CareSource

Administrative Policy Statement
MARKETPLACE PLANS

Policy Name	Policy Number	Date Effective
Clinical Review of Formulary and Non-Formulary Medications	PAD-0067-MPP	01/01/2026

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.

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Table of Contents

A. Subject

Clinical Review of Formulary and Non-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 or Clinical Review**: 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).
- **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 the guidance of the Affordable Care Act (ACA) as essential health benefits and may be subject to prior authorization or other limitations.
- **Prior Authorization:** Requirement for clinical 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.
- **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 clinical best practice, and cost-effective care

D. Policy

This policy will not supersede drug-specific criteria developed and approved by the P&T Committee nor drug or therapeutic category benefit exclusions

I. A Formulary drug that is subject to a Prior Authorization will be denied at the point of purchase unless CareSource has received a request for Clinical Judgement and approved 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 reflect 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/or member-specific documentation which supports Clinical Judgement.
   B. Prior Authorization requests can be submitted via fax, phone, mail or electronically.

II. Prior Authorization requests will be reviewed and notification of the determination made according to the timing of Prescription Drug Request Determinations outlined in the Member's EOCA 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 has received and approved a Prescription Drug Exception request. When CareSource approves a request for a Formulary drug that is subject to Step Therapy, the member's cost share will be 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 based on submitted documentation and medical history.

III. A Formulary drug 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 has received and approved a Prescription Drug Exception request. When CareSource approves an Exception request for a Formulary drug that is subject to Quantity or Dose Limits, the member's cost share will be 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:

EITHER

A. The requested quantity or dose of the drug does not 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

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

IV. CareSource will approve the use of non-formulary drugs when the criteria below have been met. Drug and therapeutic category benefit exclusions can be found in the member's EOC. Drug exception (Non-Formulary Drug) requests should be submitted for each non-formulary medication and should include chart notes and/or documentation. Use of non-formulary drugs will be approved when the following criteria are met:

A. The drug is being used for an FDA approved indication or meets the criteria laid out in the Off Label policy, AND
B. The requested dose of the drug is based on FDA approved labeling for the member's age and indication, AND
C. The submitted documentation includes ONE of the following:
    1. 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

2. If the member was enrolled with CareSource at the time of the treatment trial, the documentation must be supported by paid claims, OR
3. 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
4. In the absence of a clinically adequate trial, documentation should be submitted with 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
   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.

D. 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.
E. 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.

Renewal Criteria:

I. Documentation has been provided showing the member has had a positive response to therapy; AND
II. The requested use and dosage remain consistent with FDA-approved prescribing information in the drug package insert.

Authorization Period: Through the end of the member's plan year unless otherwise indicated in drug-specific policies or criteria or otherwise determined by the clinical judgement of the reviewer

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 Benefit Medications** policy.

V. Conditions of Coverage

NDC
HCPCS

CPT

VI. Related Policies/Rules

Any applicable drug-specific clinical policies

Medical Benefit Medications

Off Label

VII. Review/Revision History

DATES		ACTION
Date Issued	**10/01/2020**	
Date Revised	**12/19/2022**	Removed mention of turn around times (TAT).
	12/17/2024	Combined with Non-Formulary Medications policy
Date Effective	**01/01/2026**	
Date Archived		

VIII. 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. 2021 NCQA Standards and Guidelines for the Accreditation of Health Plans.