

Administrative Policy Statement GEORGIA MEDICAID

Policy Name		Policy Number	Date Effective
Multi-ingredient Compound Policy		PAD-0041-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

Administrative Policy Statement.....	1
A. Subject.....	2
B. Background.....	2
C. Definitions.....	2
D. Policy.....	2
E. Conditions of Coverage.....	2
F. Related Policies/Rules.....	4
G. Review/Revision History.....	4
H. References.....	4



A. Subject

Pharmacy – Multi-ingredient Compound Policy.

B. Background

Pharmacy compounding is defined as the combining, mixing or altering of ingredients to create a customized medication for a specific patient. Compounded medications are made based on a practitioner's prescription in which individual ingredients are mixed together in the exact strength and dosage form required by the patient.

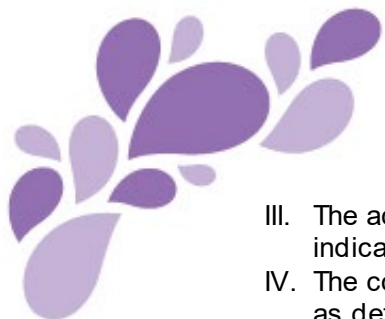
C. Definitions

- **Multi-ingredient Compound** – a product containing two or more ingredients that is not FDA approved and is prepared upon the order of a physician for a patient.
- **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
 - iii. 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

All **multi-ingredient compounds** (except topical pain compounds) will be considered medically necessary when **ALL** of the following criteria are met:

- I. The primary active ingredients in the compound are approved by the FDA for the indication, age or route of administration; OR
- II. If any active ingredient in the compound is not FDA approved for the requested indication, age, or route of administration, must have evidence from TWO published studies from major scientific or medical peer-reviewed journals to support the use of the compound as safe and effective AND



- III. The active ingredients are prescribed in therapeutic amounts based on FDA approved indications AND
- IV. The compound contains only one active ingredient per any specific therapeutic class of drugs as defined by First Data Bank AND
- V. If a compound is similar to a commercially available product but differs in dosage, dosage form, or inert ingredient (such as flavoring, dye, or preservative), chart notes are required from the prescriber supporting the need for the compound (i.e. documented difficulty or inability to swallow oral dosage forms, documented allergies to inactive ingredients) AND
- VI. If any ingredient in the compound, active or inactive, otherwise requires prior authorization, the member must meet criteria established for medical necessity for that ingredient AND
- VII. The member has tried and failed a trial at least 3 preferred medications (if available) that can be used to treat the member's condition. Trial dates must be included with prior authorization request AND
- VIII. Compound will not be covered under the following circumstances:
 1. The compound is being used for an excluded benefit (e.g., cosmetic, obesity, sexual dysfunction, infertility, etc.)
 2. The compound contains ingredients that were withdrawn or removed from the market for safety reasons
 3. The compound is for a product that is commercially available
 4. The compound is for purposes of convenience only.

Topical pain compounds will be considered medically necessary when **ALL** of the following criteria are met:

- I. Member must have a diagnosis of chronic moderate to severe pain associated with neuropathic pain or nociceptive pain AND
- II. Member must have tried at least 3 of the following drugs from different groups for at least 30 days each:
 - a. Non-opioid oral medications or a documented contraindication
 - b. Diclofenac sodium gel 1% or over-the-counter (OTC) Voltaren gel
 - c. Topical lidocaine (e.g., lidocaine cream 3%, 4%, lidocaine patch 4%)
 - d. Topical capsaicin AND
- III. The compound contains no more than 1 active ingredient per any specific drug class as defined by First Data Bank AND
- IV. The compound contains no more than 3 drug classes for active ingredients AND
- V. The compound does NOT contain any controlled substances AND
- VI. The active ingredients must be FDA approved or compendia supported for topical use and for the pain indication.

Reauthorization:

Pain compound:

- Member must have documented improvement of pain supported by chart notes (defined as improvement of at least 3 points on a 0 to 10 point pain scale)

All other compounds:

- Evidence of effectiveness and safety for compound must be documented in chart notes for continuation of approval.

Additional notes:



- Reimbursement will not be provided for additives such as flavorings, dyes, or preservatives.
- Requests resulting from a drug shortage will be considered on a case-by-case basis.

E. Conditions of Coverage

HCPCS

CPT

AUTHORIZATION PERIOD

Initial approval: 3 months or prescriber's requested length of therapy (if shorter than 3 months)

Reauthorization: 12 months

F. Related Policies/Rules

Medical Necessity for Non-Formulary Medications Policy

Medical Necessity - Off Label, Approved Orphan and Compassionate Use Drugs

Member Handbook (Services Not Covered)

G. Review/Revision History

DATES		ACTION
Date Issued	07/01/2016	Initial Release to P&P Committee
Date Revised	08/01/2016	2016 Annual Review with No Changes
	06/01/2017	2017 Annual Review with No Changes
	02/01/2018	Updated criteria to limit compounds to having one ingredient per drug class and 30 day trial of preferred medications
	06/11/2020	Policy moved to the new template. No changes.
	11/30/2021	Updated criteria to include requirement of 2 published studies for off-label requests, reauth criteria, approval durations. Added separate criteria set for pain compounds. Revised trial requirement to be 3 preferred medications. Changed MediSpan to First Data Bank. Removed "not medically necessary" section under Additional notes.
	11/16/2022	Added individual ingredieents must be FDA Approved via indication, age and ROA; Added EOC for Marketplace related policies
	5/21/2024	Annual review, no changes.
	5/22/2025	Annual review, no changes.
	2/12/2026	Updated medical necessity definition to align with O.C.G.A § 33-21A-13 and updated related policies/rules.
Date Effective	TBD	
Date Archived		

H. References

- a. Official Code of Georgia Annotated. § 33-21A-13.



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