

Compounded Drug Products Policy

POLICY

I. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- a. Each active ingredient used in the compound are included on the prior authorization request (e.g. dosage form, strengths, quantities, manufacturer National Drug Code (NDC)) OR
- b. The dispensing pharmacy claim has been submitted with all active and inactive ingredients used in the compound (e.g. dosage form, strengths, quantities, manufacturer National Drug Code (NDC))

*Any compounded drug request missing the above documentation may be dismissed as invalid.

II. CRITERIA FOR APPROVAL

- a. Compounded drug products will be covered with prior authorization when the following criteria are met:
 - i. The compounded product contains at least one legend drug.
 - ii. Each of the active ingredients in the compound are FDA-approved for the indication for which the compound is being prescribed or a medically accepted indication as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or peer-reviewed published medical literature indicating that sufficient evidence exists to support use.
 - iii. Each of the active ingredients in the compound are FDA-approved drugs or compendia supported and the compound route of administration is the same as the FDA-approved route of administration for each active ingredient, if applicable.
 - iv. The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration AND the prescribed dose of the compounded product falls within the FDA-approved labeling or within compendia supported dosing guidelines.
 - v. All relevant documentation (e.g. lab values, treatment plan, medical chart notes) is provided.
 - vi. One of the following criteria is met:
 1. There is a current supply shortage of the commercially manufactured product OR the commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or efficacy.
 2. The member has a medical need for a dosage form or dosage strength that is not available commercially or manufactured.
 3. The member has experienced an inadequate treatment response or intolerance (e.g., allergen or adverse effects due to inactive ingredients) to all commercially

available formulary first line agents, including the generic and biosimilar alternative, if available.

III. CONTINUATION OF THERAPY

- a. Member meets all initial criteria in section I & II
- b. Member is tolerating treatment and is not experiencing any unacceptable toxicity from the drug.
- c. Member has disease stabilization or improvement in disease (as defined by established clinical practice guidelines).

IV. EXCLUSION CRITERIA

- a. The requested compounded medication contains an ingredient considered not medically necessary in a compound.
- b. The requested compounded medication contains any ingredients that are not covered per the Neighborhood Health Plan of Rhode Island Pharmacy Benefit Exclusion policy or are being used for any non-covered indication per the Neighborhood Health Plan of Rhode Island Pharmacy Benefit Exclusion policy (e.g. drugs used for cosmetic purposes).
- c. For Neighborhood Medicaid benefit requests only: The requested compounded medication (both active and inactive ingredients) contains drugs or products whose manufacturer does not participate in the Medicaid Drug Rebate Program (MDRP).

V. COVERAGE DURATION

- a. Up to 12 months as determined by FDA dosing guidance and internal policies and procedures.