Effective Date: 11/01/2020
Last P&T Approval/Version: 10/27/2021
Next Review Due By: 10/2022
Policy Number: C20382-A

Global 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 VERIFYTHERAPY 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

A. ALL INDICATIONS

1. Documentation of the member's diagnosis which the compound is intended to treat AND that requested active agent is 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** the following:
   a. Quantity of each drug contained in the compound
   b. Quantity of each non-active/inert ingredient contained in the compound
   c. Route of administration and directions for use
   d. Anticipated duration of therapy

   AND
3. Documentation of ONE (1) of the following:
   a. That the primary active drug ingredient has been approved by the U.S. Food and Drug Administration (FDA) for the member's indication AND that 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 drugproduct.
   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 (2) major peer-reviewed journals providing evidence of both safety and efficacy for the requested compound.
   d. 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", is prescribed for an FDA approved indication, AND the provider attests that the commercially available product will be used as soon as it is available. [Molina Reviewer: Verify shortage at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages]

   AND
4. If any of the active drug ingredients require prior authorization, the criteria for authorization of that drug must besatisfied.
   AND
5. Documentation of one of the following:
   a. Member has tried and failed ALL commercially available products indicated for the member's diagnosis [NOTE TO REVIEWER: 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-formularyproducts
      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

   AND
6. 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. Documentation of no 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 forthe treatment of member's condition and provider attestation that the same clinicaleffect cannot be achieved using a commercially available product or combination of products.

DURATION OF APPROVAL:
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, Up to 12 months on continuation of therapy request.

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
No age requirement

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

Maximum Quantity Limits – per FDA label

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:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
A prescribing provider on behalf of the member, may make a request to obtain a medication that is not on the health plan's formulary. The plan will review the medical necessity of this request and respond back to the prescribing provider and the member per regulatory and/or accreditation standards.

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."

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. Compound will not be approved if member has any contraindications to any drug or excipient in the compounded product. [Molina Reviewer to review for labeled contraindications to the requested drugs and excipients.]

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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 UnderSection 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