Administrative Policy Statement
WEST VIRGINIA MARKETPLACE

Policy Name	Policy Number	Date Effective
Medical Necessity for Non-Formulary Medications	PAD-0037-WV-MPP	01/01/2022

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Table of Contents

A. Subject

Medical Necessity for Non-Formulary Medications

B. Background

CareSource uses a Marketplace Formulary Drug List that is established, reviewed, and approved by a Pharmacy and Therapeutics (P&T) Committee and applicable state and federal regulatory agencies. Drugs on the Marketplace Formulary Drug List are classified into tiers as explained in the Member's Evidence of Coverage (EOC). The Marketplace Formulary Drug List is reviewed routinely for addition or deletion of drugs and for movement of drugs from one tier to another. Drugs may be added to or deleted from the Marketplace Formulary Drug List in response to new clinical evidence related to safety or efficacy for the drug in question or for a comparable drug with the same indication for use. CareSource will follow the guidance of the state Marketplace programs in the states that it services to enforce clinically appropriate, low cost drugs as first line therapy through the use of the Marketplace Formulary Drug List.

The intent of CareSource Pharmacy Policy Statements is to encourage clinically appropriate and cost-effective selection of drug therapy for members according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of drugs on the Marketplace Formulary Drug List.

NOTE: *The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.*

C. Definitions

- **Clinical Judgment –** Decisions made within the scope of the expertise of a pharmacist following the review of subjective and objective medical data for a member. A pharmacist can use Clinical Judgment for a benefit determination for an exception request for a Non-Formulary Drug. If the request is outside the scope of a pharmacist's expertise, a benefit determination will be made in collaboration with a medical director.
- **Clinically Adequate Trials** – Trials of prior drug therapies indicated to treat a member's condition based on FDA-approved indications, evidence-based guidelines, evidence-based clinical literature, and peer-reviewed studies, and benefit design on the Marketplace Formulary Drug List. A clinically adequate trial must be of a sufficient duration and/or dose for treatment of the member's condition based on appropriate FDA labeling and/or compendia guidance as determined by a licensed physician or pharmacist engaged in utilization management reviews on behalf of CareSource.
- **Marketplace Formulary Drug List** (i.e., Marketplace Drug Formulary, Formulary) – A list of prescription drugs which includes a group of selected generic and brand-name drugs which are covered by CareSource at the designated member cost share in the member's EOC. The Marketplace Formulary Drug List is based on evidence based guidelines, FDA-approved indications, evidence-based clinical literature, and peer-reviewed studies, and benefit design, The Marketplace Formulary Drug List is reviewed and approved by the Pharmacy & Therapuetics Committee composed of practicing physicians, pharmacists and other health care professionals as required by 45 CFR §156.122(a)(3)(i)(B).
- **Medical Necessity** – Health care services, supplies, or drugs needed to diagnose, treat or prevent illness, injury, conditions, diseases or the associated symptoms in accordance with

accepted standards in the practice of medicine. Medical necessity will be evaluated based on the overall health and well-being of the member and when the member's day to day health would be impacted. Prescription Drugs, unless otherwise stated in the EOC, must be Medically Necessary in order to be Covered Services.

- **Potential Covered Alternatives** – Drugs that share the same clinical indication or are positioned similarly in FDA labelling, clinical guidelines, and/or clinical trials.
- **Submitted Documentation** – Information provided by the prescriber that includes, but is not limited to, chart notes specific to member's condition, previous treatments, and the provider's rationale for medical necessity. Documentation of previous treatments must include the dates of the treatment trial.
- **Therapeutic Failure** – Failure to accomplish the goals of treatment following a clinically adequate trial. Therapeutic failure can include an allergic reaction, lack of physiologic response, and/or intolerable adverse reaction to a drug.

D. Policy

CareSource will approve the use of non-formulary drugs (i.e. drugs that are not on the Marketplace Formulary Drug List) when the criteria below have been met. This policy will not supersede drug-specific criteria developed and approved by the P&T Committee nor drug or therapeutic category benefit exclusions. Drug and therapeutic category benefit exclusions can be found in the member's EOC. Formulary exception requests should be submitted for each non-formulary medication and should include chart notes and documentation supporting medical necessity.

Use of non-formulary drugs will be approved when the following criteria are met:

I. The drug is being used for an FDA approved indication or meets the criteria laid out in the **Medical Necessity – Off Label, Approved Orphan and Compassionate Drugs** policy, AND
II. The requested dose of the drug is based on FDA approved labeling for the member's age and indication, AND
III. The submitted documentation includes ONE of the following:
    A. Documentation of clinically adequate trial and therapeutic failure of:
        1. At least 3 potential covered alternatives that are included on the Marketplace Formulary Drug List, OR
        2. If fewer than 3 potential covered alternatives are available on the Marketplace Formulary Drug List, then all of the available alternatives must be tried, AND
    B. If the member was enrolled with CareSource at the time of the treatment trial, the documentation must be supported by paid claims, OR
    C. Documentation of contraindication to ALL of the alternative drugs on the Marketplace Formulary Drug List based on the member's diagnosis, medical conditions, and/or other medication therapies, OR
    D. In the absence of a clinically adequate trial, documentation of clinical reasons why the alternative drugs on the Marketplace Formulary Drug List are expected to be ineffective or less effective than the non-formulary drug. Documented clinical reasons are subject to the clinical judgement of the reviewing pharmacist or physician, AND

IV. If the request is for a combination product, the submitted documentation includes a clinical reason why the member is unable to take the active ingredients of the combination product separately as individually prescribed medications, AND
***NOTE**: This criteria is waived if the separate active ingredients are not included on the Marketplace Formulary Drug List.*

V. If the request is for a long-acting formulation, the submitted documentation includes a clinical reason why the member is unable to use the immediate-release formulation of the drug, AND
***NOTE:** This criteria is waived if the immediate-release formulation is not included on the Marketplace Formulary Drug List.*

VI. If the request is for a multi-source branded drug, the submitted documentation includes trial and therapeutic failure of a minimum of two generic manufacturers of the requested brand name medication. The submitted documentation must include information about the therapeutic failure that was experienced by the member for each generic manufacturer and is subject to the clinical judgement of the reviewing pharmacist or physician.

Limitations of Scope:

- Requests for drugs that are provider administered or that are otherwise billed through the medical benefit should meet the criteria in the Marketplace **Medical Necessity for Medical Benefit Medications** policy.

E. Conditions of Coverage

Applicable NDCs

AUTHORIZATION PERIOD – 1 year unless otherwise determined by the clinical judgement of the reviewer

F. Related Policies/Rules

Any applicable drug-specific clinical policies
Medical Necessity Determinations
Medical Necessity for Medical Benefit Medications
Medical Necessity – Off Label, Approved Orphan and Compassionate Use

G. Review/Revision History

DATES		ACTION
Date Issued	**12/06/2013**	
Date Revised	**09/01/2021**	
	04/20/2017	Policy separated by State/LOB.
	06/19/2018	Definitions added. All sections updated.
	06/11/2020	Policy moved to the new template.
	09/16/2021	Annual review
Date Effective	**01/01/2022**	Approved by P&T
Date Archived		

H. References

1. Definitions for Formulary, Medical Necessity: Healthcare.gov.
2. Definitions for Clinical Judgement: Ombudsman Saskatchewan, Canada; “Administrative versus Clinical Decisions” January 2016.
3. 45 CFR - Chapter A - Subchapter B - §156.122 - Prescription drug benefits.
4. 2021 NCQA Standards and Guidelines for the Accreditation of Health Plans.