Pharmacy Management Drug Policy

SUBJECT: Compounded Drug Products
POLICY NUMBER: PHARMACY-10
EFFECTIVE DATE: 11/2010
LAST REVIEW DATE: 1/24/2019

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. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

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 of 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 listed in DrugDex as recommendation class IIA or higher. If the exact compounded product is listed as IIb or is not listed, then the **provider must submit** 1 published article or 2 published abstracts with a sufficient number of subjects demonstrating that the use of the exact compounded drug product is generally safe and results in clinically meaningful outcomes.

6. For off-label cancer - the use of the **active ingredient** must be listed in NCCN as recommendation class IIA or higher. If the active ingredient is listed as IIb or is not listed, then the **provider must submit** 1 published article or 2 published abstracts with a sufficient number of subjects demonstrating that the use of the active ingredient is generally safe and results in clinically meaningful outcomes.

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

POLICY GUIDELINES:

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

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

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

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

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

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

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UPDATES:

Date	Revision
1/19	Reviewed
6/18	Revised
2/18	Reviewed
5/17	P&T Approval
2/17	Revised
5/16	Revised
11/14	Revised
4/14	Reviewed
4/13	Reviewed