Administrative Policy Statement
GEORGIA MEDICAID

Policy Name	Policy Number	Date Effective
Medical Necessity for DAW	PAD-0008-GA-MCD	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

- Allergic Reaction: an allergic reaction, as defined by the American Academy of Allergy Asthma & Immunology, occurs when the immune system overreacts to a harmless substance. Types of allergic symptoms to medications range from skin rashes or hives, itching, respiratory problems, and swelling to anaphylaxis. All medications have the potential to cause side effects, but only about 5 to 10% of adverse reactions to drugs are allergic.[1]
- 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.
- DAW: dispense as written.
- 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 DAW medications and consider their use as medically necessary when the following criteria have been met. 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.

I. Member has tried and failed both of the following:
   A. Two generic manufacturers of the requested brand name medication at an adequate dose for an adequate duration (information must be provided regarding the treatment target or goal that was inadequately met) AND
   B. All formulary alternatives within the same drug class as the requested brand name medication that have an FDA-approved indication to treat the member's condition OR

II. The member had a serious adverse event with the generic version(s) and the prescriber has provided a copy and confirmation of a MedWatch form submission to the FDA documenting the adverse outcome experienced by the member that includes one of the following (Note: The MedWatch form is available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf):
   A. Was life threatening
   B. Required hospitalization
   C. Caused disability or permanent damage
   D. Required intervention to prevent permanent impairment/damage OR

III. Member has a history of allergic reaction to an inactive ingredient in the generic product and the prescriber has documented the inactive ingredient, the reaction (dates and clinical details), and the manufacturer of the generic product.

IV. Initial approval duration for DAW product request: up to 6 months

V. Subsequent approvals may be renewed for up to 12-month durations, such that chart notes are submitted with the request which clearly document all of the following:
   A. Initial criteria were previously met
   B. Positive clinical response to therapy with the requested brand name product
   C. No toxicities or serious adverse reactions have been experienced with the brand name product

All other uses of Brand Name Medications are considered not medically necessary.

Requests will not be approved for treatment of non-FDA approved diagnoses or conditions not supported by compendia evidence. Please refer to the Medical Necessity – Off-Label policy.

Notes:

- If the requested medication has a Medication Specific Policy, the member will need to meet those requirements in addition to the DAW policy.
- The start date and duration of the trial must be provided.
- There must be paid claims if the member was enrolled with CareSource when a trial of a medication occurred.
- Documented diagnoses must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization requests. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.

Refer to the product package insert for dosing, administration and safety guidelines.

E. Conditions of Coverage

As above.

F. Related Policies/Rules

Medical Necessity – Off Label

G. Review/Revision History

DATES		ACTION
Date Issued	**08/01/2018**	
Date Revised	**08/01/2020**	Reviewed content, transferred to new template, added note about non-coverage of off-label/non-supported use.
	10/28/2022	Section D, part I: Changed bullet A to address inefficacy rather than adverse events, since adverse events are addressed in part II. Created criteria to specify durations of approval and requirements for re-authorization. Made grammatical/wording changes for readability.
Date Effective	**01/01/2023**	
Date Archived		

H. References

1. deShazo RD, Kemp SF. Allergic reactions to drugs and biologic agents. JAMA. 1997;278:1895–906.

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.