Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Compounded Medications

Policy Number: 5.01.513
Origination: 10/2002
Last Review: 10/2018
Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for compounded medications when the criteria shown below are met.

When Policy Topic is covered

Any prescription that requires a pharmacist to compound a drug prior to dispensing will require prior authorization if the submitted cost is over $50.00.

- The prior authorization request is to be generated by the physician.
- All active ingredients must be documented on the prior authorization form.
- Diagnosis and indication for the compounded medication is required.

A compounded prescription may be considered medically necessary when all of the following criteria below are met:

- The primary active ingredient in the compounded product must be a legend medication.
- The primary active ingredient must be in therapeutic amounts, based on peer reviewed scientific literature or national compendia.
- The safety and effectiveness for the compounded medication and its route of administration (including the delivery system) is supported by peer reviewed scientific literature, clinical trials, or national compendia. It is the responsibility of the requesting prescriber to provide this documentation.
- If a compounded 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 compound.

When Policy Topic is not covered

Compounded medications are considered not medically necessary if the criteria above are not met.

Compounded formulations in which the legend ingredient(s) are being used for treatment other than those indications approved by the FDA are considered investigational (for example ketamine containing compounds for topical application in the treatment of pain syndromes).

Considerations

Members who purchase compounded products and submit for reimbursement must meet the same requirements before reimbursement will be approved.

For criteria for coverage of compounded hormone replacement therapy, please refer to policy 5.01.503 Custom Compounded Hormone Replacement Therapy.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and

Comparisons, National specialty guidelines, Medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Drug compounding is 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 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.

Rationale

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 when:

- A medication has been withdrawn from the market for economic concerns, NOT safety.
- The patient has trouble swallowing and requires liquid formulations or rectal suppositories.
- Due to allergies to dyes, preservatives, or fillers in commercial products the patient requires allergen free medications.

Drug compounding for the purposes of a convenience is not considered medically necessary.

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.

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

Resources

1. Federal Food and Drug Administration. FDA Regulation of Compounded Drugs. www.fda.gov/cder/pharmcomp/default.htm. (accessed October, 2008).

Billing Coding/Physician Documentation Information

N/A

Additional Policy Key Words

5.01.513

Policy Implementation/Update Information

10/2002	Policy origination date
10/2003	Reviewed – no changes made
10/2004	Reviewed – no changes made
07/2005	Revised – policy became administrative
10/2005	Reviewed – no changes made
10/2006	Reviewed – no changes made

10/2007 Reviewed – no changes made
10/2008 Revised – updated policy statement to reflect: A compounded prescription may be considered medically necessary when all the following criteria below are met: The primary active ingredient in the compounded product must be a legend medication. The primary active ingredient is in therapeutic amounts, based on peer reviewed scientific literature or national compendia. The safety and effectiveness for the compounded medication and its route of administration (including the delivery system) is supported by peer reviewed scientific literature, clinical trials, or national compendia. If a compounded 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 compound.
10/2009 Reviewed – no changes made
10/2010 Reviewed – no changes made
10/2011 Reviewed – no changes made
10/2012 Reviewed – no changes made
10/2014 Reviewed – no changes made
10/2015 Reviewed – no changes made
10/2016 Reviewed – no changes made
10/2017 Reviewed – no changes made
10/2018 No changes made
