Clinical Policy: Non-Formulary and Non-Preferred Drug Not Otherwise Specified
Reference Number: WA.PHAR.61
Effective Date: 01/2018
Last Review Date: 01/2020, 01/2021, 07/2021 Revision Log
Line of Business: Medicaid

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

Description
To outline criteria for Non-Formulary (not on the Apple Health Preferred Drug List) and Non-Preferred Drugs defined by the Washington State Health Care Authority.

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-formulary or non-preferred medications are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria (must meet all):

1. Prescribed indication is FDA-approved
    a) Requests for off-label use should be reviewed against CP.PMN.53 Off-Label Use
2. Request meets one of the following (a or b):
    a) Trial and failure of at least TWO* preferred drugs supported by all of the following (must meet all):
        i. Drugs must be within the same pharmacologic class**
        ii. Trial and failure of preferred agents is supported by claims data or within provider chart notes
        iii. Drugs must be tried up to maximally indicated or tolerated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment unless clinically significant adverse effects are experienced
        iv. Any sample drugs are not counted in the above criteria as preferred drugs
    b) Contraindications of preferred products within same class do not allow 2 preferred products to be tried. Must document contraindications
3. 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 (must meet all):

1. Currently receiving medication via Centene benefit, or member has previously met initial approval criteria;
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 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

***** If there is only 1 formulary agent within the same therapeutic class as the prescribed agent, member must use at least one additional agent that is recognized as a standard of care for the treatment of the relevant diagnosis, provided that such agent exists
**The same pharmacologic class is defined as the most specific class contained in the Apple Health Preferred Drug List (e.g. use SSRI class and not just Antidepressants; use DPP-4 inhibitor class and not just Antidiabetics)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	01/2018	01/09/2019
Minor formatting changes made to the WA.PHAR.61 Request for Drug not on PDL addendum	01/2020	01/14/2020
Annual Review- No Changes	01/2021	01/12/2021
Overall revision to streamline criteria	06/2021	07/13/2021

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.