POLICY AND PROCEDURE

POLICY NAME: Precision Drug Action Committee	**POLICY ID:** CC.PHAR.21
BUSINESS UNIT: Please refer to system of record – Archer	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 09/19	**PRODUCT(S):** Commercial, Federal Services – Non-TRICARE, Marketplace (On Exchange and Off Exchange), Medicaid, Medicare
REVIEWED/REVISED DATE: 9/25	
REGULATOR MOST RECENT APPROVAL DATE(S):	

PURPOSE:
The purpose of the Centene Precision Drug Action Committee (PDAC) is to define comprehensive Centene best practices around the utilization management, financial management, and distribution processes that are unique to PDs. PDs fall outside conventional specialty pharmacy distribution and provider buy-and-bill channels and contracting for PDs and administrative services represent a significant financial risk to Centene health plans due to their high cost. Each PD is expected to have limitations on its distribution channel from manufacturer to member and may require multiple contracts between Centene and the drug manufacturer, Centene and a specialty pharmacy, and Centene and the treating provider. Reimbursement for PDs and associated administrative costs often fall outside of standard hospital inpatient contracts or outpatient contracts and may require specialized contracts and single case agreements.

SCOPE:
Centene Corporation, Centene Affiliate Health Plans, & Pharmacy Services (CPS) will support the management of Precisions Drugs (PD) through the integration of clinical, operational, financial, logistical, contractual, and economical evaluations. The Committee will define best practices to ensure a Centene standard for medical necessity, procurement, and monitoring for members and providers involved in the administration of these PD. Where Marketplace is indicated as a Product applicable to this policy, this includes both On Exchange and Off Exchange plans.

DEFINITIONS: N/A

PROCEDURE:

MEMBERSHIP & ORGANIZATION
Committee members will be composed of cross-functional business leaders from Centene and affiliate companies. A quorum shall consist of at least 51% of committee members or their designee (including the Chairperson or designee); a quorum is required to transact business and make decisions. Committee members will identify a designee to attend meetings in their absence. Other subject matter experts may be invited to Committee meetings as non-voting guests on an ad hoc basis for additional advice and input.

1. Committee Co-Chairs: Centene Medical Affairs Senior Medical Director and Centene Pharmacy Services Drug Information Manager Formulary Development
2. Committee Secretary: Centene Pharmacy Services Drug Information Director of Pharmacy Operations
3. Other Committee Members:
    a. Centene Pharmacy Services, Drug Information, Director
    b. Centene, Actuarial Services, VP Product
    c. Centene, Health Policy, Senior Manager, Health Policy
    d. Centene, Government Relations, Senior Director
    e. Centene, Public Policy, Staff Vice President
    f. Centene, Medical Affairs, Senior Director, Clinical & Payment Policy
    g. Centene, Medical Affairs, Senior Medical Director
    h. Centene, Medical Affairs, Supervisory Medical Director
    i. Centene, Medical Affairs, VP, Medical Director
    j. Centene, National Contracting Staff VP, Network Strategy and Development
    k. Centene Pharmacy Services, Contract Management, Director
    l. Centene Pharmacy Services, Contract Management, Director
    m. Centene Pharmacy Services, Data Analytics & Reporting, Director Clinical Pharmacy Services
    n. Centene Pharmacy Services, Key Accounts & Vendor Management, Director
    o. Centene Pharmacy Services, Referral & Authorization, Senior Director, Pharmacy Operations
    p. Centene Pharmacy Services, VP Regional Pharmacy
    q. Centene Pharmacy Services, VP, Pharmacy Clinical Operations

r. Centene Pharmacy Services, Director, MED-Pharmacy, Fidelis Market
s. Centene Pharmacy Services, Senior Director, Clinical Pharmacy Services

4. Other subject matter experts may be invited to Committee meetings as non-voting guests on an ad hoc basis for additional advice and input and can include:
   a. Medical Directors aside from those listed as voting members;
   b. Pharmacy Market leadership;
   c. Strategy Development Committee leadership;
   d. CPS Fraud Waste and Abuse leadership;
   e. Drug Utilization Review and Oversight Committee leadership;
   f. CPS Trade leadership;
   g. CPS Pharmacy Program leadership;
   h. Actuarial Services aside from those listed as voting members;
   i. Drug Information aside from those listed as voting members.

EXPECTATIONS

PDAC will carry out its purpose and perform its duties in the following cross-functional areas:

