftor) is a combination of deutivacaftor, a CFTR potentiator, tezacaftor, and vanzacaftor indicated for the treatment of cystic fibrosis (CF) in patients 6 years of age and older who have at least 1 F508del mutation or another responsive mutation in the CFTR gene.
- How Supplied: Alyftrek™ comes as fixed-dose combination tablets in the following strengths:
    - Vanzacaftor 4mg/tezacaftor 20mg/deutivacaftor 50mg
    - Vanzacaftor 10mg/tezacaftor 50mg/deutivacaftor 125mg
- Dosage and Administration: Alyftrek™ is taken once daily with a fat-containing food and the dose is based on age and weight
- Liver function tests (LFTs) should be obtained prior to initiating therapy with Alyftrek™ and monitored every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter.
- Alyftrek™ should not be used in patients with severe hepatic impairment and is not recommended in those with moderate hepatic impairment unless the benefit outweighs the risk. If used, no dose adjustment is recommended but LFTs should be monitored closely.
- Concomitant use with strong or moderate CYP3A inducers is not recommended.

- Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218730s000lbl.pdf
- Coverage: Alyftrek™ will be covered with a hard PA with the criteria listed below.
- Quantity Limit(s):
  - Alyftrek™ 4/20/50mg: 84 tablets per 28 days
  - Alyftrek™ 10/50/125mg: 56 tablets per 28 days

- **SYSTEMATIC ANTIHISTAMINES**
  - **GENERAL INFORMATION**
    - Adults Members: OTC antihistamines not covered for adult members (members older than 20 years of age). Common Approved Diagnosis:
      - Allergic rhinitis
      - Seasonal allergies
      - Hayfever
      - Urticaria
      - Psoriasis
      - Hypnotic
      - Asthma
      - Extrapyramidal symptoms
    - NDC's for both OTC and RX formulations of tier 2 & 3 antihistamines are to be reviewed using the OHCA clinical criteria as stated in OHCA Respiratory – Antihistamines.
    - Other issues to consider:
      - Requests for 2nd generation antihistamines are not exempt from an OTC trial solely due to the diagnosis of pregnancy.
      - Requests for 2nd generation antihistamines are not exempt from an OTC trial solely due to the diagnosis of hypertension.
      - Petitions listing an OTC failure of Benadryl due to sedation should not be accepted unless other, less sedating, OTC antihistamines have been tried as well.
      - If diagnosis is itching /dermatitis need supporting information, documenting it is result of an allergic reaction.
    - Approval Length: 1 year
    - Please consider approval of antihistamine QL requests for doses exceeding the FDA maximum for the diagnosis of chronic idiopathic urticaria. High dose trials (4X the FDA maximum) are required for use of Xolair. It would be much more cost effective (and is recommended by the guidelines) for the member to use the antihistamines at high doses rather than Xolair. The required trial duration of these antihistamines must be at least 14 days so consider approval of quantity limit requests for at least 3 months.
- **INHALED ANTI-INFECTIVE AGENTS**
  - **BETHKIS, KITABIS PAK, TOBI PODHALER, CAYSTON, PULMOZYME**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Preferred inhaled tobramycin products:

- Generic Tobi (300mg/5mL nebulized solution) – GCN 61551
- Brand Kitabis (300mg/5mL nebulized solution) – GCN 37569
- Non-preferred inhaled tobramycin products:
- Generic Kitabis (300mg/5mL nebulized solution) – GCN 37569
- Brand or generic Bethkis (300mg/4mL nebulized solution) – GCN 16122
- Brand Tobi Podhaler (28mg inhalation powder) – GCN 30025
- Please give special consideration when evaluating requests for Tobi® Podhaler™ (tobramycin inhalation powder). If they have recent claims for the nebulizer and have made a good faith effort to try the nebulizer but are unable to stay compliant, we should consider approval of the Podhaler™. We don't want them to not be on anything and then wind up in the hospital.
- Inhaled tobramycin medications: Please consider approval for those with chronic bronchial infection with pseudomonas aeruginosa (Class IIb) or persistent pseudomonas aeruginosa infection in bronchiectasis without cystic fibrosis. Chronic treatment with inhaled aminoglycosides, similar to the approach for patients with CF is suggested. (Grade 2C) Prescriber should be pulmonologist or infectious disease specialist and should be held to 28 days of therapy per 56 days.
- Fakhoury, K, Kanu A. Management of Bronchiectasis in Children Without Cystic Fibrosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on June 10, 2014.)
- Inhaled tobramycin may be considered as potential additional antibiotic in patients with multidrug resistant gram-negative bacilli (acinetobacter baumannii and/or pseudomonas aeruginosa) in patients with ventilator- associated pneumonia. Duration of therapy would typically be 14 to 21 days. File, TM. Treatment of Hospital-Acquired, Ventilator-Associated, and Healthcare-Associated Pneumonia in Adults. In: UpToDate, Barlett, JG (Ed), UpToDate, Waltham, MA. (Accessed on June 10, 2014.)
- Dornase Alfa (Pulmozyme): may be considered for inpatient pediatric pulmonary atelectasis. Tom Hendriks, Matthijs de Hoog, Maarten H Lequin, Annick S Devos, Peter JFM Merkus Crit Care. 2005; 9(4): R351–R356. Published online 2005 May 20. doi: 10.1186/cc3544

- **SHORT ACTING BETA2 AGONIST (SABA) AGENTS**
  - **GENERAL INFORMATION**
    - Generic albuterol HFA can be approved for IHS (INDIAN HEALTH SERVICES PHARMACY) if the diagnosis is appropriate.
- **INHALER SPACERS**
  - **GENERAL INFORMATION**
    - A quantity limit of 2 spacers per year will apply allowed as one spacer per claim, 2 claims per year. Please submit spacer claims with a quantity of 1 and a day supply of 30.
    - Inspirachamber will be covered similar to other spacer products with a maximum allowable cost. No PA required. Possible FAQs regarding spacers:

        - Do spacers count towards the 6 prescription limit for adults? No, spacers do not count as one of the 6 prescriptions for adults. These do not count against the prescription limit, but co-pays do apply.
        - Is there copay for spacers? SoonerCare members greater than 20 years of age will have a copay of $4.00.
        - Is there a dispensing fee for spacers? No
        - Is there an age restriction for spacers? No
        - Is there a quantity limit for spacers? Yes, a quantity limit of 2 spacers per year applies. The limit is 1 spacer per 30 days, 2 spacers per year. This is a rolling 365 days. If dispensing one spacer, then the pharmacy should bill a quantity of 1 for 30 days.
        - What if a member needs 2 spacers, one for home and one for school? A quantity limit override and reasoning for multiple spacers will be required.
        - Are spacers a pharmacy benefit? No, spacers are a DME benefit. They are allowed to be billed through pharmacy point of sale system to improve access.
        - Is reimbursement the same when billed as a DME claim as when billed as a pharmacy claim? Yes the $18.00 MAC (maximum allowable cost) is the same.
        - Does the member need a prescription for the spacer? Yes, a prescription is required.
        - The claim denied with edit 4004 NDC not on file, can this NDC be added to the file? NDC's with this denial cannot be added to the reference file.
    - Below is a list of the covered products. Keep in mind that if they lose one or something these should be treated just like a medication and they can request an early fill override.
        - Ace Aerosol Cloud Enhancer
        - AeroChamber
        - Easivent
        - E-Z Spacer
        - InspiraChamber
        - Inspirease
        - Nessi Spacer
        - Watchhaler
    - Effective March 2, 2016, Inhaler assist devices (spacers) will have maximum allowable cost (MAC) pricing applied when billed as a pharmacy claim. The MAC rate will be $18.00 when billed through the pharmacy point of sale system. This rate is equal to the reimbursement if billed as a Durable Medical Equipment (DME) provider. Spacers will continue to be payable as a DME item with HCPCS code A4627.
- **SYNAGIS**
    - **2025 GENERAL INFORMATION**

