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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Miscellaneous Products	**Original Policy Date:**	July 1, 2014
Subject:	Compound High Dollar Limit	**Page:**	1 of 3

Last Review Date: March 12, 2021

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 and if the conditions indicated below are met.

Compounded drug products may be considered **investigational** in diagnoses that are used 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

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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.

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

Date	Action
June 2014	Addition to PA
September 2015	Annual review
December 2016	Annual editorial review Policy code changed from 5.11.10 to 5.99.10
June 2017	Annual review
June 2018	Annual review
June 2019	Annual review
June 2020	Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.