1. **Ensure that all Centene Health Plans, pharmacy departments, and/or utilization management teams report cases of PD utilization to the PDAC for tracking across Centene.**
2. **The Pipeline Committee will identify and communicate the potential PDAC drugs based on the following criteria:**
   a. The PDs covered under pharmacy and medical benefits that warrant additional cross-functional oversight and management by PDAC. PDs which fit into PDAC oversight may include, but are not limited to:
      i. Drugs & biologicals with mechanisms of action that involve cell therapy and gene therapy:
      ii. Drugs associated with unique contracting, access, actuarial, and clinical outcomes tracking challenges:
      iii. PDAC drugs are typically ultra-high cost and may have single dose administration:
      iv. Other medications defined by PDAC.
   b. The list of drugs in the PDAC scope are in this Charter's Appendix A.
3. **Data Analytics, Monitoring, & Reporting**
   a. Determine which PDs are likely to be managed with outcomes-based agreements or other unique contracting arrangements, whether with drug manufacturers or specialty drug providers.
   b. Determine need to track outcomes of individual members and aggregated data for members receiving selected PDs, to leverage for potential outcomes-based agreements or other unique contracting arrangements.
4. **Utilization Management**
   a. PDAC will monitor clinical policy creation from the Centene Pharmacy & Therapeutics Committee (P&T), and formulary management decisions from the Pharmacy Services Strategic Development Committee (SDC) as it relates to PDAC's purpose and responsibility for the management of PDs.
   b. The Health Plan or Centene Pharmacy Services will make all final determinations, after reviewing PDAC recommendations and report the decision back to the PDAC team for tracking.
   c. PDAC will advise Centene on future Utilization Management operations and best practices.
5. **Provider Contracting & Procurement**
   a. PDAC will pair clinical expertise with the Centene National Network Development & Contracting team to address specific challenges in the market related to the distribution, acquisition, and pricing of PDs.
   b. Efforts on contracting support shall:
      i. Assure fair and best prices are achieved across all Centene health Plans on PDs:
      ii. Use Centene's national membership footprint to negotiate single contracts with providers, pharmaceutical manufacturers, and pharmacies for PDs covered outside of standard pharmacy and specialty pharmacy contracts and traditional pharmaceutical manufacturer rebates agreements, whether under the medical benefit (buy & bill) or pharmacy benefit, as allowed by benefit plan contract:
      iii. Provide centralized support to health plan network contracting teams with contract language, terms, and conditions as needed for Outcomes Based Agreements (OBAs), Letters of Agreement (LOAs), and Single Case Agreements (SCAs) around PD, as allowed by benefit plan contract:
      iv. Collect and store health plan and Centene corporate contracts to develop best practices for market negotiations.
6. **Rate Setting, Reinsurance Contracts, & Outcomes Based Agreements**
   a. Support Centene Health Plans for negotiations with state Medicaid agencies for drug carve-out opportunities and other payment risk arrangements in the markets.
   b. Maintain a current list of states with high-cost drug carve-out or other exceptions resulting in state payment coverage of PDs in lieu of Health Plan liability for the drug's payment.

7. **Public Policy**
   PDAC will collaborate with Centene Government Affairs to comment on rules and regulations, either directly from Centene or through other payer forums, to shape policy as the industry experiences a rapid growth in PDs.
8. **Documentation**
   Maintain the Precision Drug Resource SharePoint Site for PDAC resources, including the following: https://cnet.centene.com/sites/HighCostDrugResource/SitePages/Home.aspx)
   a. Links to the Clinical pharmacy policies
   b. Discussion chat forum for Centene internal stakeholder questions & blog
   c. Single case agreement examples, templates, and best practices
   d. States and LOBs with carve-outs or other exceptions
   e. Reinsurance contracts
   f. Process and best practice documentation
   g. Pipeline reports
   h. Reports
   i. Useful links & documents
9. **Communication**
   Communication of PDAC resources & responsibilities with Centene, Health Plans, and Pharmacy Services leadership teams on activities, opportunities, and process as needed to remain aligned to standard operations.

MEETINGS

PDAC meetings will occur monthly or on an ad hoc basis.

1. **Committee Agenda**
   Agenda will be distributed to committee membership approximately two business days prior to each meeting.
   a. Committee Chairperson will develop the meeting agenda with assistance from the secretary.
   b. Sources for agenda topics will come from:
      i. Pipeline Reporting & Tracking. Pharmacy Services drug Pipeline Committee, which tracks the drug development pipeline and develops prediction of potential and probable spend and utilization of high-cost drug therapy within Centene:
      ii. Utilization Management Updates:
      iii. Clinical Policy Updates:
      iv. Data Analysis. Data analysis and trend reporting from Pharmacy Services, Centene Corporate, or Health Plan markets conducted on a regular schedule, such as monthly, quarterly, or annually:
      v. Health Plan Financial Performance Reviews. Discussions surrounding high-cost drug therapies that originate from review of Health Plan financial performance:
      vi. Pipeline Market Intelligence. Market-based new releases, reports, publications, and information pertaining to the coverage rules, payment policy, distribution channels, current/future implications of the utilization and costs of high-cost drug therapies and their impact on Centene:
      vii. Government Rules & Regulations. Change in coverage rules or payment policies made within Centers for Medicare & Medicaid Services (CMS), state Medicaid or state insurance agencies, or any governing body with authority or who is party to a contract with a Centene health plan:
      viii. Committee Members. Any committee member may request a topic be added based on their expertise.
2. **Committee Minutes**
   Minutes from the previous meeting will be prepared within 5 calendar days of the meeting and distributed before the next meeting. Minutes shall include agenda topics, key discussion points, recommendations, applicable vote results, and action items.
   a. Action items from meetings will be maintained on an action item list, managed by the Committee Chairperson and secretary.

