Pharmacy Policy Bulletin: J-0198 Compounded Medications – Commercial and NY Healthcare Reform	
Number: J-0198	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Not applicable**
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** For HCR Plans, policy only applies to NY Plans.
Version: J-0198-016	**Original Date:** 09/04/2013
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Compounded Medications
FDA-Approved Indication(s):	• Various

Background:	• Compounded medications may provide unique dosage forms that allow for a medication to be administered in a way that is not commercially available. However, compounded medications are not regulated by the Food and Drug Administration (FDA) and are not subject to the traditional controlled clinical trials used to determine dosing, efficacy, and safety. • Federal legend drug is defined as a medication product that by Federal law bears the statement "Caution – Federal (U.S.A.) law prohibits dispensing without a prescription" or words of similar meaning (such as "Rx only"). Bulk chemicals, medical food supplements and nutritional additives not approved for dispensing by prescription are not considered federal legend drugs. • This policy addresses requests for compounded medications and the criteria for approval. Coverage may be provided on individual consideration review for pediatric members (age less than 18), members in an active hospice election period, or members with a cancer diagnosis. • The use of Makena (hydroxyprogesterone caproate) to reduce the risk of preterm birth in women with a prior spontaneous preterm birth was not shown to be effective by the FDA. • The FDA states that a health care practitioner considering to prescribe a compounded product containing hydroxyprogesterone caproate should be aware that the FDA has determined Makena and it's generics to not be effective in reducing the risk of preterm birth in women with a prior spontaneous preterm birth.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of compounded medications may be approved when all of the following criteria are met **(A. through E.)**:

A. The compounded medication does not contain any items precluded from coverage unless a covered benefit (for example, items for a cosmetic purpose or erectile dysfunction).
B. The identical product is not commercially available.
C. The compounded product contains at least one FDA approved ingredient and is being used for an FDA-approved indication.
D. The compounded product does not contain any "experimental" or "investigational" ingredients.
E. The member has tried and failed all commercially available formulary products that are FDA approved for the diagnosis being treated.

II. Reauthorization

When a benefit, reauthorization of compounds may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. Compounded medications made from *bulk chemicals* will not be covered by the plan. Bulk chemicals are intended for manufacturing purposes and not dispensing.
III. The use of Makena (hydroxyprogesterone caproate) or hydroxyprogesterone caproate to reduce the risk of preterm birth will not be covered by this policy.

Authorization Duration

Initial Authorization

- Commercial and NY HCR Plans: If approved, up to a 3 month authorization may be granted.

Reauthorization

- Commercial and NY HCR Plans: If approved, up to a 6 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. U.S Food and Drug Administration. Human Drug Compounding. Available at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding. Accessed May 9, 2023.
2. U.S Food and Drug Administration. Makena (hydroxyprogesterone caproate injection) Information. Available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information. Accessed May 9, 2023.