ADMINISTRATIVE POLICY STATEMENT
Kentucky Marketplace

Original Issue Date	Next Annual Review		Effective Date
07/2016	08/2018		06/2017
Policy Name			**Policy Number**
Multi-ingredient Compound Policy			AD-0043
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

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, or any experimental/investigational purpose OR
- The compound uses legend ingredients for non-FDA approved indications or uses that are not compliant with CareSource Policy for Medical Necessity – Off Label OR CORPORATE POLICY / PROCEDURE
- The compound contains ingredients that were withdrawn or removed from the market for safety reasons OR
- The compound uses an unapproved route of administration to deliver a drug product OR
- The compound is for a product that is commercially available OR
- The compound is for purposes of convenience only.

Exceptions include:

- Compounds for those members who have documented difficulty or inability to swallow standard oral dosage forms.
- Compounds for those members who have documented allergies to dyes, preservatives, excipients or other inactive ingredients found in commercial preparations.

NOTE:

- Compounded implantable hormone replacement pellets or granules (such as estrogen-based implantable pellets) are generally not FDA approved.
- 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.
- Prescriber must submit clinical documentation and/or evidence from TWO published studies from major scientific or medical peer-reviewed journals that are < 5 years old preferred and <10 years required to support the proposed use for the specific medical condition as safe and effective.
- Requests resulting from a drug shortage will be considered on a case by case basis.

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:
- The primary active ingredient in the compound is a federal legend drug AND
- The active ingredients are prescribed in therapeutic amounts based on FDA approved indications AND
  - 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), clinical documentation is required from the prescriber supporting the need for the compound AND
  - 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.

E. CONDITIONS OF COVERAGE

F. RELATED POLICIES/RULES

Medical Necessity for Non-Formulary Medications Policy
Medical Necessity - Off Label policy

G. REVIEW/REVISION HISTORY

07/2016 Initial Release to P&P Committee, 08/2016

DATES		ACTION
Date Issued	7/2016	Initial Release to P & P Committee
Date Revised	8/2016	2016 Annual Review with No Changes
Date Effective	6/2017	2017 Annual Review with No Changes

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.