

**Regence BlueCross BlueShield of Oregon · Regence BlueShield
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho
Independent licensees of the Blue Cross and Blue Shield Association**

Medication Policy Manual

Policy No: dru135

Topic: Compounded Medications

Date of Origin: July 28, 2006

Revised/Effective Date: July 17, 2009

Next Review Date: July 2010

IMPORTANT REMINDER

This Medical 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 medical policy is to provide a guide to coverage. Medical 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. Government legislation, such as the Federal Drug and Cosmetic Act (FDCA) of 1938, and the Food and Drug Administration Modernization Act (FDAMA) of 1997, exempts drug compounding, so long as providers of the compounded drugs abide by several restrictions listed in the FDA Compliance Policy Guide.

In order to be covered, a compounded prescription 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, 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 may be considered medically necessary when all the following criteria below are met:

A. The active ingredient in the compounded product contains at least one legend medication component.

AND

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

AND

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

AND

D. If a compound 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 compound.

II. Authorization Period

Authorization may be given for up to 1 year when the patient meets the above criteria. Authorization shall be reviewed to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

Summary

- Drug compounding is defined 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.
- The FDA recognizes pharmacists or physicians to engage in traditional extemporaneous drug compounding of reasonable quantities of drugs on response and receipt of a valid prescription.
- Drug compounding may be required to fit the medical needs of a patient because a medication is not commercially available in the 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 that cannot or may have trouble swallowing and require liquid formulations or rectal suppositories.
 - * Allergies to dyes, preservatives, or fillers in commercial products and 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 are not manufacturing and distributing of an unapproved new drug.

- Regulation of compounding is generally done at the state level. States may vary in their regulation and definitions of compounding.

References

1. Federal Food and Drug Administration. The practice of pharmacy compounding. www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.t.htm (accessed June 23, 2009).

Cross References
None

Codes	Number	Description
N/A		