



## Administrative Policy Statement NORTH CAROLINA MARKETPLACE

Policy Name		Policy Number	Date Effective
Medical Necessity for Medical Benefit Medications		PAD-0013-NC-MPP	01/01/2023
Policy Type			
Medical	<b>ADMINISTRATIVE</b>	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 Pharmacy Policy Statements to determine coverage for medications that are covered under the medical benefit, as determined by the CareSource Pharmacy and Therapeutics (P&T) Committee. Pharmacy Policy Statements contain criteria designed to ensure that CareSource members safely receive effective medication.

Some medical benefit medications may not be addressed by a specific Pharmacy Policy Statement. In that case, the reviewing pharmacists will make a medical necessity determination based on the information outlined here.

## B. BACKGROUND

The intent of CareSource 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 preferred drugs. The CareSource 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 product or 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 Judgement: decisions made within the scope and expertise of a pharmacist following the review of subjective and objective medical data for a member. A pharmacist can use Clinical Judgement for the benefit determination for an exceptions request for a Medical Benefit 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 drug, etc.).
- Medical Benefit Drug: a drug that is usually administered by a healthcare provider or in a supervised healthcare setting and is billed to CareSource through the medical benefit and is subject to the appropriate member cost share based on the Schedule of Benefits (SOB) and/or Summary of Benefits and Coverage (SBC).



- **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-Preferred Drug:** a drug that has been determined by CareSource to be less clinically efficacious or cost-effective for an FDA-approved use than other available drugs by the CareSource P&T Committee.
- **Preferred Drug:** the drug of choice for CareSource for an FDA-approved use as indicated on a Pharmacy Policy Statement available on the CareSource website and based on clinical efficacy and cost as determined by the CareSource P&T Committee.
- **Specialty Drug:** a drug which treats highly 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. Medical Benefit Drugs may require review and approval by a pharmacist and/or medical director before being approved for payment. This policy will not supersede drug-specific clinical criteria developed and approved by the CareSource P&T Committee. When CareSource approves coverage of a Medical Benefit Drug it will be considered Medically Necessary when ALL of the following criteria have been met:
  - A. Prior Authorization requests should be submitted for each Medical Benefit 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 the use of the requested Medical Benefit Drug is approved by the Food & Drug Administration (FDA) or an indication supported in the compendia or current peer-reviewed literature or evidence-based guidelines AND
  - C. One of the following is true:
    1. The Medical Benefit Drug is a Preferred Drug by CareSource OR
    2. The member is unable to take the Preferred Drug(s) because:
      - a. The member has a clinical condition for which there is no Marketplace Preferred Drug and/or needed dosage form suitable to treat the member's diagnosis OR
      - b. The Marketplace Preferred Drug(s) is/are not recommended based on published guidelines or clinical literature OR
      - c. The Marketplace Preferred Drug(s) is/are expected to be ineffective or less effective for the member based on submitted documentation and medical history OR
      - d. The Marketplace Preferred Drug(s) is/are expected to cause an adverse effect based on submitted documentation and medical history.



**E. CONDITIONS OF COVERAGE**  
**HCPCS**  
**CPT**

**AUTHORIZATION PERIOD: as determined by the approving pharmacist’s Clinical Judgement**

**F. RELATED POLICIES/RULES**

- AD-0035: Medical Necessity for Non-Formulary Medications
- AD-0063: Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs
- AD-0047: Medical Necessity Determinations
- Drug-specific policies posted on the CareSource website may apply

**G. REVIEW/REVISION HISTORY**

DATES		ACTION
<b>Date Issued</b>	<b>11/07/2019</b>	Drafted policy language; updated references to SOB and SBC
<b>Date Revised</b>	<b>11/17/2021</b>	Annual review, no changes.
	<b>12/19/2022</b>	Annual review, no changes.
<b>Date Effective</b>	<b>1/1/2023</b>	
<b>Date Archived</b>		

**H. REFERENCES**

1. Definitions for Medical Necessity: 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.