# Compounded Medications Coverage Exception/Formulary Exception Program Summary

This program applies to all BCBS MN closed plans.

**BACKGROUND[1,2]**
**Position Summary:**

- Drug compounding is defined as the process by which a pharmacist or physician combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs.
- The FDA recognizes pharmacists or physicians have traditionally engaged in extemporaneous drug compounding of reasonable quantities of drugs in response to and upon receipt of a valid prescription for an individually identified patient.
- Drug compounding may be required:
  - For preparation of a medication that has been withdrawn from the marketplace due to economic concerns, NOT safety;
  - To fit the medical needs of a patient because a medication is not commercially available in the strength required;
  - For children and other patients that cannot or have trouble swallowing and require an alternative dosage form (i.e., liquid, suppository);
  - For those patients who have sensitivity to dyes, preservatives, or fillers in commercial products and require allergy-free medications.

**REFERENCES**


1. Federal Food and Drug Administration. Compliance Policy Guide Section 460.200 Pharmacy Compounding. May 2002. http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html Accessed September 8, 2009.
2. Federal Food, Drug, and Cosmetic Act. Drugs and Devices Section 353a. Pharmacy Compounding. https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section353a&num=0&edition=prelim. Accessed July 6, 2021.




 Effective: 11/01/2023

## Compounded Medications Coverage Exception/Formulary Exception

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Compounded Medications** will be approved when ALL of the following are met:

1. The product contains at least one non-formulary prescription ingredient
   **AND**
2. The non-formulary prescription ingredient(s) is/are not excluded from coverage on the pharmacy benefit
   **AND**
3. The non-formulary prescription ingredient(s) is/are FDA approved for medical use in the United States
   **AND**
4. ALL non-formulary prescription ingredients in the compounded product are being used for an FDA approved indication (including the final route of administration)
   **AND**
5. The compounded medication is not a copy of a commercially available FDA-approved drug product UNLESS that commercially available product is the subject of a drug shortage making it unavailable for dispensing
   **AND**
6. If the compounded product is similar to a commercially available product, but differs in dosage, dosage form, and/or omission of dye, sweetener, flavoring, or preservative, then the requested medication is being compounded to meet a specific patient need for which an FDA approved product is not available (e.g., compounding of liquid formulations for patients unable to swallow; compounding for patients with sensitivities to dyes, preservatives or fillers; compounding of therapeutic strengths not commercially available when the dose is not above FDA labeled maximum dose)
   **AND**
7. ONE of the following:
   A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives for the diagnosis being treated with the requested agent
      **OR**
   B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or harm for the patient
      **OR**
   C. The prescriber has attested that the patient has been stabilized on the requested agent for a minimum of 90 days and that switching could potentially cause harm or a health risk

If the compound contains more than one non-formulary prescription ingredient listed above ALL criteria must be met for each individual ingredient. If any component does not meet the criteria, the entire compound will not be covered.

**Length of Approval:** 12 months for compounds containing only non-controlled substances
6 months for compounds containing at least one controlled substance



 