Compound High Dollar Limit

Description

Compound High Dollar Limit

Background
Pharmacy compounding is an ancient practice in which pharmacists combine, mix or alter ingredients to create unique medications that meet specific needs of individual patients. Some examples of the need for compounding products would be: the dosage formulation must be changed to allow a person with dysphagia (trouble swallowing) to have a liquid formulation of a commercially available tablet only product, or to obtain the exact strength needed of the active ingredient, to avoid ingredients that a particular patient has an allergy to, or simply to add flavoring to medication to make it more palatable.

The compounded formulations can contain just one active drug in a base vehicle or they may contain a combination of active drugs. Certain drug compounds would not be covered by the plan. Below is a list of reasons why a compound would not be covered:

1) No FDA-approved indication supporting the use of the compounded product
2) Dosage form and strength is commercially available
3) Drug strength exceeds the FDA-approved maximum dose of the ingredient

Compounded products used in the treatment of erectile dysfunction (ED) or for cosmetic purposes are excluded from coverage.

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Compounded drug products may be considered **medically necessary** if the compounded product is being used for an FDA-approved indication, the formulation requested is an FDA-approved formulation; the strength requested is not available commercially and does not exceed the FDA-approved strength of the product; and is not being used for cosmetic, performance enhancement or erectile dysfunction purposes.

Compounded drug products may be considered **investigational** in diagnoses that are off-label or in formulations that do not have a confirmed FDA approval of use.

**Prior-Approval Requirements**

**Diagnoses**

The compounded product must have **ALL** of the following:

1. FDA-approved indication supporting the use of each compounded ingredient for the diagnosis provided
2. Dosage form and strength of each ingredient is **NOT** commercially available
3. Drug strength of each ingredient does **NOT** exceed the FDA-approved maximum dose of the ingredient
4. If a compounded medication is equivalent to a commercially available product, but differs from the commercially available products with the omission of a sweetener, dye, flavoring or preservative, clinical documentation is required from the prescriber supporting the need for the compound.

**AND NOT** the following:

1. Used for cosmetic (including but not limited to anti-wrinkle, hair growth / removal, scar prevention, scar diminishing, skin lightening / tanning, anti-aging), performance enhancing or erectile dysfunction purposes

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None
5.99.10

Section: Prescription Drugs
Effective Date: July 1, 2019
Subsection: Miscellaneous Products
Original Policy Date: July 1, 2014
Subject: Compound High Dollar Limit
Page: 3 of 3

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Compounded drug products may be considered medically necessary if the compounded product is being used for an FDA-approved indication, the formulation requested is an FDA-approved formulation; the strength requested is not available commercially and does not exceed the maximum FDA-approved strength of the product; and is not being used for cosmetic, performance enhancement or erectile dysfunction purposes.

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of compounded drug products while maintaining optimal therapeutic outcomes.

Policy History

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<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>June 2014</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2015</td>
<td>Annual review</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review</td>
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<tr>
<td></td>
<td>Policy code changed from 5.11.10 to 5.99.10</td>
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<tr>
<td>June 2017</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.