

RATIONALE FOR INCLUSION IN PA PROGRAM

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.

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.