ADMINISTRATIVE POLICY STATEMENT
INDIANA MEDICAID

Original Issue Date	Next Annual Review		Effective Date
07/01/2016	06/15/2019		06/15/2018
Policy Name			**Policy Number**
Multi-ingredient Compound Policy			AD-0045-IN-MCD
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.

Contents of Policy

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.
- **Federal Legend Dug** – a drug required by the FDA to have on its label, "Caution: Federal law prohibits dispensing without a prescription."

D. POLICY

Multi-ingredient compounds will be considered medically necessary when **ALL** of the following criteria are met:

I. The primary active ingredient in the compound is a federal legend drug **AND**
II. The active ingredients are prescribed in therapeutic amounts based on FDA approved indications **AND**
III. The compound contains only **one** prescription drug from any specific therapeutic class of drugs as defined by MediSpan **AND**
IV. 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**
V. 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**
VI. The member has tried and failed a **30 day trial** with **ALL** preferred medications that can be used to treat the member's condition. Trial dates must be included with prior authorization request.

Compounds **will not be covered** under the following circumstances:

- The compound does not contain a federal legend drug covered by the plan **OR**
- The compound is being used for cosmetic purposes, performance enhancement, obesity, sexual dysfunction, infertility, other excluded benefit as defined by or any experimental/investigational purpose **OR**
- The compound uses legend ingredients for non-FDA approved indications that is not compliant with CareSource Policy for Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs **OR**
- The compound has an active ingredient that is not FDA approved to be given by the requested route of administration and the requested active ingredient does not meet the requirements set forth in the CareSource Policy for Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs **OR**

- The compound contains ingredients that were withdrawn or removed from the market for safety reasons **OR**
- The compound is for a product that is commercially available **OR**
- The compound is for purposes of convenience only.

Additional notes:

- The following compounded preparations **are not considered medically necessary** by CareSource as they have not been proven to be more effective than commercially available products:
  - Compounded implantable hormone replacement pellets or granules (such as estrogen-based implantable pellets)
  - Bioidentical hormones
  - Topical compounds containing baclofen, gabapentin, and ketamine.
- Reimbursement **will not be** provided for additives such as flavorings, dyes, or preservatives.
- The safety and effectiveness of the compound and its route of administration (including delivery system) must be supported by FDA indication or medical and scientific evidence.
- For compounds used to treat off-label indications, please reference the CareSource Policy for Medical Necessity – Off Label, Approved Orphan and Compassionate Use Drugs for additional requirements for authorization.
- Requests resulting from a drug shortage will be considered on a case-by-case basis.

E. CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

Medical Necessity for Non-Formulary / Non-Preferred Medications Policy
Medical Necessity - Off Label, Approved Orphan and Compassionate Use Drugs

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 criterial to limit to compounds to having one ingredient per drug class and 30 day trial of preferred medications
Date Effective	06/15/2018	

H. REFERENCES

N/A

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