Medication Policy Manual | **Policy No:** dru135

Topic: Compounded Medications | **Date of Origin:** July 28, 2006

Committee Approval Date: August 11, 2017 | **Next Review Date:** August 2018

Effective Date: September 1, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

The FDA defines drug compounding as the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs.

In order to be covered, a compounded prescription medication must contain at least one federal legend drug in therapeutic amounts. A federal legend drug is defined as a medication product that by Federal law bears the statement "Caution – Federal (U.S.A.) law prohibits dispensing without a prescription" or words of similar meaning (such as "Rx only"). Bulk chemicals, medical food supplements and nutritional additives not approved for dispensing by prescription are not considered federal legend drugs. The policy below defines criteria that must be met in order for compounded prescriptions to be covered.

Policy/Criteria

I. A compounded prescription medication may be considered medically necessary when the following criteria are met:

A. The active ingredient in the compounded prescription medication contains at least one federal legend drug component.

AND

B. The active ingredient is present in therapeutic amounts, based on scientific literature or national compendia.

AND

C. The safety and effectiveness for the compounded medication and its route of administration (including the delivery system) is supported by scientific literature or national compendia.

AND

D. If a compounded prescription medication is similar to a commercially available product, but differs from the commercially available product in dosage, dosage form, and/or omission of dye, sweetener, flavoring, or preservative, then clinical documentation is required from the prescriber supporting the clinical need for the compounded medication.

II. Authorization may be reviewed annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

Summary

- The FDA recognizes the ability of pharmacists or physicians to engage in traditional extemporaneous drug compounding of reasonable quantities of drugs in response to receipt of a valid prescription. [1]
- Drug compounding may be required to fit the medical needs of a patient because a medication is not commercially available in the necessary strength or dosage form. Drug compounding may also be required for:
  * Preparation of a medication that has been withdrawn from the market for economic concerns, NOT safety.
  * Patients who require liquid formulations or rectal suppositories due to difficulty or inability to swallow.
  * Allergies to dyes, preservatives, or fillers in commercial products which require allergy-free medications.
- Drug compounding for the purposes of a convenience is not considered medically necessary.

Federal and State Regulation

- The FDA provides rules and guidance to assure compounding activities performed by pharmacies and/or physician offices are maintained within the realm of traditional pharmacy practice and that activities are not those that would be considered manufacturing and distributing of an unapproved new drug. [1,2]
- The FDA receives guidance from the Pharmacy Compounding Advisory Committee (PCAC), which was established to advise the FDA on scientific, technical, and medical issues related to drug compounding. The FDA will also consult with the PCAC before issuing certain regulations. [2,3]
- Regulation of compounding is generally done at the state level. States may vary in their regulation and definitions of compounding. The FDA has oversight when compounding is considered manufacturing.

References

1. Federal Food and Drug Administration. The practice of pharmacy compounding. www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm (accessed February 20, 2017).
2. Federal Food and Drug Administration. FDA implementation of the Compounding Quality Act. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm (accessed February 20, 2017).
3. Federal Food and Drug Administration. Pharmacy Compounding Advisory Committee Roster. https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm381301.htm (accessed March 16, 2015).

Revision History

Revision Date	Revision Summary
08/11/2017	No changes to coverage criteria with this annual update.
03/10/2017	No changes to coverage criteria with this annual update.