

## Clinical Policy: Formulary Medications without Specific Guidelines

Reference Number: HIM.PA.33

Effective Date: 05.01.16

Last Review Date: 05.20

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 formulary drugs that require prior authorization where there are no specific guidelines or 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<sup>®</sup> that formulary medications without specific guidelines are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Formulary Medications without Specific Guidelines (must meet all):

1. Request is for a drug on the formulary;  
*\*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 or 2A;
3. 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. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

## II. Continued Therapy

### A. Formulary Medications without Specific Guidelines (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. 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**

### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

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

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

## 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.PHAR.21 for health insurance marketplace or evidence of coverage documents.

## 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.

## 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
Converted to new template	01.17	05.17
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

**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

## CLINICAL POLICY

### Formulary Medications Without Specific Guidelines



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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