- **AS OF 3/28/25 - The RSV positivity in Oklahoma has decreased and remained below 10% (the most recent data shows 4.8% for the week ending 3/22/25). We are ending coverage of Synagis today and not approving any further doses.**
- ~~Synagis® (palivizumab): Based on current RSV levels in the state, SoonerCare coverage of Synagis® will begin on 01/03/2025. Based on the American Academy of Pediatrics (AAP) Red Book 2024-2027 recommendations, the Synagis® criteria will be updated with the changes shown below.~~
- ~~In November 2024, the AAP further clarified that "the only instance when palivizumab should be administered is when nirsevimab is recommended but is not available and the patient is eligible to receive palivizumab" in accordance with the 2024 Red Book recommendations. Patients who are 20-24 months of age at the start of the RSV season are not eligible to receive nirsevimab and, therefore, would no longer be considered eligible to receive palivizumab if nirsevimab is unavailable.~~
- ~~Nirsevimab was expected to be broadly available by 10/01/2024, and we're not aware of any nirsevimab availability issues for the 2024-2025 RSV season. We would expect very limited utilization of Synagis® during the current RSV season unless nirsevimab supply issues emerge. Nirsevimab must be obtained through a Vaccines for Children (VFC) provider and is not covered as an outpatient drug through SoonerCare.~~
- ~~Prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis and AAP's updated Red Book 2024-2027 recommendations for RSV monoclonal antibody prophylaxis.~~
- ~~**INTERIM CRITERIA *(if applicable):***~~
- ~~*Synagis® (Palivizumab) Approval Criteria:*~~

~~*A. Member Selection:*~~

- ~~*Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:*~~
  - ~~*Born before 29 weeks, 0 days gestation; or*~~
  - ~~*Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or*~~
  - ~~*Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or*~~
  - ~~*May be considered for:*~~
    - ~~*Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or*~~
    - ~~*Infants who undergo cardiac transplantation during RSV season; or*~~
    - ~~*Infants who are profoundly immunocompromised during RSV season; or*~~

- ~~*Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or*~~

- ~~*Infants 12 to 24 through 19 months of age at the start of RSV season:*~~
  - ~~*Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or*~~
  - ~~*May be considered for:*~~
    - ~~*Infants who undergo cardiac transplantation during RSV season; or*~~
    - ~~*Infants who are profoundly immunocompromised during RSV season; or*~~
    - ~~*Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.*~~

~~*B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab-alip), as recommended by the CDC, must be provided. Per the AAP Red Book 2024-2027 recommendations, the only instance when palivizumab should be administered is when nirsevimab is recommended but is not available and the patient is eligible to receive palivizumab. Additionally, the prescriber must confirm the member has not already received Beyfortus® for the current RSV season. Concomitant use with Beyfortus® will not be approved.*~~

~~*C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial and subsequent approvals will be for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus®.*~~

~~*D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.*~~

~~*E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.*~~

- **BEYFORTUS**
  - **GENERAL INFORMATION**

- Beyfortus (nirsevimab): Beyfortus is not covered as an outpatient drug through SoonerCare. Nirsevimab is included in the child and adolescent immunization schedule from the ACIP/CDC. Childhood vaccines for Medicaid recipients are obtained through the vaccines for children (VFC) program by a VFC provider. Vaccines are not covered as outpatient drugs for reimbursement through SoonerCare for members younger than 19 years of age. PA requests should not be approved for Beyfortus.
- Most children receive vaccinations from their primary care physician in an office setting; however, there are a handful of VFC pharmacies in the state, so there are NDCs for Beyfortus that are active in ICE for VFC billing only (and it would only pay $0.01 for the drug because the medication is obtained for free through the VFC program).
- Synagis (palivizumab) should not be approved as an alternative to Beyfortus just because the provider is not a VFC provider. The member would still need to obtain Beyfortus from a VFC provider, as with all their other childhood vaccines.
- Here are some links regarding the VFC program for more information:
  - https://www.cdc.gov/vaccines-for-children/about/index.html
  - https://www.cdc.gov/vaccines-for-children/hcp/program-eligibility/index.html

SKELETAL SYSTEM

- **GOUT AGENTS**
  - **GLOPERBA, MITIGARE, COLCRYS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Colchicine was shown to be effective in treatment of Pericarditis - can approve (will need override).
    - Approve Colcrys for diagnosis of Behcet's Disease, first line for arthritis due to this disease.
    - Probenecid is contra-indicated during acute gouty attack. The recommendation is to initiate therapy once attack has subsided. However, some members may have attacks so frequent the dr. doesn't want to use colchicine/probenecid. In these cases, please approve Colcrys.
- **MUSCLE RELAXANT AGENTS**
  - **Updated Tier Chart 10/03/25**

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
orphenadrine (Norflex®)		carisoprodol 250mg (Soma®)

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
tizanidine tabs (Zanaflex®)		carisoprodol 350mg (Soma®)
		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		metaxalone 640mg tabs
		methocarbamol 1,000mg tabs (Tanlor®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)

- **ZANAFLEX**
  - **Interim Criteria (*if applicable*):**
  - *Zanaflex® (Tizanidine) Capsules Approval Criteria:*
  1. *Tizanidine tablets must be tried prior to consideration of the capsules.*
  2. *The capsules may be considered for approval only if there is supporting information as to why the member cannot take the tablets; and*
  3. *For Zanaflex® 8mg capsule, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose must be provided.*
  - **Additional Internal Notes (*for consideration toward approval*):**
- **SOMA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Be sure if they only put "MS" that it is multiple sclerosis, not just for muscle spasms
- **METAXALONE 640MG TABS**
  - **Interim Criteria (*if applicable*):**
  - *Metaxalone 640mg Tablet Approval Criteria:*
  1. *A patient-specific, clinically significant reason why the member cannot use all other appropriate lower-tiered products must be provided.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Metaxalone 640mg tablet is available as a new strength of metaxalone and is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions in adult and pediatric patients 13 years of age and older.
    - How Supplied: 640mg oral tablet
  - Dosing and Administration:
    - Recommended dosage is 640mg orally, with or without food, 3 to 4 times a day
    - Maximum recommended daily dosage is 4 tablets or 2,560mg

