Original Effective Date: 11/01/2020
Current Effective Date: 12/28/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C20382-A

Prescription Compounded Product

PRODUCTS AFFECTED

Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounded drug may include formulary and non-formulary products combined or mixed to create a medication tailored to individual patient need.

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
NA

REQUIRED MEDICAL INFORMATION:
NOTE: PRIOR TO ANY REVIEW FOR EXCEPTION REVIEWER SHOULD VERIFY THERAPY ELIGIBILITY FOR BENEFIT EXCLUSION
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. Clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:

1. Documentation of the member's diagnosis which the compound is intended to treat AND that requested active agent(s) is/are used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)
   AND
2. Documentation of ALL of the following [DOCUMENTATION REQUIRED]:
   a. Quantity of each drug contained in the compound
   b. Quantity of each non-active/inert ingredient contained in the compound
   c. Directions for use
   d. Anticipated duration of therapy

   AND
3. Documentation route of administration is oral, topical, IM, subcutaneous or other route intended for outpatient self-administration
   MOLINA REVIEWER NOTE: See Background for information on requests submitted for reconstitution or as a HCPCS/CPT code
   AND
4. Documentation of ONE of the following [DOCUMENTATION REQUIRED]:
   a. The primary active drug ingredient(s) has/have been approved by the U.S. Food and Drug Administration (FDA) for the member's indication AND the drug is bioavailable in the requested formulation, as evidenced by the route of administration of the compounded product being the same as the FDA-approved route of administration for each active drug product.
   b. The requested compound is supported by compendial supported extemporaneous compounding (e.g., Clinical Pharmacology, AHFS, Micromedex, current accepted guidelines)
   c. Prescriber has submitted copies of relevant full-text articles from at least two major peer-reviewed journals providing evidence of BOTH safety and efficacy for the requested compound.

   AND
5. If the request is for a compounded drug that is usually commercially available but appears on the FDA's drug shortage data base as "currently in shortage", BOTH of the following are met:
   a. Compound is prescribed for an FDA approved indication
      AND
   b. The provider attests that the commercially available product will be used as soon as it is available.
      MOLINA REVIEWER NOTE: Verify shortage at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

   AND
6. Prescriber attests or clinical reviewer has found that the requested compound is not a copy (unless the FDA approved drug is on the FDA shortage list) (See Appendix)
   AND
7. If any of the active drug ingredients require prior authorization, the criteria for authorization of that drug must be satisfied.
   AND
8. Documentation of one of the following:
   a. Member has tried and failed ALL commercially available products indicated for the member's diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
      NOTE: There is preferencing for formulary and generic non-formulary products
      OR
   b. Provider documents ALL commercially available drugs are contraindicated (e.g., allergy to flavoring, dye, preservative), less likely to be effective, or cause an adverse reaction or other harm for member
      OR
   c. The member is currently receiving the requested medication and is at medical risk if therapy changes

   AND

9. Prescriber attests member would be unable to achieve the therapeutic effect of the compound product by using multiple commercially available products.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
2. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.
   AND
3. Documentation that compounded product continues to be medically necessary for the treatment of member's condition
   AND
4. Provider attests that the same clinical effect cannot be achieved using a commercially available product or combination of products.
   AND
5. If the request is for a compounded drug that is usually commercially available but appears on the FDA's drug shortage data base as "currently in shortage", BOTH of the following are met:
   a. Compound is prescribed for an FDA approved indication
      AND
   b. The provider attests that the commercially available product will be used as soon as it is available.
      MOLINA REVIEWER NOTE: Verify shortage at https://www.fda.gov/drugs/drug-safety- and-availability/drug-shortages.

DURATION OF APPROVAL:

Initial authorization: Limited to the time required to evaluate and establish clinical benefit. This time period is dependent on the drug/regimen being requested and the condition being treated- Maximum of 3 months for initial authorization
Continuation of Therapy: up to 6 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

NA

QUANTITY:

To be dispensed in quantity enough for 1 month of therapy or to complete treatment course if treatment is completed in less than 1 month

PLACE OF ADMINISTRATION:

NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Topical, IM/ Subcutaneous

DRUG CLASS:

NA

FDA-APPROVED USES:

NA

COMPENDIAL APPROVED OFF-LABELED USES:
NA

APPENDIX

APPENDIX:
FDA legal restrictions on making copies of FDA-approved drugs (FDA.gov):
Compounded drugs are not approved by FDA. FDA-approved drugs go through FDA's rigorous review for safety, effectiveness, and quality as part of the premarket approval process. Compounded drugs must meet conditions to qualify for exemptions under sections 503A and 503B of the Federal Food, Drug and Cosmetic (FD&C) Act. Among the conditions are:

- Section 503A of the FD&C Act includes restrictions on compounding drugs that are essentially copies of a commercially available drug. When a drug shortage is resolved, FDA generally considers the drug to be commercially available. Certain amounts are permissible under the law as long as the compounding is not done "regularly or in inordinate amounts."
- Section 503B of the FD&C Act restricts outsourcing facilities from making compounded drugs that are essentially a copy of one or more FDA-approved drugs. Among other things, this means the compounded drug may not be identical or nearly identical to an FDA-approved drug unless the approved drug is on FDA's drug shortage list.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
For a drug to be compounded it must qualify for an exception under section 503b of the Federal Food, Drug, and Cosmetic Act (FD&C Act). It must not be "essentially a copy of one or more approved drug products."
As used in section 503b of the FD&C Act, the term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Requests for compounds submitted as a HCPCS or CPT code will be reviewed using the Molina Healthcare, Inc. Physician Administered Drug Policy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Compounded drugs are not FDA-approved and may be considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. Off-label policy. All FDA labeled contraindications are exclusions to any therapy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	NA

AVAILABLE DOSAGE FORMS:
NA

REFERENCES

1. Human Drug Compounding. (2020). Retrieved 7 October 2020, from https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug- compounding
2. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry. (2018). Retrieved 7 October 2020, from https://www.fda.gov/media/98964/download
3. Drug Shortages. (2020). Retrieved 7 October 2020, from https://www.fda.gov/drugs/drug- safety- and-availability/drug-shortages
4. Guidelines for Compounding Practices. (2020). In *The Art, Science and Technology of Pharmaceutical Compounding*. Retrieved from https://www.pharmacist.com/sites/default/files/files/Allen_%20Chap_%201_Art,%20Scien ce%20and %20Technology%20of%20Pharmaceutical%20Compounding,%204e.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Duration of Approval Appendix Contraindications/Exclusions/Discontinuation	Q4 2024
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2023
REVISION- Notable revisions: Title Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Background	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file