

Clinical Policy: No Coverage Criteria

Reference Number: CP.PMN.255

Effective Date: 12.01.20

Last Review Date: 11.21

Line of Business: Medicaid, HIM-Medical Benefit

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

This policy is to be used to determine medical necessity of formulary, existing or newly approved drug therapy where there are no coverage criteria.

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 all medical necessity determinations for drug therapy without Centene[®] coverage criteria be considered on a case-by-case basis by a physician, pharmacist or ad hoc committee, using the guidance provided within this policy.

I. Initial Approval Criteria

A. Labeled Use without Coverage Criteria (must meet all):

1. Request is for a formulary drug without custom coverage criteria;
 - *All requests for non-formulary drugs, under the pharmacy benefit, should be reviewed against CP.PMN.16 - Request for Medically Necessary Drug Not on the PDL.*
2. 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;
3. Member meets one of the following (a or b):
 - a. For Medicaid pharmacy requests: Failure of an adequate trial of at least two preferred* FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at maximum indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;
 - *Generic is preferred, if available generically*
 - b. For HIM-Medical Benefit requests: Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at maximum indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;
4. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products

CLINICAL POLICY

No Coverage Criteria



- 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. 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)

II. Continued Therapy

A. Labeled Use without Coverage Criteria (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, 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, 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)

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

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents;
- B. Indications or diagnoses in which the drug has been shown to be unsafe or ineffective.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

Appendix B: Therapeutic Alternatives

Varies by drug product

CLINICAL POLICY

No Coverage Criteria



Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

These criteria are to be used only when specific prior authorization criteria do not exist.

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

1. Food and Drug Administration. Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. January 2009. Available at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm>. Accessed July 22, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy CP.PMN.53; no significant changes from previously approved policy; references reviewed and updated.	07.13.20	11.20
4Q 2021 annual review: added requirement for diagnoses; added requirement that request is for a formulary drug; added notation that generic alternatives are preferred; modified dosing requirements to allow off-label dosing; references reviewed and updated.	07.22.21	11.21

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

CLINICAL POLICY

No Coverage Criteria



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.

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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.

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