Clinical Policy: Request for Non-Preferred Medically Necessary Drug - Not on PDL

Reference Number: NH.PMN.16
Effective Date: 09.19
Last Review Date: 10.22
Line of Business: Medicaid

Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene for drugs that are non-preferred.

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 all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that non-preferred drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for a Non-Preferred Drug (must meet all)**:**

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);
2. Failure of preferred agent(s) (**refer to NH Healthy Families PDL at https://www.nhhealthyfamilies.com/providers/pharmacy.html to determine how many agents must be tried and failed for a specific drug class**) within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such agents exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment unless (a, b, c, d, e, f, g, or h):
   a. Allergy to medications within the same class on the PDL;
   b. Contraindication to or drug-to-drug interaction with medications within the same class on the PDL;
   c. History of unacceptable or toxic side effects to medications within the same class on the PDL;
   d. Therapeutic failure of medications within the same class on the PDL;
   e. An indication that is unique to a non-preferred drug and is supported by peer-reviewed literature or a unique federal FDA-approved indication;
   f. An age-specific indication;
   g. Medical co-morbidity or other medical complication that precludes the use of a preferred drug; or;

h. Clinically unacceptable risk with a change in therapy to a preferred drug.

3. Trial and failure of PDL agents is supported by one of the following (a, b, or c):
   a. Presence of claims in pharmacy claims history supporting failure of preferred agents as described in criteria 2 above;
   b. Documented contraindication(s) or clinically significant adverse effects to preferred agents within the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of member's diagnosis;
   c. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
4. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
   **Use of a copay card or discount card does not constitute medical necessity*
5. 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 for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months (whichever is less)

II. Continued Therapy

A. Request for a Non-preferred Drug (must meet all)**:**

1. 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, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology) with documentation that supports that member has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   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: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HIV: human immunodeficiency virus
PDL: preferred drug list

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

V. Dosage and Administration
Varies by drug product.

VI. Product Availability
Varies by drug product

VII. References
Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	06.19	07.19
Annual Review. No Changes	07.20	07.20
Annual review. No significant changes. Clarified claims history for non-PDL drug requests must support requirements for failure of preferred agents.	10.20	10.20
Annual Review. No changes	10.21	10.21
Annual Review. No Changes	10.22	10.22

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.