CareSource

Administrative Policy Statement
WEST VIRGINIA MARKETPLACE PLANS

Policy Name	Policy Number	Date Effective
Utilization Management of Formulary Medications	PAD-0070-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.

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A. Subject

Utilization Management of Formulary Medications

B. Background

CareSource uses a Marketplace Formulary Drug List (i.e., Marketplace Formulary) that is established, reviewed and approved by the Pharmacy and Therapeutics (P&T) Committee and applicable state and federal regulatory agencies. Drugs on the Marketplace Formulary are classified into tiers as explained in the Member's Evidence of Coverage (EOC) 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 that have been added to the Marketplace Formulary under any tier may be subject to Utilization Management. Utilization Management could include a Prior Authorization, Quantity or Dose Limit, or Step Therapy. Any applicable Utilization Management associated with a specific drug will be indicated on the Marketplace Formulary. Drugs that have been added to the Marketplace Formulary under any tier that are not subject to Utilization Management are available to members at the appropriate cost share as described in the member's EOC.

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. 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 Evidence of Coverage (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. Prescription Drugs, unless otherwise stated in the EOC, must be Medically Necessary in order to be Covered Services.

- 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 other limitations.
- Prior Authorization: Requirement for medical necessity review for a Formulary drug that may not be clinically appropriate for all members or may be associated with risk to the member if used inappropriately. A provider will be required to submit additional clinical information to CareSource for review and approval prior to the drug being available to the member.
- Quantity Limit or Dosage Limit: Limits that may restrict the amount dispensed per prescription order, refill, time period, total quantity or total dose.
- 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.
- Step Therapy: A member may need to use a medication or a series of medications before the requested medication.
- Utilization Management: Use of Prior Authorization, Quantity or Dose Limits, or Step Therapy to ensure that coverage of a Formulary Medication is consistent with Medical Necessity, clinical best practice, and cost-effective care

D. Policy

I. A Formulary drug that is subject to a Prior Authorization will be denied at the point of purchase unless CareSource receives a request for Clinical Judgement for coverage. Requests for Clinical Judgement for Formulary drugs that are subject to a Prior Authorization will be reviewed against drug-specific criteria that has been developed and approved by the P&T Committee. When CareSource approves coverage of a Formulary drug that is subject to a Prior Authorization, the member's cost share will the appropriate tier as indicated on the Marketplace Drug Formulary and explained in the Member's EOC.

   A. Prior Authorization requests should be submitted for each Formulary drug that is subject to a Prior Authorization with chart notes and member-specific documentation which supports Medical Necessity for Clinical Judgement.
   B. Prior Authorization requests can be submitted via fax, phone, or mail or electronically.
   C. Prior Authorization requests will be reviewed and notification of the determination made according to the Prescription Drug Exception Process outlined in the Member's EOC. Notification of determination for the request will be made within 72 hours for standard requests or within 24 hours for expedited requests.

II. A Formulary drug that is subject to Step Therapy will be denied at the point of purchase unless the member has previously had a paid claim for the prerequisite drug(s) required by the Step Therapy criteria or CareSource receives and approves a Prescription Drug Exception request. When CareSource approves an Exception request for a Formulary drug that is subject to Step Therapy, the member's cost share will the appropriate tier as indicated on the Marketplace Drug Formulary and explained in the Member's EOC. An Exception request will be approved in the following cases:

A. The member has previously used the prerequisite drug(s) or a drug in the same therapeutic class or with the same mechanism of action as the prerequisite drug(s) but discontinued the drug due to lack of efficacy, diminished effect, or adverse event based on submitted documentation and medical history. (If the member does not have previous paid claims for the prerequisite or related drug(s), documentation of the previous trials will be required for an exception request to be approved.) OR

B. The member is currently using and is stable on the requested drug and is expected to experience adverse outcomes (e.g. worsening of a comorbid condition, decreased ability to achieve or maintain reasonable functional ability in performing daily activities, etc.) as a result of switching drug therapy based on submitted documentation and medical history, OR

C. The member has an allergy or intolerance to one or more of the prerequisite drug(s) required by the Step Therapy criteria based on submitted documentation and medical history, OR

D. The prerequisite drug(s) required by the Step Therapy criteria is/are expected to cause an adverse effect based on submitted documentation and medical history, OR

E. The prerequisite drug(s) required by the Step Therapy criteria is/are expected to be ineffective or less effective for the member based on submitted documentation and medical history, OR

F. The prerequisite drug(s) required by the Step Therapy criteria is/are expected to cause a significant barrier to the member's adherence or compliance with the plan of care.

III. A Formulary drug that that is subject to Quantity or Dose Limits will be denied at the point of service for any claim that exceeds these limits unless CareSource receives and approves a Prescription Drug Exception request. When CareSource approves an Exception request for a Formulary drug that is suject to Quantity or Dose Limits, the member's cost share will be the appropriate tier as indicated on the Marketplace Drug Formulary an explained in the Member's EOC. An Exception request will be approved in the following cases:

EITHER

A. The requested quantity or dose of the drug does <u>not</u> exceed the maximum recommended dose approved by the FDA and is medically necessary based on submitted documentation and medical history AND

B. The requested quantity or dose of the drug does not exceed the limits as covered by the plan or applicable State and Federal laws

OR

C. The provider has submitted clinical documentation supporting the use of an off-label quantity or dose in accordance with the **CareSource Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs Policy**, and the requested quantity or dose of the drug is medically necessary based on submitted documentation and medical history.

Conditions of Coverage:
NDC
HCPCS
CPT

AUTHORIZATION PERIOD: through the end of the member's plan year unless otherwise indicated in drug-specific policies or criteria

IV. Related Policies/Rules

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

Other drug-specific Clinical Criteria may apply.

V. Review/Revision History

DATES		ACTION
Date Issued	**10/01/2020**	
Date Revised	**09/01/2021**	Annual Review
Date Effective	**01/01/2022**	Approved by P&T
Date Archived		

VI. 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.