Administrative Policy Statement
WEST VIRGINIA MARKETPLACE PLANS

Policy Name	Policy Number	Date Effective
Medical Necessity for Non-Formulary Medications	PAD-0037-WV-MPP	07/02/2020

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.

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A. Subject

CareSource uses a Marketplace Formulary Drug List (i.e., Marketplace Formulary) that is established, reviewed and approved by the CareSource Pharmacy and Therapeutics (P&T) Committee and applicable state and federal regulatory agencies. Drugs on the Marketplace Formulary are classified as explained in the Member's Evidence of Coverage (EOC) into tiers including: Preventive, Preferred, Non-preferred, and/or Specialty. The Marketplace Formulary is reviewed routinely for addition or deletion of drugs and for tier selection of formulary drugs.

Drugs may be removed from the Marketplace Formulary when the brand drug becomes generically available, is withdrawn by a manufacturer, or when it is no longer as safe, efficacious or cost-effective comparative to current Marketplace Formulary drugs. For new drugs or new indications for use of existing drugs, the P&T Committee generally reviews for formulary status decisions after 180 days from market release. CareSource will follow the guidance of the state Marketplace programs in the states that it services to enforce clinically appropriate lower cost drugs as first line therapy in accordance to our Marketplace Formulary.

B. Background

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of drug therapy for members according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of Marketplace Formulary drugs. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our members with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

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

- Administrative Review/Approval/Denial: a decision for coverage or non-coverage of a drug which is made regarding the organization and delivery of the drugs according to a member's benefits, policies & procedures and/or legislature & regulation which do not require clinical expertise or subject knowledge.
- 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.
- Drug: a medication or substance which induces a physiologic effect on the body of a member (i.e., medication, agent, drug therapy, treatment, product, biosimilar drugs, etc.).
- 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.
- 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.

- Non-Formulary Drug: a drug not on the Marketplace Formulary Drug List.
- Non-Preferred Drug: a drug on the Marketplace Formulary Drug List placed at a higher member cost share than Preferred Drugs as explained on the member's EOC (e.g., tier 3 and tier 5).
- Preferred Drug: a drug on the Marketplace Formulary Drug List placed at a lower member cost share as explained on the member's EOC (e.g., tier 2 and tier 4).
- Preventive Drug/Service: routine drug or service which prevents illnesses, disease or other health problems from occurring. These drugs are identified through guidance of the The Affordable Care Act (ACA) as essential health benefits and may be subject to prior authorization or certain limitations.
- Specialty Drug: a drug which treats complex diseases and/or requires special handling or distribution and is usually high cost. Many of these drugs require prior authorization and may be dispensed at limited locations. Please see CareSource's Specialty Drug List on the CareSource website.

D. Policy

I. A Non-Formulary Drug is Administratively Denied at the point of purchase unless CareSource receives a request for Clinical Judgment for coverage and issues subsequent approval. This policy will not supersede drug-specific criteria developed and approved by the CareSource P&T Committee. When CareSource approves coverage of a Non-Formulary drug, the member's cost share will be the appropriate Non-Preferred Drug tier or Non-Preferred Specialty Drug tier and will be considered Medically Necessary when ALL of the following criteria have been met:

A. Prior authorization requests should be submitted for each Non-Formulary Drug with chart notes and member-specific documentation which supports Medical Necessity for Clinical Judgement AND

B. The member's indication, dose, and duration for use of the requested Non-Formulary Drug is approved by the Food & Drug Association (FDA) or an indication supported in the compendia or current peer-reviewed literature or evidence based guidelines AND

C. Member is unable to take ALL the available Marketplace Formulary Drug(s) for the given diagnosis due to a clinically adequate trial(s) without adequate treatment response(s), intolerance or adverse reactions of all Marketplace Formulary Drugs (actual or expected), or contraindication to the Marketplace Formulary Drug(s) OR

D. Member is unable to take the Marketplace Formulary Drug(s) because:

1. The member has a clinical condition for which there is no Marketplace Formulary Drug and/or needed dosage form suitable to treat the member's diagnosis OR
2. The Marketplace Formulary Drug(s) is/are not recommended based on published guidelines or clinical literature OR
3. The Marketplace Formulary Drug(s) is/are expected to be ineffective or less effective for the member based on submitted documentation and medical history OR

4. The Marketplace Formulary Drug(s) is/are expected to cause an adverse effect based on submitted documentation and medical history.

E. Conditions of Coverage

NDC
HCPCS
CPT

If a Non-Formulary Drug is approved for coverage, it will be processed at the member's appropriate Non-Preferred Drug or Non-Preferred Specialty Drug cost share as explained on the member's EOC.

AUTHORIZATION PERIOD: through the end of the member's plan year.

F. Related Policies/Rules

Medical Necessity - Off Label, Approved Orphan and Compassionate Use Drugs

Other drug-specific policies may apply.

G. Review/Revision History

DATES		ACTION
Date Issued	**12/06/2013**	
Date Revised	**12/01/2015**	
	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.
Date Effective	**07/02/2020**	Approved by VAC
Date Archived		

H. References

1. Definitions for Formulary, Non-Formulary, Medical Necessity, Preventive Drug: Healthcare.gov.
2. Definitions for Administrative Review or Clinical Judgement: Ombudsman Saskatchewan, Canada; "Administrative versus Clinical Decisions" January 2016.
3. 45 CFR - Chapter A - Subchapter B - §156.122 - Prescription drug benefits.
4. 2018 NCQA Standards and Guidelines for the Accreditation of Health Plans.