        - Metaxalone 640mg tablets and Skelaxin® (metaxalone) 800mg tablets are not mutually substitutable on a mg-to-mg basis due to differences in pharmacokinetic profiles
        - See full Prescribing Information for details regarding switching between metaxalone products, when appropriate
    - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fc6de1a6-26aa-47ac-a5d2-bf127a6ca563
    - Coverage: Metaxalone 640mg tablet will be placed in the Special PA Tier of the Muscle Relaxant Medications Tier chart with the additional criteria listed below.
        - Quantity Limit: 120 tablets per 30 days
- **TANLOR**
    - **Interim Criteria (*if applicable*):**
    - *Tanlor® (Methocarbamol 1,000mg Tablet) Approval Criteria:*

1. *A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using methocarbamol 500mg or 750mg tablets to achieve the requested dose, must be provided.*

    - **Additional Internal Notes (*for consideration toward approval*):**

- **NSAIDS**
    - **GENERAL INFORMATION**
        - The clinical exceptions for the NSAIDs in higher tiers are demonstrated by the following conditions (if reasoning member cannot try celecoxib for GI indications or indomethacin for gout indications provided):
        - history of upper GI bleeding; or
        - history of NSAID-induced ulcer, or
        - active peptic ulcer disease, or
        - concurrent use of warfarin, or
        - concurrent chronic use of oral corticosteroids, or
        - chronic NSAID therapy in elderly or debilitated patients, or
        - diagnosis of gout – indomethacin only.
        - After an individual has received Tier-2 NSAID coverage, the individual has Tier-1 and Tier-2 coverage for the duration of their continuous NSAID therapy. Individuals who have not acquired an NSAID for 120 days will be considered to have discontinued their continuous NSAID therapy and the previous approval will no longer be in effect. Dates and dosing information for Tier-1 trials must be included on the petition for authorization. Trials with OTC formulations of Tier-1 medications must be dosed at full prescription strength.
    - **IBUPROFEN 300MG TABLET**
        - **Interim Criteria (if applicable):**
        - *NSAIDs Special Prior Authorization (PA) Approval Criteria:*

1. *A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or*
2. *Previous use of at least 2 Tier-1 NSAID products (from different product lines); and*
3. *A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and*

4. *Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose; and*
5. *Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and*
6. *Additionally, use of ibuprofen 300mg tablets will require a patient-specific, clinically significant reason why the member cannot use all Tier-1 strengths of ibuprofen tablets and all other lower-tiered NSAIDs; and*
7. *Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and*
8. *Additionally, use of Tivorbex® will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **XIFYRM**
  - **Interim Criteria (if applicable):**
  - *Xifyrm™ (Meloxicam Injection) Approval Criteria:*
  1. *An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and*
  2. *Member must be 18 years of age or older; and*
  3. *Member must be well hydrated before administration to reduce the risk of renal toxicity; and*
  4. *Should be used for the shortest duration consistent with individual patient treatment goals; and*
  5. *A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and*
  6. *A quantity limit of 3 vials per 3 days will apply; and*
  7. *For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.*
  - **Additional Internal Notes (*for consideration toward approval*):**
- **DOLOBID**
  - **Interim Criteria (if applicable): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Dolobid™ (diflunisal) is indicated for acute or long-term use for symptomatic treatment of mild to moderate pain, osteoarthritis, or rheumatoid arthritis.
  - How Supplied: 250mg and 375mg oral tablets
  - Dosing and Administration:

    - For mild to moderate pain, an initial dose of 1,000mg followed by 500mg every 12 hours is recommended for most patients. Following the initial dose, so patients may require 500mg every 8 hours.
    - A lower dosage may be appropriate depending on such factors as pain severity, patient response, weight, or advanced age; for example, 500mg initially followed by 250mg every 8 to 12 hours.
    - For osteoporosis and rheumatoid arthritis, the suggested dosage range is 500mg to 1,000g daily in 2 divided doses. The dosage may be increased or decreased according to patient response.
    - Maintenance doses higher than 1,500mg per day are not recommended.
    - The tablets should be swallowed whole, not crushed or chewed.
    - Prescribing Information: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=725234b2-0e23-45c3-a42d-eb4e62273f9b&type=pdf
    - Coverage: Dolobid™ will be placed into the Special PA Tier of the Non-Steroidal Anti-Inflammatory Drug (NSAID) Tier chart.
    - Quantity Limit: 90 tablets per 30 days
- **ZORVOLEX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - capsules (18mg and 35mg) are not interchangeable with other formulations of oral diclofenac even if the milligram strength is the same.
- **INDOMETHACIN**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Quantity limit of 8/day
    - Indocin (indomethacin) oral suspension: Indomethacin is the treatment of choice for patients with chronic paroxysmal hemicranias (CPH). Please consider approval of indomethacin suspension for members with a CPH diagnosis if they are unable to use Tier-1 indomethacin capsules. We also cover naproxen oral suspension for members needing a liquid NSAID.
- **SPRIX**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.
- **TORADOL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Therapy should not exceed 5 days, all routes combined.
    - There is a quantity limit in place. If the client tries to fill a claim for more than 22 tablets or 5 days supply, whichever is less, the drug hits a PA requirement.
- **OSTEOPOROSIS AGENTS**
    - **BILDYOS/CONEXXENCE/BONIVA/JUBBONTI/PROLIA/STOBOCLO**

- **Interim Criteria (*if applicable*):**
- *Bildyos® (Denosumab-nxxp), Boniva® [Ibandronate Intravenous (IV) Solution], Conexxence® (Denosumab-bnht), Jubbonti™ (Denosumab-bbdz), and Prolia® (Denosumab), and Stoboclo® (Denosumab-bmwo) Approval Criteria:*

1. *A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or*
2. *Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and*
3. *For Bildyos®, Conexxance®, Jubbonti™ and Stoboclo®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **FORTEO, BONSITY**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - For a diagnosis of non-healing fracture the diagnosis must be specifically stated but can be approved without trials of bisphosphonate. This diagnosis was based on a study of Forteo, since Bonsity has not yet been designated by the FDA as therapeutically equivalent (A-rated) to Forteo, then this indication will only apply to Forteo.
  - Approval Length: 1 year; with maximum of 2 years of therapy
- **FOSAMAX**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - It is important to note that the alendronate solution has the same requirements as the tablets of sitting up for at least 30 minutes after taking it. The solution does have a smaller water requirement (2 ounces of water with the solution versus 6-8 ounces with the tablets). If someone was on fluid restriction the solution could be approved.
  - Approval Length: 1 year
- **PROLIA/BONIVA/STOBOCLO**
  - **Interim Criteria (*if applicable*):**
  - *Boniva® [Ibandronate Intravenous (IV) Solution], Jubbonti™ (Denosumab-bbdz), and Prolia® (Denosumab), and Stoboclo® (Denosumab-bmwo) Approval Criteria:*

