Clinical Policy: No Coverage Criteria

Reference Number: HIM.PA.33
Effective Date: 05.01.16
Last Review Date: 11.21
Line of Business: HIM

Revision Log

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

Description

This policy is to be used for drugs that require prior authorization where there are no specific guidelines or coverage criteria.*

**All requests for non-formulary drugs, under the pharmacy benefit, should be reviewed against HIM.PA.103 – Brand Name Override and Non-Formulary Medications or medication specific prior authorization criteria when available*

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. Pharmacy Benefit: Labeled Use without Drug-specific Coverage Criteria (must meet all)**:**

1. Request is for a drug on the formulary without custom coverage criteria;
   **All requests for non-formulary drugs, under the pharmacy benefit, should be reviewed against HIM.PA.103 – Brand Name Override and Non-Formulary Medications or medication specific prior authorization criteria when available*
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. 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 contraindicated, clinically significant adverse effect are experienced, or request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
   **Generic is preferred, if available generically*

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), unless request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
   **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 product and 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 12 months, whichever is less

B. Medical Benefit: Labeled Use without Drug-specific Coverage Criteria (must meet all)**:**

1. Request is for a drug without custom coverage criteria;
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. 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, all are contraindicated, or request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
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), unless request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
   **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 12 months, whichever is less

II. Continued Therapy

A. Pharmacy or Medical Benefit: Labeled Use without Drug-specific 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 policy – HIM.PA.154 for health insurance marketplace 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
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

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.

Appendix E: States with Regulations against Redirections in Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if "clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	For stage 4 metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

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
2Q 2018 annual review: no significant changes	02.23.18	05.18
Revised to include NCCN Compendium category 1, 2A, and 2B supported uses; added continuation of care language.	12.06.18	02.19
2Q 2019 annual review: added requirement to ensure requested product is on the formulary with reference to HIM.PA.103 if product is non-formulary.	02.19.19	05.19
2Q 2020 annual review: Section IA, 2b removed NCCN category 2B recommendation from approvable off-label uses; clarified reference for non-formulary medications that may be reviewed using medication specific prior authorization criteria when available.	02.17.20	05.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2020 annual review: added NCCN 2B as an acceptable level of evidence for off-label use per Compliance; added criteria for combinations products and alternative dosage forms or strengths of existing drugs; added requirement for redirection to two preferred FDA-approved drugs; delete reference to off-label use policy in Section I and II.	08.06.20	11.20
4Q 2021 annual review: Section III added exclusion for indications or diagnoses in which the drug has been shown to be unsafe or ineffective; revised reference from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	07.22.21	11.21
Added criteria set for requests through the medical benefit adapted from CP.PMN.255 (HIM-Medical Benefit line of business removed from this policy); modified policy title from "Formulary Medications without Specific Guidelines" to "No Coverage Criteria"; added redirection bypass for states with regulations against redirections in cancer along with Appendix E.	01.06.22	

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.