Administrative Policy Statement
ARKANSAS PASSE

Policy Name	Policy Number	Date Effective
Medical Necessity for Non-Formulary Medications	PAD-0900-AR-PASSE	01/01/2023

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 formulary medication list that is established, reviewed and approved by the CareSource Pharmacy and Therapeutics (P&T) Committee and the regulatory bodies in each state in which CareSource functions. The formulary is reviewed routinely, and medication can be removed from the formulary list when the brand name becomes generically available or when it is no longer cost-effective compared to other existing or newer products.

For new drugs or new indications for drugs, the P&T Committee generally reviews for formulary status decision after 180 days from market release. CareSource will follow the guidance of the state Medicaid programs in the states that it services to enforce clinically appropriate lower cost agents as first line therapy for our formulary agents.

B. Background

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of members for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of formulary agents. 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

- **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.).
- **Formulary Drug List:** a list of prescription drugs which includes a group of selected generic and brand-name drugs which are covered by CareSource.
- **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 Formulary Drug List.

D. Policy

CareSource will approve the use of non-formulary medications and consider their use as medically necessary when the following criteria have been met for situations as listed below. This policy will not supersede drug-specific criteria developed and approved by the CareSource P&T

Committee nor drug or therapeutic category benefit exclusions. Prior authorization requests should be submitted for each non-formulary medication with chart notes and documentation supporting medical necessity.

Initial Criteria:

I. In accordance with the drug's package insert, the requested medication meets **ALL** of the following:
   a. FDA-approved indication and age;
   b. FDA-approved dosage;
   c. Member does not have any contraindication; AND

II. Chart notes along with any relevant screening results are provided to confirm the diagnosis; AND

III. The requested medication is being prescribed by or in consultation with an appropriate specialist, when applicable *(e.g., a formulary product from the same class requires a specialist in its prior authorization criteria, or the indication is a complex/rare disease state likely to require experience managing the specific diagnosis*); AND

IV. Documentation has been provided supporting **one** of the following:
   a. Adequate trial and failure or intolerance of ALL formulary alternatives in the same drug class that can be used for the same diagnosis (*start/end dates must be provided or if member was a Caresource member during trial, must have paid claims in history*); OR
   b. If there is no alternative in the same drug class, must have adequate trial and failure or intolerance of TWO formulary alternatives, if available, that can be used for the requested indication according to clinical guidelines or standard of care (*start/end dates must be provided or if member was a Caresource member during trial, must have paid claims in history*); OR
   c. Member has contraindication to ALL other formulary medications based on the member's diagnosis, medical conditions, or other medication therapies; OR
   d. There are no other medications available on the formulary to treat member's condition (e.g., orphan drug); AND

V. If the requested medication is a combination product, the member has also tried a 90-day trial of the active ingredients separately taken at the same time AND a clinical reason supported by chart notes why the separate agents cannot be used (*request for the purpose of convenience does not meet medical necessity*); AND

VI. If the requested medication is a long-acting product, the member has also tried a 90-day trial of a short-acting product AND/OR have a clinical reason why the short-acting product cannot be used.

Initial approval is limited to the length of request but no more than 6 months.

Renewal Criteria:

I. Chart notes have 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.

Renewal approval is limited to the length of request but no more than 12 months.

Notes:

- Adequate trial is defined as a stable dose for up to 90 days or a duration specified in treatment guidelines or package insert as a sufficient duration to observe benefit from

treatment. The pharmacist reviewer may also use clinical judgement to determine a sufficient duration of treatment.

- The member's medication trials and adherence are determined by review of pharmacy claim data over preceding 12 months or as reported in chart notes. Additional information may be requested on a case-by-case basis to complete the clinical review.
- All other uses of Non-Formulary medications are considered experimental/investigational; therefore, will follow CareSource's Medical Necessity – Off Label policy.
- Any request for a non-formulary branded medication when a generic is available must follow CareSource's Medical Necessity for DAW policy.

E. Conditions of Coverage

As above.

F. Related Policies/Rules

Medical Necessity for DAW

Medical Necessity – Off Label

G. Review/Revision History

DATES		ACTION
Date Issued	**12/06/2013**	
Date Revised	**08/01/2020**	Policy copied to a new template. The diagnostic requirement and drug trial requirement revised. Added durations for initial authorization and reauthorization. Added reauthorization criteria.
	11/08/2022	Section D part III: Added complex/rare disease states. Changed renewal duration from up to 6 months to up to 12 months.
Date Effective	**01/01/2023**	
Date Archived		

H. References

Not applicable.

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.