Administrative Policy Statement
MARKETPLACE PLANS

Policy Name	Policy Number	Date Effective
Multi-ingredient Compound Policy	PAD-0027-MPP	7/13/2023

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

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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.

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 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 <u>not</u> 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

Non-Formulary Medications Policy

Off Label Medication Requests Policy

Evidence of Coverage ("Prescription Drugs" and "What is 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 ingredients must be FDA Approved via indication, age and ROA; Added EOC for Marketplace related policies
	6/6/2023	Removed “medical necessity,” updated Related Policies and Rules to align with other updated policy names.
Date Effective	**7/13/2023**	
Date Archived		

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.