1. *A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or*
2. *Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and*

3. *For Jubbonti™ and Stoboclo®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Prolia: Please approve for dx of cancer in patients who are receiving aromatase inhibitors for breast cancer, or men on androgen deprivation therapy for nonmetastatic prostate cancer.
    - Approval Length: 1 year
    - Coverage: Biosimilar Stoboclo® will be covered with a hard PA and placed in the Special PA Tier of the Osteoporosis Medications Tier chart
- **TYMLOS**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Approval Length: 1 year; with maximum of 2 years of parathyroid hormone analog therapy
    - Quantity Limit: 1 pen per 30 days

SPECIAL FORMULATIONS

- **VARIOUS SPECIAL FORMULATIONS**
    - **DICYCLOMINE 40MG TABLETS**
        - **Interim Criteria (*if applicable*):**
        - *Dicyclomine 40mg Tablet Approval Criteria:*
        1. *An FDA approved diagnosis; and*
        2. *A patient specific, clinically significant reason why the member cannot use the 20mg tablet to achieve the dose, which is available without a prior authorization, must be provided.*
        - **Additional Internal Notes (*for consideration toward approval*):**
    - **AVERI**
        - **Interim Criteria (*if applicable*):**
        - *Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Femlyv [Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis (drospirenone/estetrol tablet), and Slynd (drospirenone tablet) Approval Criteria:*
        1. *A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.*
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Other formulations of desogestrel-ethinyl estradiol (under GCN 68811 in ICE) have inert ingredients in their 7 off day pills whereas Averi has ferrous bisglycinate in the 7 day off tablets. There are other oral contraceptives with ferrous sulfate [i.e. Lo

Loestrin FE (GCN 29264), Microgestin FE (GCN 68101), JUNEL FE (GCN 26629)] if the member needs iron.

- **BUCAPSOL**
  - **Interim Criteria (*if applicable*):**
  - *Bucapsol™ (Buspirone Capsule) Approval Criteria:*
  1. *A patient-specific, clinically significant reason why the member cannot use buspirone tablets, even when the tablets are crushed, must be provided.*
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Buspirone tablets can be crushed and made into an oral solution. See: https://www.uspharmacist.com/article/buspirone-25-mg-ml-oral-liquidd
- **IVRA**
  - **Interim Criteria (*if applicable*):**
  - *Ivra (Melphalan 90mg/mL) Approval Criteria:*
  1. *A patient specific, clinically significant reason why the member cannot use generic melphalan 50mg/10mL vial, which is available without a prior authorization, must be provided.*
  - **Additional Internal Notes (*for consideration toward approval*):**
- **ABSORICA LS**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Clinical Exception for adult members with hidradenitis suppurativa used as a second- or third-line treatment
  - The age override edit will need to be added to the PA.
  - Per the North American Clinical Management Guidelines For Hidradenitis Suppurativa, isotretinoin should be considered only as a second- or third-line treatment or in patients with severe concomitant acne
  - Isotretinoin has B/II strength of recommendation for the treatment of hidradenitis suppurativa
  - This isotretinoin recommendation and the guidelines for the treatment of hidradenitis suppurativa can be found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9131892/
  - Please note: Absorica LD (isotretinoin) requires prior authorization and will generally not be approved for this indication. . Please ask them use other isotretinoin capsules available without a prior authorization.
- **KLOR-CON PACKET**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Potassium chloride ER tablet is a film coated tablet and must be swallowed whole. It is available in 8mEq, 10mEq, and 20mEq strengths.
  - For those who have difficulties swallowing, potassium chloride ER dispersible tablet, potassium chloride ER sprinkle capsules, potassium chloride oral solution, and potassium chloride packet for oral solution are available.
  - Potassium chloride ER dispersible tablet can be split in half or disintegrated in water. It is available in 10mEq, 15mEq, and 20mEq strengths.

    - Potassium chloride ER sprinkle capsules may be sprinkled onto a spoonful of soft food such as applesauce then swallowed immediately without chewing then followed with a glass of water. It is available in 8mEq and 10mEq strengths.
    - Potassium chloride oral solution must be diluted with 4oz of cold water before use. It is available in a 20mEq/15mL and 40mEq/15mL strength.
- **NEXTSTELLIS, SLYND**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Slynd is a progestin-only oral contraceptive.
    - Nextstellis is combination birth control that contains estetrol a new type of estrogen.
- **FEMLYV**
    - **Interim Criteria (*if applicable*):**
    - *Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:*

    1. *A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided*.

    - **Additional Internal Notes (*for consideration toward approval*):**
- **RELTONE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The current Wholesale Acquisition Cost (WAC) for Reltone is significantly more than the generic ursodiol. For example, for members taking 600mg per day ($19/200mg capsule) the cost would be $1,710.00 per 30 days compared to generic ursodiol ($1.02/300mg capsule) at $61.20 per 30 days. The use of generic ursodiol is appropriate for both indications of Reltone.
    - For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss, obesity is defined as a BMI ≥30. As a point of reference for rapid weight loss, patients in the clinical trials experienced rapid weight loss of 64 to 72 pounds in 6 months.
- **TAYTULLA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Currently all products for GCN 34576 require prior authorization, and the current Taytulla criteria will apply. Gemmily and Merzee are FDA approved generics for Taytulla, while Greenstone brand norethindrone/ethinyl estradiol/ferrous fumarate (NDC 59762159905) was FDA approved as new drug and is listed as a brand medication.
    - GCN 11481 contains all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate that do not require a PA.
- **<u>ORAL ANTIBIOTIC SPECIAL FORMULATIONS</u>**
    - **Interim Criteria (*if applicable*):**

- *Oral Antibiotic Special Formulation Approval Criteria:*

1. *Member must have a patient-specific, clinically significant reason why the immediate release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used*
2. *The following oral antibiotic currently require prior authorization and the special formulation approval criteria will apply:*
    - *Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR)*
    - *Cephalexin 250mg and 500mg tablets I*
    - *Cephalexin 750mg capsules*
    - *Doxycycline hyclate 75mg and 150mg tablets (Acticlate)*
    - *Doxycycline hyclate 50mg (Targadox)*
    - *Doxycycline hyclate delayed-release (DR) tablets (Doryx, Doryx MPC)*
    - *Doxycycline monohydrate 150mg capsules and tablets*
    - *Doxycycline monohydrate DR 40mg capsules (Oracea)*
    - *Metronidazole 125mg tablets*
    - *Minocycline ER capsules (Ximino)*
    - *Minocycline ER tablets (Minolira)*
    - *Minocycline ER tablets (Solodyn)*
    - *Nitrofurantoin 50mg/5mL suspension*

- **Additional Internal Notes (*for consideration toward approval*):**
- **Metronidazole 125mg tablets**: Use dosing regimens that utilize 250mg or 500mg tablets (no PA required) unless clinically indicated dose cannot be achieved with the 250mg and 500mg tablets; these tablets are not scored and some are film-coated; therefore, there is not enough support for splitting or crushing.

