CareSource

Administrative Policy Statement
GEORGIA MEDICAID

Policy Name		Policy Number	Date Effective
Medical Necessity – Off Label		PAD-0061-GA-MCD	TBD
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 are based upon generally accepted medical practices in light of Conditions at the time of treatment. Medically Necessary Services are those that are:

i. Required to correct or ameliorate a defect, physical or mental illness, or a Condition
ii. Appropriate and consistent with the diagnosis and the omission of which could adversely affect the eligible Member's medical Condition
iii. Compatible with the standards of acceptable medical practice
iv. Provided in a safe, appropriate, and cost-effective setting given the nature of the diagnosis and the severity of the symptoms
v. Not provided solely for the convenience of the Member or the convenience of the Health Provider
vi. Not primarily custodial care unless custodial care is a Covered Service or benefit under the Member's evidence of coverage
Provided when there is no other effective and more conservative or substantially less costly treatment, service and setting available

Medically necessary services for Mental Health or Substance Abuse Disorder include a service or product addressing the specific needs of that patient for the purpose of screening, preventing, diagnosing, managing or treating an illness, injury, condition, or its symptoms, including minimizing the progression of an illness, injury, condition, or its symptoms, in a manner that is in accordance with the generally accepted standards of mental health or substance use disorder care, clinically appropriate in terms of type, frequency, extent, site, and duration, and not primarily for the economic benefit of the insurer, purchaser, or for the convenience of the patient, treating physician, or other health care 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.

Table of Contents

A. Subject

Medical Necessity – Off Label

B. Background

The U.S. Food and Drug Administration (FDA) approves drugs for specific indications included in the drug's product information label. Off-label or "unlabeled" drug use is the utilization of an FDA approved drug for uses other than those listed in the FDA approved labeling or in treatment regimens or populations that are not included in approved labeling. Many off-label uses are effective, well documented in the peer-reviewed literature, and widely used even though the manufacturer has not pursued the additional indications.

The FDA advises physician's use of off-label or "unlabeled" drugs must be done in a well-informed manner in conjunction with firm scientific rationale and medical evidence. CareSource will employ, at its discretion, drug utilization management programs (i.e., prior authorization) to ensure appropriate and safe use of medications.

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

- **FDA Approved medication**: Is the official description of a drug product which includes indication; who should take it; adverse events; instructions for uses in pregnancy; children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.
- **Off-label or "unlabeled" drug use**: Is the use of a drug approved by the U.S. Food and Drug Administration (FDA) for other uses that are not included in approved labeling. The FDA approves drugs for specific indications that are included in the drug's labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well documented in the literature, and widely used.
- **Medically Necessary Services (includes concepts of Medically Necessary and Medical Necessity):** Based upon generally accepted medical practices in light of Conditions at the time of treatment, Medically Necessary Services are those that are:
    i. Required to correct or ameliorate a defect, physical or mental illness, or a Condition
    ii. Appropriate and consistent with the diagnosis and the omission of which could adversely affect the eligible Member's medical Condition
    iii. Compatible with the standards of acceptable medical practice
    iv. Provided in a safe, appropriate, and cost-effective setting given the nature of the diagnosis and the severity of the symptoms
    v. Not provided solely for the convenience of the Member or the convenience of the Health Provider
    vi. Not primarily custodial care unless custodial care is a Covered Service or benefit under the Member's evidence of coverage
    vii. Provided when there is no other effective and more conservative or substantially less costly treatment, service and setting available

- **Medically Necessary Services (Mental Health or Substance Use Disorder):** The treatment of a mental health or substance use disorder, service or product addressing the specific needs of that patient for the purpose of screening, preventing, diagnosing, managing or treating an illness, injury, condition, or its symptoms, including minimizing the progression of an illness, injury, condition, or its symptoms, in a manner that is:
    i. In accordance with the generally accepted standards of mental health or substance use disorder care;
    ii. Clinically appropriate in terms of type, frequency, extent, site, and duration; and
- Not primarily for the economic benefit of the insurer, purchaser, or for the convenience of the patient, treating physician, or other health care provider.

D. Policy

CareSource will review prior authorization requests for coverage based on medical necessity. This policy will not supersede drug-specific criteria developed and approved by the CareSource Pharmacy and therapeutics Committee (P&T).

Requests for off-label uses of a drug will be considered for approval according to the following criteria:

I. Documentation must be submitted showing the member has tried and failed the existing FDA approved and/or clinical guideline recommended therapies unless contraindicated or not tolerated; AND

II. The prescribed use must be supported by one or more of the following:
    a. Narrative information from American Hospital Formulary Service Drug Information (AHFS) or Clinical Pharmacology
    b. Lexicomp: Evidence level A
    c. Micromedex: Recommendation class I, IIa, or IIb
    d. Evidence from at least two published studies from major scientific or medical peer reviewed journals demonstrates safety and efficacy for the specified condition in a comparable population (i.e., age group, level of disease severity, etc.)
    If applicable clinical trial is yet to be published but interim results are supportive, this may be taken into consideration by the clinician reviewer.

III. Requests for members less than 21 years old are reviewed for coverage for Early and Periodic Screening, Diagnosis, and Treatment (ESPDT) on a case-by-case basis in addition to the criteria above.

NOTE: For off-label use of oncology drugs, please refer to the policy titled "Oncology Regimens" accessible from the CareSource website.

For Reauthorization:

I. Documentation has been provided showing the member has had a positive response to therapy; AND

II. Documentation has been provided showing the member is compliant with therapy.

E. Conditions of Coverage

AUTHORIZATION PERIOD

Approved authorizations are designated an appropriate authorization period. Continued treatment may be considered when the member has shown tolerability and a positive clinical response.

F. Related Policies/Rules

Oncology Regimens

G. Review/Revision History

DATES		ACTION
Date Issued	**06/06/2013**	
Date Revised	**10/30/2014**	Added definition to excluded indications
	05/05/2015	Removed indications in reference of plan specific member handbooks, EOC, etc. Removed specialty and subspecialty associations and combined with no determinations policy
	12/15/2015	Revised class/category and defined evidence criteria for article submissions
	01/11/2018	Updated format
	02/12/2021	Updated format, copied to new template. General edits for clarity. Added note about clinical trials in progress. Removed content related to orphan drugs and compassionate use. Removed cancer drug section and refer to separate policy. Added component that member must try and fail available FDA approved on label drugs first. Amended list of acceptable compendia to include Lexicomp. Updated reference section.
	11/02/2022	Updated the title of the oncology policy that is referenced. No other changes.
	2/24/2023	Added note on EPSDT.
	5/21/2024	Annual review, no updates.
	5/22/2025	Added reauth criteria.
	2/12/2026	Updated medical necessity definition to align with O.C.G.A. 33-21A-13.
Date Effective	**TBD**	
Date Archived		

H. References

1. Medical Benefit Policy Manual. CMS website. Updated August 7, 2020. Accessed February 12, 2021. https://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
2. Official Code of Georgia Annotated. § 33-21A-13.

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.