Clinical Policy: Request for Medically Necessary Drug Not on the PDL

Reference Number: CP.PMN.16
Effective Date: 09.01.06
Last Review Date: 11.18
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 not on the preferred drug list (PDL).

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-PDL drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);
2. If request is 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*
3. Failure of at least two PDL agents 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;
4. 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;
   b. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL 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;
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-PDL 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
Reviewed current policy with no changes	12.14	12.14
Converted to new guideline template Modified approval duration to duration of request or 12 months – (whichever is less) Updated product type. Reviewed and updated description.	11.15	11.15
Modified duration of treatment of ≥ 30 days requirement to include appropriate duration of treatment; Clarified options for trial and failure and added requirements for PDL sample use; Removed requirement for trial and failure of one PDL agent within the past 60 days; Added generalized max dose and health plan approved daily quantity limit requirement to initial approval criteria; Added criteria for drug therapy initiated with drug samples not on the PDL and specified disease states eligible for COC consideration Continued approval: modified to include health plan approved daily quantity limit to FDA approved maximum recommended dose requirement; Updated background section.	05.16	08.16
Converted to new integrated template; Criterion 2: modified to include only members new to the health plan, updated list of disease states eligible for COC, and added office notes as an acceptable form of documentation that member has been on medication for at least 1 month;	10.16	11.16
Converted to new template. Initial IA2c: Modified one month to 30 days. Continued approval: Added requirement that member is responding positively to therapy.	08.14.17	11.17
4Q 2018 annual review: added requirement that request is for an FDA-approved indication or supported by standard pharmacopeias; added criteria for and moved continuation of care language requirements from Section I to Section II; added criteria for combinations products and alternative dosage forms or strengths of existing drugs.	08.14.18	11.18

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.