- **<u>CORTICOSTEROID SPECIAL FORMULATIONS</u>**
    - **KHINDIVI**
        - **Interim Criteria (*if applicable*):**
        - *Khindivi® (Hydrocortisone Oral Solution) Approval Criteria:*

        1. *An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and*
        2. *A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when the tablets are crushed, must be provided.*

        - **Additional Internal Notes (*for consideration toward approval*):**
    - **ORAPRED ODT**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - This may be a good option if they have trouble taking the preferred generic prednisolone liquid due to taste.
    - **VERIPRED, MILLIPRED**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**

- Veripred and Millipred generics are grape flavored and alcohol free. The main difference between Veripred and Millipred versus the preferred products is the strength.
- Generic prednisolone 25mg/mL (GCN: 93945) does not require a prior authorization and may be an option for those who require a small volume as it is the highest strength available.
- See below in the table for a list of prednisolone solution GCNs that are alcohol free and do not require a PA.

GCN	93945	33806	911504
Strength	25mg/5ml	15mg/5ml	5mg/5ml
Flavor	Grape flavored	Grape flavored	Raspberry flavored

- Improving palatability and administration of Prednisolone Oral Solution:
- Prednisolone oral solution (25mg/5mL, 15mg/ml, and 5mg/ml) is currently available without prior authorization and is the preferred alternative for Millipred® (10mg/5ml) and Veripred 20® (20mg/5ml). The preparations available have been noted to have an extremely bitter taste leading to poor patient compliance, particularly when given to pediatric patients.
- Several additives have been shown to improve taste and compliance when combined with prednisolone oral solution in a 50/50 (v/v) dilution. These are, in order, from most to least effective:
    - Chocolate syrup
    - Honey (if age appropriate)
    - Simple syrup
    - Orange juice liquid concentrate
    - Fruit punch liquid concentrate
- Changes in administration techniques have also been shown to improve the palatability of prednisolone:
    - Use popsicle/ice to temporarily numb the mouth prior to administration
    - Use an oral syringe to administer dose to far back and side of mouth
    - Combine prednisolone dose with 1 cup lemon-lime carbonated beverage or 1 cup chocolate milk
    - Immediately follow dosing with 1 tsp powdered sugar + 1 tsp water mixture
- Prescribers may also consider other glucocorticoid solid-dosage- form preparations wrapped in fruit leather or similar product. Additionally, children age 5-12 show a demonstrated taste preference for dexamethasone over prednisolone.
- Many pharmacies offer flavoring options to their patients. While this service is not a covered benefit for SoonerCare patients, they may consider it as an option. Flavors demonstrated to effectively mask prednisolone bitterness include: chocolate, apple, bubble gum, grape, and raspberry.

    - If these recommendations do not meet the needs of the member, a prescriber may choose to submit a prior authorization for consideration, including patient-specific, clinically significant supporting information for use of the requested medication.
- **ZILRETTA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Medical Only
    - Zilretta has been shown to cause less of an increase in blood sugar compared to Kenalog; however, please don't approve Zilretta for a member with diabetes without a previous trial of Kenalog or Depo-Medrol. If they have tried one and they noted the member had elevated blood sugars, we can consider it at that point.
- **IMKELDI**
    - **Interim Criteria (*if applicable*):**
    - *Imkeldi (Imatinib Oral Solution) Approval Criteria:*
    1. *An FDA approved diagnosis; and*
    2. *A patient-specific, clinically significant reason why the member cannot use imatinib tablets, which are available without a prior authorization, must be provided. Imatinib tablets may be dispersed in a glass of water or apple juice to form a suspension for members who cannot swallow the film-coated tablets.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Imkeldi (imatinib oral solution) is a kinase inhibitor that is a new formulation of imatinib. It is FDA approved for the same indications as Gleevec® (imatinib tablet). Generic imatinib 100mg and 400mg tablets are available without a prior authorization and may be dispersed in a glass of water or apple juice to form a suspension prior to administration for patients who are unable to swallow the film-coated tablets whole.
    - How Supplied: 80mg/mL strawberry flavored oral solution in a 140mL bottle
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219097s000lbl.pdf
    - Coverage: Imkeldi will be covered with a hard PA with the criteria listed above.

TOPICAL

- **LIDOCAINE TOPICAL AGENTS**
    - **LIDODERM PATCH**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Do not approve requests for injection site pain. SoonerCare does cover lidocaine 2.5%/prilocaine 2.5% cream without a prior authorization. There is a quantity limit applied to the cream. It is based on the tube size. One 30 gm tube for 30 days or a 5-gram tube for 30 days.
- **TOPICAL ANTIFUNGAL AGENTS**
    - **Updated Tier Chart 10/03/25**

Topical Antifungal Products		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	**econazole nitrate 1% topical foam**
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Loprox®, Penlac®)	efinaconazole (Jublia®)
clotrimazole (OTC)* cream	clotrimazole 1% solution	tavaborole (Kerydin®)
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole nitrate 1% cream	ketoconazole foam (Extina®)	
ketoconazole cream, shampoo	ketoconazole gel (Xolegel®)	
nystatin cream, ointment, powder	luliconazole cream (Luzu®)	
terbinafine (OTC)* cream	miconazole/zinc oxide/white petrolatum (Vusion®)	
tolnaftate (OTC)* cream	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

- **ECONAZOLE NITRATE 1% TOPICAL FOAM**
    - **Interim Criteria (*if applicable*):**
    - *Econazole 1% Topical Foam Approval Criteria:*

1. *An FDA approved diagnosis of interdigital tinea pedis caused by Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosumin; and*
2. *Member must be 12 years of age and older; and*
3. *A patient specific, clinically significant reason why the member requires a special dosage form and cannot use econazole nitrate 1% cream, which is available without prior authorization, must be provided; and*
4. *A patient specific, clinically significant reason why the member cannot use all other cost-effective therapeutic alternative medications in Tier 1 appropriate for the diagnosis must be provided; and*
5. *A quantity limit of 70 grams per 28 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **TOPICAL CORTICOSTEROIDS**
    - **DESOXIMETASONE, CLOCORTOLONE PIVALATE**
        - **Interim Criteria (*if applicable*): n/a**
        - **Additional Internal Notes (*for consideration toward approval*):**
        - Please consider approval of desoximetasone or clocortolone pivalate if the prescriber is a dermatologist/allergy specialist, indicates the member has an allergy to topical steroids, and member has >1 topical corticosteroid paid claims in claims history.
        - Links for reference: https://www.jaad.org/article/S0190-9622(05)04955- 8/fulltext https://www.mdedge.com/dermatology/article/11229/pediatrics/sdef-contact-allergy-corticosteroid-stealth-allergy
- **MOLLUSCUM CONTAGIOSUM AGENTS**
    - **YCANTH**
        - **Interim Criteria (*if applicable*):**

