Clinical Policy: Request for 3rd Brand Name Fill

Reference Number: OK.CP.PMN.05
Effective Date: 02.15.25
Last Review Date: 01.08.25
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The state limits members to six covered prescriptions per month, including up to two brand-name drug products per month. When available, generic drug product dispensing is required unless the state prefers the branded drug as designated on the Brand Required Drug List. Approval may be granted for one additional brand-name drug product per month based on information submitted, claims history, and the criteria outlined below.

FDA Approved Indication(s)

Varies by drug product.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met approval criteria.

I. Initial Approval Criteria

A. Request for a Third Brand-Name Drug per Month (must meet all)**:**

1. Failure of an adequate trial of, clinically significant adverse effects to, or excipient contraindication to all available generic, brand-required, or biosimilar drug product alternatives within the clinically applicable therapeutic class as outlined on OHCA Prior Authorization website;
2. If clinically significant adverse effects were experienced to alternative therapies required in criterion 1, provider submits chart note documentation;
3. Provider submits clinical rationale supporting why the requested brand-name drug will be more effective than, or will not produce the same adverse effects as the available alternatives;
4. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against CP.PMN.53 – Off-Label Use Policy*
5. Request is not for a benefit excluded use (e.g., cosmetic);
6. Request meets *one* of the following (a *or* b):
   a. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: Varies by drug product

II. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information
- Examples of failure of a generic drug include:
  - Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug;
  - Increase or worsening in symptoms (e.g., increase in seizure activity) when switched to a generic drug that is not attributed to progression of the disease state, increase in member age or weight, or member non-compliance.

IV. Dosage and Administration
Varies by drug product

V. Product Availability
Varies by drug product

VI. References
1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed November 9, 2023.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed November 9, 2023.
3. FDA MedWatch Reporting Forms at http://www.fda.gov/Safety/MedWatch/HowToReport. Accessed November 9, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created to provide review criteria for requests for fills of a 3rd brand-name drug product within a month	01.08.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.