Pharmacy Management Drug Policy

SUBJECT: Compounded Drug Products **POLICY NUMBER: PHARMACY-10** **EFFECTIVE DATE: 11/2010** **LAST REVIEW DATE: 09/13/2024**
If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application		
Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Traditional pharmacy compounding is defined as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription.

POLICY:

Based upon our review and assessment of the peer-reviewed literature, compounded drug products are considered **medically necessary if ALL the following criteria is met:**

1. For orally administered drugs, the compound must be a unique dosage form required for the patient's age, weight, or inability to take a solid dosage form.
2. For safety and efficacy of topical compound preparations (e.g., creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous or any other topical route), requested compound must not contain any FDA approved ingredient that is not FDA approved for TOPICAL use. ***Refer to the policy guidelines for ingredients that are not FDA approved for topical use.***
3. Must not be used for cosmetic purposes. A non-cosmetic indication is defined as a condition that causes physical impairment in a member's ability to perform activities of daily living. ***Refer to the policy guidelines for ingredients commonly used for cosmetic purposes.***
4. Must have documented intolerance or therapeutic failure to two (2) formulary alternatives used to treat the same diagnosis as requested for the compounded product.
5. For Off-Label Non-Cancer - the use of the **exact compounded product** (same dosage form, strength, ingredient mix, etc.) must be:
   A. Listed in DrugPoints or DrugDex and the use is considered medically acceptable if the strength of recommendation is listed as Class I or IIa. If use is not listed, or is listed as IIb, proceed to letter B.
   B. The off-label use is considered medically acceptable if there is supporting published clinical research that meets all the following criteria:
      i. At least one phase III clinical trial that definitively demonstrates safety and effectiveness of the off-label use of the requested drug

ii. The trial must be published in national or international peer-reviewed (editorial committee is comprised of physicians) journal. This excludes case reports, letters, posters, and abstracts
iii. The trial must establish appropriate dose and dosing frequency (approvals will be limited to the dosing regimen established in the literature)
iv. In determining whether the clinical trial is definitively supportive, the following will be assessed:
    a. The prevalence of the disease and subject size sufficient to determine statistical validity
    b. Whether the clinical characteristics of the patient and the indication are adequately represented in the published evidence
    c. The effect on the individual's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, and signs and symptoms)
    d. Whether the study outcomes represent clinically meaningful outcomes experienced by patients
    e. Appropriateness of study design (accepted study design: randomized, double blind, placebo controlled clinical trial)

C. If the request is not supported by compendia or literature as listed above, then the request is not considered medically appropriate and will be denied as experimental and/or investigational.

6. For Off-Label Cancer - the use of the **active ingredient** must be:

A. Listed in DrugPoints or DrugDex and the use is considered medically acceptable if the strength of recommendation is listed as Class I or IIa. If use is not listed, or is listed as IIb, proceed to letter B.

B. Consult NCCN Drugs and Biologics Compendium. Use is considered medically acceptable if the indication is given a category of 1 or 2a. If the use is not listed, or is listed as category 2b, proceed to letter C.

C. Consult AHFS and/or Clinical Pharmacology. Use is considered medically acceptable if the narrative text for the indication is supportive. If the use is not listed or supported proceed to letter D.

D. Consult peer-reviewed literature for support. Use is considered medically acceptable if there is at least 1 published article in a major professional peer reviewed journal, which supports the off-label use of the requested drug. Article should reference a sufficient number of subjects in relation to the incidence of the disease being treated. The article should also support that the off-label use is generally safe in relation to the severity of the disease being treated and the other existing treatment options. Evidence of clinically meaningful outcomes should be experienced by patients. If there are no full articles available in peer reviewed literature proceed to letter E.

E. If the request is not supported by compendia or articles as listed above, then the request is not considered medically appropriate and will be denied as experimental and/or investigational.

7. For All Medicare Compound Requests, please refer to DLP 020, Medicare Part-D, Evaluating Compound Claims.

8. Approvals will be for 1 year. Recertification requires documented compliance with the same compound as originally approved (same dosage form, strength, ingredient mix, etc.).

9. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

POLICY GUIDELINES:

1. Consideration for coverage of all compounded prescription drug products requires that the dispensing pharmacy electronically submit within the claim a compound ingredient list only containing National Drug Codes (NDCs) recognized by the point-of-sale claims adjudication system of the pharmacy benefits manager (PBM). If any NDCs of compound ingredients listed within a claim are not recognized by the point-of-sale claims adjudication system (e.g., claim rejects, or would reject in the case of a retrospective paper claim, for missing or invalid NDC), then the compounded drug product cannot be considered for coverage determination and coverage will not be allowed. Should a member pay out-of-pocket for a compounded prescription drug product that contains ingredient NDCs not recognized by the point-of-sale claims adjudication system, consideration for coverage will similarly not be allowed on retrospective review if the member requests reimbursement from the plan for their out-of-pocket costs. Members are advised to exercise caution when electing to pay out-of-pocket for compounded drug products. If a pharmacy is unwilling or unable to submit electronic claims for compounded drug products which contain *only* NDCs recognized by the point-of-sale claims adjudication system, a member should assume that such a compounded drug product will not be covered by the plan.

2. Common ingredients that are NOT FDA-approved for topical use and are therefore excluded (list is not all-inclusive):

• amantadine	• levocetirizine
• amitriptyline	• meloxicam
• baclofen	• morphine
• chorionic gonadotropin (human)	• nabumetone
• cyclobenzaprine	• orphenadrine
• diclofenac (except for topical ophthalmics and products with NDA or ANDA which are not excluded)	• oxycodone
• flurbiprofen (except for topical ophthalmics which are not excluded)	• oxytocin
• gabapentin	• pentoxyifylline
• hydrocodone	• piroxicam
• ketamine	• sumatriptan
• ketoprofen	• tramadol
• lamotrigine	

3. Common ingredients that are used for cosmetic purposes (list is not all-inclusive):

• acetyl hexapeptide-8	• PCCA Spira-Wash™
• Chrysaderm day cream™	• Pracasil tm-plus™
• Chrysaderm night cream™	• tocopheryl acid succinate
• hydroquinone	• Versapro™
• Lipopen ultra™	

4. The following ingredients used in the usual practice of extemporaneous compounding have been reviewed as medically necessary and will be approved:

• Cherry Syrup	• Ora-Sweet
• Ora-Plus	• Sodium bicarbonate solution

UPDATES:

Date	Revision
09/13/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
1/29/2024	Reviewed
08/11/2023	Revised
04/01/2023	Revised
02/09/2023	P&T Committee Approval
01/25/2023	Reviewed
02/10/2022	Reviewed / P&T Committee Approval
1/26/2022	Reviewed
2/11/2021	P&T Approval
1/14/2021	Reviewed
2/13/2020	P&T Approval
2/20	Revised
1/20	Reviewed
1/19	Reviewed
6/18	Revised
2/18	Reviewed
5/17	P&T Approval
2/17	Revised
5/16	Revised
11/14	Revised
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