- *Ycanth™ (Cantharidin 0.7% Solution) Approval Criteria:*

1. *An FDA approved indication for the treatment of molluscum contagiosum lesions; and*
2. *Member must be 2 years of age or older; and*
3. *Member must meet 1 of the following:*
    - *Is immunocompromised; or*
    - *Is experiencing itching or pain; or*
    - *Has concomitant bacterial infection; or*
    - *Has concomitant atopic dermatitis; or*
    - *There is concern for contagion (e.g., siblings, daycare) and the spread of lesions cannot be reasonably prevented using good hygiene or covered using a bandage; and*
4. *Prescriber must attest that it has been at least 6 months since the onset of the current infection unless the member is experiencing severe symptoms; and*
5. *Member must have a trial of at least 1 of the following procedures or medications for the removal of molluscum contagiosum lesions in the last 6 months:*
    - *Cryotherapy; or*
    - *Curettage; or*
    - *Laser therapy; or*
    - *Cimetidine; or*
    - *Potassium hydroxide; or*
    - *Salicylic acid; and*
6. *Member must not have lesions exclusively on genitals or around eyes; and*
7. *Ycanth™ must be dispensed to and administered by a health care professional (HCP) trained in the administration of Ycanth™. Approvals will not be granted for self-administration. Requests must indicate who will administer Ycanth™ and in what setting; and*
8. *Prescriber must attest that the member or caregiver has been counseled to wash off lesions treated with Ycanth™ with soap and water 24 hours after application and to avoid skin contact with water, including bathing, prior to the 24-hour mark; and*
9. *Prescriber must attest that the member or caregiver has been counseled on all precautions prior to and during treatment with Ycanth™ that are listed in the package labeling, including avoiding contact with the eyes and mouth and avoiding close contact with open flames, even after the medication has dried; and*
10. *Approvals will be for a maximum of 12 weeks of therapy; and*
11. *A quantity limit of 2 applicators every 3 weeks for a maximum of 4 applications will apply; and*
12. *Reauthorization is not permitted. A new prior authorization request must be submitted, and the member must meet all initial approval criteria for each molluscum contagiosum infection.*

- **Additional Internal Notes (*for consideration toward approval*):**
- OHCA has added pharmacy coverage for Ycanth® (only for NDC 71349-0070-11) with a quantity limit of 2 applicators per 21 days. Ycanth® should only be administered by a trained health care professional and should not be dispensed to a

member. The criteria is being updated to ensure that the medication is dispensed to a health care provider.

- **<u>ACTINIC KERATOSIS AGENTS</u>**
  - **ZYCLARA**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - There is currently a generic 5% imiquimod cream (generic Aldara) available without prior authorization that has the same indications plus superficial basal cell carcinoma.
    - Zyclara (imiquimod) 2.5% and 3.75% cream is indicated for the treatment of actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults. The 3.75% cream is also indicated for the topical treatment of external genital and perianal warts/condyloma acuminate (EGW) in patients 12 years and older. Efficacy of imiquimod cream was not demonstrated for molluscum contagiosum in children 2 to 12 years of age.
- **<u>TOPICAL ACNE, PSORIASIS, ROSACEA AGENTS</u>**
  - **GENERAL INFORMATION**
    - Medications for rosacea and acne (including oral antibiotics) are only covered for members 0-20 years of age. Use of these medications in adults (21 years of age or older) for acne or rosacea are considered a "cosmetic use" and are a coverage exclusion. OHCA coverage exclusions: 317:30-5-72.1. Drug benefit (oklahoma.gov).
    - We do not cover OTC or prescription acne medications containing benzoyl peroxide.
    - Retin-A (tretinoin): No tretinoin topical medications are covered for any age unless reviewed under the EPSDT Policy
      - Even with EPSDT review, only 3 NDCs of tretinoin are currently coverable & reflected with age limits on the PDL (51672139409, 51672140709, 51672140700)
  - **ACZONE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - The 7.5% strength has a minimum age of 9 years and the 5% does not have a minimum age. Both products are only covered in patients 20 years of age or younger.
  - **CLINDACIN ETZ KIT**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - NDC for the Clindacin ETZ kit is 43538017360. Clindacin swabs (CGN 45411) and Cleocin T generics (GCN 45410) do not require a PA. Only covered for pediatric members (only FDA approved for acne).
  - **CLINDAGEL, EVOCLIN**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Topical clindamycin clinical exception for members with hidradenitis suppurativa (L73.2), including adult members with this diagnosis:

    - Preferred formulations of topical clindamycin (e.g., lotion, solution, swabs, and generic Cleocin T gel) can be approved for a diagnosis of HS.
    - The NDC v. age override edit will need to be added to the PA.
    - HS guidelines recommend topical clindamycin as a treatment option, but other topical antibiotics are not mentioned https://www.jaad.org/article/S0190-9622(19)30368-8/fulltext
    - Non-preferred formulations of topical clindamycin (e.g., Clindacin ETZ Kit, Clindagel, Evoclin) should not be approved off-label for HS.
    - Only covered for pediatric members (only FDA approved for acne)
    - Clindagel generics (GCN 20176) require PA, but Cleocin T generics (GCN 45410) do not
- **DUOBRII**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please note: Tazarotene and some TCS may require PA
    - Per the prescribing information, the maximum total dosage should not exceed approximately 50g per week because of the potential for the drug to suppress the HPA axis; please keep this in mind if reviewing a QLO request.
- **METROGEL**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Metronidazole 0.75% cream, gel, and lotion also have an age restriction (only covered for ages 0-20 years): used for rosacea.
    - Metronidazole 0.75% vaginal gel (GCN 49261) does not require a PA and does not have an age restriction.
    - GCN's requiring prior authorization: 24926 & 31774 (MetroGel 1%) and 43204 (Noritate 1%); GCN's available without prior authorization for members 0 to 20 years of age: 43201, 43202, & 43203 (generic metronidazole 0.75% cream, gel, and lotion)
- **NORITATE**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Metronidazole 0.75% cream, gel, and lotion also have an age restriction (only covered for ages 0-20 years): used for rosacea.
    - Metronidazole 0.75% vaginal gel (GCN 49261) does not require a PA and does not have an age restriction.
    - GCN's requiring prior authorization: 24926 & 31774 (MetroGel 1%) and 43204 (Noritate 1%); GCN's available without prior authorization for members 0 to 20 years of age: 43201, 43202, & 43203 (generic metronidazole 0.75% cream, gel, and lotion)
- **TAZORAC**
    - **Interim Criteria (*if applicable*):**
    - *Tazorac® (Tazarotene Cream and Gel) Approval Criteria:*

1. *An FDA approved diagnosis of acne vulgaris or plaque psoriasis; and*
2. *Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and*

3. *For the diagnosis of acne vulgaris, the following must be met:*
    - *Member must be 20 years of age or younger; and*
    - *Tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and*
4. *Tazarotene 0.05% cream, 0.05% gel, and tazarotene 0.1% gel will require a patient specific, clinically significant reason why the member cannot use tazarotene 0.1% cream, which is available without prior authorization for members 20 years of age and younger; and*
5. *A quantity limit of 100 grams per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**
- As of 5/12/25 Tazarotene 0.05% cream (generic Tazorac®) will require a PA. Members currently utilizing tazarotene 0.05% cream will need to switch to tazarotene 0.1% cream or a PA request will need to be submitted with patient-specific information.

