



ADMINISTRATIVE POLICY STATEMENT Indiana Medicaid

Original Issue Date	Next Annual Review	Effective Date
07/2016	08/2018	06/2017
Policy Name		Policy Number
Multi-ingredient Compound Policy		AD-0045
Policy Type		
Medical	ADMINISTRATIVE	Pharmacy
		Reimbursement

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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- The compound contains ingredients that were withdrawn or removed from the market for safety reasons OR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 Drug – 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	07/2016	Initial Release to P&P Committee
Date Revised	08/2016	2016 Annual Review with No Changes
Date Effective	06/2017	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.