REVIEW OF CHARTER

PDAC will review this charter annually from the date of original approval or revision date, whichever is more current.

REFERENCES: Precision Drug Action Committee SharePoint Site
https://cnet.centene.com/sites/HighCostDrug Resource/SitePages/Home.aspx

ATTACHMENTS:
CC.PHAR.21 Attachment A List of Precision Drugs
CC.PHAR.21 Attachment B Precision Drugs UM Process and MD Review Process
CC.PHAR.21 Attachment C Precision Drug Action Committee Job Aid
CC.PHAR.21 Attachment D Precision Drug Action Committee Check List

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Policy created	New policy created	08/19
Ad-hoc	Policy updated to include Attachment A List of Precision Drugs	02/20
Ad-hoc	Policy updated to include Attachment B Precision Drugs UM Process	05/20
Annual Review	Annual review. Updated Attachment A to include Tecartus. Guests updated to include Envolve Pharmacy Solutions staff.	08/20
Ad-hoc	Charter changes to limit the scope and membership	10/20
Ad-hoc	Updated Attachment A updated to include Breyanzi.	02/21
Ad-hoc	Updated Attachment A updated to include Amondys 45.	03/21
Ad-hoc	Updated Attachment A updated to include Abecma and the new indication for Yescarta.	04/21
Annual Review	Annual review. Updated Attachment B to include Compass as one of the EPS systems in B.1.	08/21
Ad-hoc	Updated committee members under membership. Updated Attachment A to remove Spinraza, Amondys, Exondys, Vyondys and Viltepso.	11/21
Ad-hoc	Updated Chairperson by removing SVP of Medical Affairs and replaced Envolve Pharmacy Solutions with Pharmacy Services. Updated the list of drugs to include: Zolgensma, Luxturna and all CATR-T (Yescarta, Kymriah, Tecartus, Breyanzi, Abecma and Carvykti).	05/22
Ad-hoc	Updated the Chairperson from Centene's Chief Medical Officer to the Chief Medical Officer of Centene Pharmacy Services. Also updated secretary, VP of Clinical and VP of Health Plan Strategy to reflect Pharmacy Services.	08/22
Annual Review	Annual review. Updated Attachment A to add Zynteglo. Updated the committee members. Clarified the pipeline committee will identify and communicate the PDAC drugs. Clarified that outcomes could be tracked based on selected drugs and not all drugs.	08/22
Ad-hoc	Updated Attachment A to add Hemgenix and Roctaviane. Added additional members: Director of Government Affairs, VP Regional Pharmacy, VP Pharmacy Operations	1/23
Ad-hoc	Updated Attachment A to add Elevidys for treatment of Duchenne muscular dystrophy (DMD) and Roctavian for treatment of Hemophilia A.	6/23
Annual Review	Annual review. Updated Attachment A to include cost estimates. Updated Attachment B to include Shared Services. Added Attachment C PDAC Job Aid	8/23
Ad-hoc	Updated Attachment A to include Casgevy and Lyfgenia. Updated Chairperson to Co-Chairs	12/23
Ad-hoc	Added Attachment D Precision Drug Action Committee Check List and Attachment E PDAC MD Review Process.	1/24
Ad-hoc	Updated Attachment A to include Amtagvi.	2/24
Ad-hoc	Update Attachment A to include Lenmeldy.	3/24
Ad-hoc	Updated Attachment A to include fidanacogene elaparvovec (Beqvez) for the treatment of adults with moderate to severe hemophilia B (congenital factor IX [FIX] deficiency.	5/24
Annual Review	Annual review. Added Director, MED-Pharmacy, Fidelis Market.	8/24

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad-hoc	Update Attachment A to include Tecelra.	8/24
Ad-hoc	Update Attachment A to include Aucatzyl.	11/24
Ad-hoc	Converted to new template. Replaced responsibilities with expectations after membership. Updated Attachment A to include Kebilidi, and updated HCPCS codes.	11/24
Ad-hoc	Updated Attachment A to include the manufacturers.	1/25
Ad-hoc	Updated Attachment A to clarify Kebilidi (known as Upstaza in Europe). Updated the functional area from Pharmacy Operations which no longer exists to Utilization Management. Updated membership with new organizational titles.	2/25
Ad-hoc	Updated Attachment A to include the new HCPCS code for Tecelra effective 4.1.25. Updated Amtagvi, Aucatzyl, Kebildi, Lenmeldy and Skysona to include unspecific HCPCS of J3490, J3590, J9999, C9399. Added Ryoncil to Attachment A.	3/25
Annual Review	Annual review done to align with Centene University training annual review. Updated Attachment A to include Encelto and Zevaskyn. Combined Attachment B and E to create revised PDAC UM and MD Review Process, Attachment B and retired Attachment E. Updated scope to include the acronym (CPS) and updated the membership to identify non-voting guests serving as ad hoc advisors. Updated attachment A with current wholesale acquisition cost (WAC).	5/25
Ad-hoc	Update Attachment A to include Papzimeos. Updated Products to include on and off exchange.	9/25

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.