Compounding Kits

Description

Compounding Kits

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

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Compounding kits may be considered medically necessary if each ingredient in the compounded product is FDA approved for the requested diagnosis, each ingredient is a legend...
drug, the formulation requested is an FDA-approved formulation, the strength requested is not available commercially, and each ingredient does not exceed the FDA-approved strength for the ingredient.

Compounding kits 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

The compounded product must have ALL of the following:
1. Each ingredient must be FDA approved for the requested diagnosis
2. Each ingredient must be a legend drug
3. Dosage form of each ingredient is commercially available
4. Strength requested is not available commercially
5. Each ingredient does NOT exceed the FDA-approved maximum dose of the ingredient

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Compounding kits 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 each ingredient does not exceed the maximum FDA-approved strength of the ingredient.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2014</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>December 2016</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Addition of strength requested is not available commercially</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.11.13 to 5.99.13</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

### Keywords

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