- **VTAMA**
    - **Interim Criteria (*if applicable*):**
    - *Vtama® (Tapinarof) Approval Criteria [Atopic Dermatitis Diagnosis]:*

1. *An FDA approved diagnosis of atopic dermatitis; and*
2. *Member must be 2 years of age or older; and*
3. *Must be prescribed by or in consultation with a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and*
4. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):*
    - *1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and*
    - *1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and*
    - *Eucrisa® (crisaborole); and*
5. *Initial approvals will be for the duration of 2 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and*
6. *A quantity limit of 60 grams per 30 days will apply.*

- **Additional Internal Notes (*for consideration toward approval*):**

- **WINLEVI**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Approval may be considered without a trial of oral isotretinoin if the prescriber documents oral isotretinoin is not appropriate for the member due to the contraindications and warnings associated with the medication or provides a patient-specific clinically, significant reason oral isotretinoin is not appropriate for the member. Additional information can be found online at https://ipledgeprogram.com/#Main or https://www.aad.org/public/diseases/acne/derm-treat/isotretinoin/safety.
    - Please note: For approval consideration, the member must still meet all other criteria specific to the medication being requested.

- **ZILXI**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Approval may be considered without a trial of oral isotretinoin if the prescriber documents oral isotretinoin is not appropriate for the member due to the contraindications and warnings associated with the medication or provides a patient-specific clinically, significant reason oral isotretinoin is not appropriate for the member.
    - Please note: For approval consideration, the member must still meet all other criteria specific to the medication being requested.
    - Additional information can be found online at:
    - https://ipledgeprogram.com/#Main
    - https://www.aad.org/public/diseases/acne/derm-treat/isotretinoin/safety.
- **ZORYVE**
    - **Interim Criteria (*if applicable*):**
    - *Zoryve® (Roflumilast 0.15% or 0.05% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:*

    1. *An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and*
    2. *Requested product must be FDA approved for the member's age; and*
        - *0.15% Cream: Member must be 6 years of age or older; or*
        - *0.05% Cream: Member must be 2 to 5 years of age; and*
    3. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):*
        - *1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and*
        - *1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and*
        - *Eucrisa® (crisaborole); and*
    4. *Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and*
    5. *A quantity limit of 60 grams per 30 days will apply.*
- **ELIDEL, PROTOPIC**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Please consider approval of Elidel/Protopic for the following off-label uses when appropriate. The approval criteria for Dupixent, Opzelura, and Zoryve foam for these indications requests a trial of a topical calcineurin inhibitor before approval of these medications.
        - Nonsegmental vitiligo (only in members younger than 21 years of age)
        - Prurigo nodularis
        - Seborrheic dermatitis
    - Approval Length: Once each 90-day period

        - Please note, the first 90 days does require a PA review in our system due to the need to enforce the diagnosis, quantity limit, and one approval per 90 days. These limitations are not otherwise coded into the state PDL.
    - Quantity Limit: 30 grams for use on the face, neck, and groin, and 100 grams for all other areas
- **OPZELURA**
    - **Interim Criteria (*if applicable*):**
    - *Opzelura® (Ruxolitinib 1.5% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:*

1. *An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and*
2. *Member must be 2 years of age or older; and*
3. *Member must not be immunocompromised; and*
4. *Member must have a body surface area (BSA) involvement ≤20%; and*
5. *Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):*
    - *1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and*
    - *1 topical calcineurin inhibitor (TCI) [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]; and*
    - *Eucrisa (crisaborole); and*
6. *Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and*
7. *Prescriber must verify female members are not breastfeeding; and*
8. *If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura pregnancy registry; and*
9. *Approvals will be for a maximum duration of 8 weeks of treatment; and*
10. *Reauthorization may be considered if member has a recent TCS, TCI, or Eucrisa trial (or a contraindication or documented intolerance); and*
    - *Additionally, the prescriber must document the member had a positive response to and tolerated previous treatment with Opzelura; and*
11. *Subsequent approvals will only be considered once each 90-day period to ensure appropriate short-term and non-continuous utilization.*

    - **Additional Internal Notes (*for consideration toward approval*):**
- **PRUDOXIN, ZONALON**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Approval Length: up to 8 days
    - Quantity Limit: 1 tube
- **<u>PEDIULICIDE AGENTS</u>**
    - **GENERAL INFORMATION**
        - Need for re-treatment:

Sklice	No
Natroba	Only if live lice are seen 7 days after the first treatment
Lindane	No
Ovide	Only if live lice are present 7-9 days after the first treatment

- **OVIDE**
  - **Interim Criteria (if applicable): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Ovide*: Recommendations published by the Pediatrics, states it may be an option for kids 2 years or older if resistent to first line agents. The article is: http://pediatrics.aappublications.org/cgi/content/full/126/2/392
- **EURAX, CROTAN**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - For scabies, permethrin 5% is currently first line. The only other medications indicated for scabies are Lindane and crotamiton. We cannot require tier-2 trials for this diagnosis.
- **QUTENZA**
  - **Interim Criteria (*if applicable*): n/a**
  - **Additional Internal Notes (*for consideration toward approval*):**
  - Medical Only
  - Qutenza is applied by a physician, or other health care professional under close physician supervision. For PHN the patch is left in place for 60 minutes. For DPN, the patch is left in place for 30 minutes. Up to 4 patches may be used per treatment and may be repeated after 3 months. A topical anesthetic should be applied to the area prior to placing the Qutenza patch. Cleansing gel is included with the patch to clear any residue once the patch has been removed.
  - Quantity Limit: No more than 4 patches per treatment every 90 days

- **TOPICAL ANTIBIOTIC AGENTS**
  - **GENERAL INFORMATION**
    - Branded medications will require a Brand Name Override when generic versions are available.
  - **BACTROBAN NASAL OINTMENT 2%**
    - **Interim Criteria (*if applicable*): n/a**
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Bactroban® Nasal Ointment 2%: Should use the tier-1 ointment unless they have a really good reason for the nasal
- **HEMORRHOID AGENTS**
  - **CORTIFOAM**

- **Interim Criteria (*if applicable*):**
- *A patient-specific, clinically significant reason why the member cannot use other strengths and formulations of hydrocortisone.*
- **Additional Internal Notes (*for consideration toward approval*):**

- **MICORT**
  - **Interim Criteria (*if applicable*):**
  - *A patient-specific, clinically significant reason why the member cannot use Proctosol-HC (hydrocortisone 2.5% cream).*
  - **Additional Internal Notes (*for consideration toward approval*):**

