

Aetna Compounded Drug Products Coverage Policy (Non-Medicare Prescription Drug Plan)

PURPOSE:

The purpose of this policy is to define coverage criteria for compounded drug products.

BACKGROUND: Pharmacist compounding of medication is the combination of the art and science of pharmacy. The pharmacist begins with the unique needs of the individual patient for a medication not commercially available in the strength, flavor, or dosage form required. Pharmacist compounding may be required:

- For preparation of a medication that has been withdrawn from the marketplace due to economic concerns, NOT safety;
- For those patients that cannot or have trouble swallowing and require a concentrated liquid or a rectal suppository;
- For those patients who have sensitivity to dyes, preservatives, or fillers in commercial products and require allergy-free medications;
- For children who require liquid medications

According to the FDA Compliance Policy Guide on Pharmacy Compounding, there is a list of factors that the FDA will consider in exercising its enforcement discretion regarding pharmacy compounding. The FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the Federal Food, Drug and Cosmetic Act, the FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency has stated that it will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.
3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

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8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

MEDICAL EXCEPTION COVERAGE POLICY

In the absence of a published Aetna Clinical Policy Bulletin to the contrary, compounded drug products are considered medically necessary if ALL of the following criteria are met:

1. The product contains at least one prescription ingredient AND
2. The prescription ingredient is FDA-approved for medical use in the United States AND
3. The compounded product is not a copy of commercially available FDA-approved drug product AND
4. The safety and effectiveness of use for the prescribed indication is supported by FDA-approval or adequate medical and scientific evidence in the medical literature.

Note: Medical and scientific evidence is defined as any one of the following:

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
- Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR).
- Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x).
- The following standard reference compendia:
 - DrugPoints® System, American Hospital Formulary Service Drug Information (AHFS-DI), MicroMedex's DrugDex, Clinical Pharmacology, and National Comprehensive Cancer Network (NCCN) Drug & Biological Compendia
- Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - Agency for Healthcare Research and Quality, National Institutes of Health,
 - National Cancer Institute, National Academy of Sciences,
 - Center for Medicare and Medicaid Services, and
 - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services

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- Peer-reviewed abstracts accepted for presentation at major medical association meetings. The following compounded preparations are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer - reviewed published medical literature of their effectiveness:
 - Bioidentical hormones (see Medical CPB 0388: Complementary and Alternative Medicine Bioidentical hormones (see Medical CPB 0388: Complementary and Alternative Medicine http://www.aetna.com/cpb/medical/data/300_399/0388.html)
 - Implantable estradiol pellets (see Medical CPB 0345: Implantable Hormone Pellets http://www.aetna.com/cpb/medical/data/300_399/0345.html)
 - Verapamil topical cream (see Medical CPB 0007: Erectile Dysfunction http://www.aetna.com/cpb/medical/data/1_99/0007.html)
 - Nebulized anti-infectives, nasal administration (see Medical CPB #593: Aerosolized Anti-infective Treatment for Sinusitis http://www.aetna.com/cpb/medical/data/500_599/0593.html)
 - Ketamine topical gel

AUTHORIZATION PERIOD AND LIMITATIONS:

Initial Approval: 1 (ONE) year

NON COVERAGE POLICY:

The following drugs/compounds are NOT covered:

1. Any drug coded as a pharmaceutical aid, such as bulk powders
2. Any drug coded as OTCs
3. Any compounding kits
4. Compounded pain patches

REFERENCES:

General Compounding

1. <http://www.fda.gov/cder/pharmcomp/default.htm>.

Bioidentical Drugs

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Implantable Estradiol Pellets

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NSAIDs in PLO (pluronic lecithin organogel)

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Hydroxyprogesterone Injection

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Verapamil in Peyronie's Disease

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Ketamine Gel

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