- **PRIMARY HYPERHIDROSIS AGENTS**
  - **SOFDRA**
    - **Interim Criteria (*if applicable*):**
    - *Sofdra™ (Sofpironium 12.45% Topical Gel) Approval Criteria:*
    1. *An FDA approved diagnosis of primary axillary hyperhidrosis in pediatric patients 9 years of age to 20 years of age; and*
    2. *Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and*
    3. *Member must have failed a trial, at least 3 weeks in duration, of 1 of the following:*
       - *Xerac® AC (aluminum chloride hexahydrate 6.25% topical solution); or*
       - *At least 1 over-the-counter Certain Dri® product; and*
    4. *Member must have failed a trial of Drysol® (aluminum chloride 20% topical solution), at least 3 weeks in duration; and*
    5. *Prescriber must verify that the member has received counseling on the safe and proper use of Sofdra™; and*
    6. *A quantity limit of 40.2mL per 30 days will apply.*
    - **Additional Internal Notes (*for consideration toward approval):***
    - Sofdra™ (sofpironium 12.45% topical gel) is a topical anticholinergic indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age or older.
    - How Supplied: 50mL bottle with multi-dose metered pump, applicator, and cap; each bottle is capable of dispensing 60 pump actuations of 0.67mL per actuation
    - Dosing: A single pump actuation should be applied to clean, dry skin under each arm once daily at bedtime. Showering should not occur 30 minutes before and 8 hours after application. Armpits should not be shaved at least 8 hours before applying Sofdra™.
    - Prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217347s000lbl.pdf
    - Coverage: Sofdra™ will be covered with a hard PA and placed with Qbrexza® in a new category called "Primary Hyperhidrosis Medications" with the criteria listed below. However, please note that Qbrexza® is not covered by SoonerCare at this time due to no federal drug rebate agreement.
      - Quantity Limit: 40.2mL per 30 days

OTHER

- **COMPOUND MEDICATIONS**
    - Compound claims >$75 require prior authorization for members older than 20 years of age based on medical necessity. Be sure that if you are reviewing claims for a compound that you don't just look at the main screen to see if it paid. You need to click the claim to open it, because it may have just been a diluent or an excipient that paid and not the actual drug product.
    - A few reminders about compound requests:
    - We have to let them submit PA's for these compounds but they must submit clinical documentation that supports the product as a compound.
    - We should be strict about medical necessity. They must have legitimate documentation.
    - There may be some biologic medications (example: hemophilia, chemotherapy) that they are running as a compound to use multiple different vial sizes without using up all their punches. For the most part, they should run these as regular claims and not as compounds since they are not technically compounding anything, however we have been told to approve hemophilia medications and chemotherapy if they want to run it this way. For other medications where they may use up all their punches and need to run it as a compound claim due to multiple vial sizes we can consider approval.
- **HIGH-INVESTMENT DRUG THERAPY CARVE OUT**
    - OHCA pays inpatient hospital claims on a DRG global payment; however, for extremely expensive therapies, the DRG payment does not come close to covering the cost of the therapies. Please see below for a list of the drugs (including HCPCS codes) which will be "carved out" of the DRG hospital payments. This list and a copy of the letter have been posted to the pharmacy page on OHCA's website https://oklahoma.gov/ohca/providers/types/pharmacy/pharmacy.html under "High Investment Drug Carve Out List".
        - Abecma (idecabtagene vicleucel) – Q2055
        - Beqvez (fidanacogene elaparvovec-dzkt) – HCPCS Pending
        - Breyanzi (lisocabtagene maraleucel) – Q2054
        - Carvykti (ciltacabtagene autoleucel) – Q2056
        - Casgevy (exagamglogene autotemcel) – HCPCS Pending
        - Elevidys (delandistrogene moxeparvovec-rokl) – J1413
        - Hemgenix (etranacogene dezaparvovec-drlb) – J1411
        - Kymriah (tisagenlecleucel) – Q2042
        - Lenmeldy (atidarsagene autotemcel) – HCPCS Pending
        - Luxturna (voretigene neparvovec-rzyl) – J3398
        - Lyfgenia (lovotibeglogene autotemcel) – J3394
        - Omisirge (omidubicel-onlv) – HCPCS Pending
        - Roctavian (valoctocogene roxaparvovec-rvox) – J1412
        - Skysona (elivaldogene autotemcel) – HCPCS Pending
        - Spinraza (nusinersen) – J2326

        - Tecartus (brexucabtagene autoleucel) – Q2053
        - Tecelra (afamitresgene autoleucel) – HCPCS Pending
        - Yescarta (axicabtagene ciloleucel) – Q2041
        - Zolgensma (onasemnogene abeparvovec-xioi) – J3399
        - Zynteglo (betibeglogene autotemcel) – J3393
    - Please note: For medications included on this list, OHCA will allow a PA to be issued using a miscellaneous HCPCS code (i.e., J3590) if a permanent HCPCS code has not yet been assigned and all approval criteria are met. These have been identified as "HCPCS Pending" in the list above, but please verify if a permanent HCPCS code exists if you receive a request using a miscellaneous code for any of these medications.
    - These PA requests should be processed like any outpatient hospital/physician administered drug PA.
- **PRENATAL VITAMINS**
    - Preferred Prenatal Vitamins - please refer to OHCA website for list of preferred prenatal vitamins:
        - https://oklahoma.gov/ohca/providers/types/pharmacy/pharmacy.html
    - No charge or copay for preferred prenatal vitamins.
    - Prenatal vitamins do not count against monthly prescription limit.
    - Preferred medications will not require prior authorization. Medications that are not listed are non-preferred and will require prior authorization.
        - PA requests for non-preferred products must include clinical rationale for why the preferred product(s) are inappropriate and member's pharmacy claims history must show trial of at least 2 preferred products.
    - Prescriptions for preferred medications may be written as "prenatal vitamins with folic acid 1mg", and other desired ingredients can be specified if necessary, such as "plus DHA".
- **VITAMIN D2 (ERGOCALCIFEROL)**
    - **Interim Criteria (*if applicable*):**
    - *Vitamin D2 (ergocalciferol) Supplement Approval Criteria:*
    1. *Diagnosis of End Stage Renal Disease (ESRD); or*
    2. *For those without ESRD, prior authorization will only be approved when medically necessary for children younger than 21 years of age.*
    - **Additional Internal Notes (*for consideration toward approval*):**
    - Must have clinically significant reason for medication, breast fed alone for infants is not adequate.
    - Coverage for vitamin D2 will be very limited—it will not be approved for regular vitamin D deficiency. (Uptodate recommends treating pediatric patients if the level is under 20ng/mL or rickets and then treat kids with levels between 20 and 30 if there are important risk factors or other signs of vitamin D deficiency.)
    - For those without ESRD, PAs will only be approved when medically necessary for children under age 21. The initial PA request for vitamin D2 for adults should be denied if it's submitted with a diagnosis of vitamin D deficiency and the member does not have a diagnosis of ESRD in their diagnosis summary. If the member does not have ESRD in their diagnosis summary, we should make the decision on the initial PA request to deny.