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PHARMACY / MEDICAL BENEFIT COVERAGE GUIDELINE – 5.01.546

Medical Necessity Criteria for Compounded Medications

Effective Date:	Mar. 1, 2025	RELATED GUIDELINES / POLICIES:
Last Revised:	Feb. 24, 2025	5.01.529 Management of Opioid Therapy
Replaces:	N/A	5.01.549 Off-Label Use of Drugs and Biologic Agents

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Introduction

A compounded medication is a specially mixed prescription drug. A licensed pharmacist makes this kind of medication if a person needs a custom dose or a different way of taking the medication. Compounded drugs can combine two or more drugs. Compounded drugs are sometimes used when other drugs are not available due to drug shortages. They can also be used if a person needs a drug in a dose or form that a drug company doesn't make. For example, if a person is unable to swallow a pill, a liquid form of the drug may be compounded. Another example would be when a person is allergic to a dye in a medication, a compounded medication can be made without that dye. It's important to note that compounded drugs are not evaluated for safety or effectiveness and are not approved by the Food and Drug Administration. This policy describes when a compounded drug may be considered medically necessary. This policy is not intended to apply to infused admixtures.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Coverage Guidelines

Medication	Medical Necessity
Compounded medications	**Compounded medications may be considered medically necessary when ALL the following criteria are met:** • The primary active ingredient in the compounded medication must be a legend medication **AND** • The active ingredients must be in therapeutic amounts, based on Food and Drug Administration (FDA) indication or adequate medical and scientific evidence **AND** • The safety and effectiveness of the compounded medication and its route of administration (including delivery system) is supported by FDA indication or adequate medical and scientific evidence (such documentation is the responsibility of the prescriber to provide) **AND** • If a compounded medication is similar to a commercially available product, but differs from the commercially available products in dosage, dosage form, and/or omission of a sweetener, dye, flavoring or preservative, clinical documentation is required from the prescriber supporting the need for the compound **AND** • If any active ingredient in the compound otherwise requires prior authorization, the member must meet criteria established for medical necessity for that ingredient **Note:** This policy does not apply to infused admixtures.

Medication	Coverage Not Provided
Compounded medications	**Coverage for compounded medications will not be provided under the following circumstances:** • Any compound that does not contain a legend drug otherwise covered by the plan **OR**

Medication	Coverage Not Provided

	• Compounds used for cosmetic, performance enhancing or experimental/investigational purposes
	OR
	• Compounds using legend ingredients for non-FDA approved indications or uses that are not compliant with the policy for off-label use of drugs and biologic agents (see **Related Guidelines/Policies**)
	OR
	• Compounded formulations that use drugs withdrawn or removed from the market for safety reasons
	OR
	• Compounded formulations that use an unproven route of administration to deliver a drug product
	OR
	• Prescription ingredients compounded for purposes of convenience only
	  ○ Exceptions include:
	  ▪ Formulation for those members who have difficulty or inability to swallow standard oral dosage forms who require the use oral liquid or non-oral routes of administration. Examples include, but not limited to, individuals requiring the use of nasogastric tubes or children who require prescription medication for which no liquid formulation is commercially available
	  ▪ Formulations for those who have documented allergies or sensitivities to one or more of the following: dyes, preservatives, excipients, or other inactive ingredients found in commercial preparations

Medication	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**
Compounded implantable hormone replacement pellets	**Compounded implantable hormone replacement pellets or granules (such as estrogen-based implantable pellets) are considered investigational:**

Medication	Investigational
	• Rationale: The FDA's Fertility and Maternal Health Drugs Advisory Committee unanimously agreed to terminate compassionate investigative new drug (IND) programs for estrogen pellets as a last-resort treatment of menopausal disorder. • The Committee noted "the risk of bleeding and infection, the lack of information on release rates, difficulty in reversibility of the drug, increased feasibility of over-dosage of the drug, and increased risk of non-compliance with safety measures [such as] the addition of progestin."

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for compound drugs may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for compound drugs may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, medication history, route of administration for compound, and ingredients in compound

Coding

Code	Description
HCPCS	
J7999	Compounded drug, not otherwise classified

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

This guideline applies to all pharmacy benefit contracts that include point of sale/prior authorization edits.

This guideline applies to all medical benefit contracts.

Background

Pharmacy compounding is the practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. Pharmacy compounding, if done properly, can serve an important public health need if an individual cannot be treated with a Food and Drug Administration (FDA)-approved medication. The end product of the compounding practice is referred to as a compounded medication or compounded formulation.

Compounded medications may replace those that are temporarily unavailable due to drug shortages, or those that are not commercially available in terms of dosage forms or combinations of medications. These forms may serve a useful function for individuals who are unable to swallow standard oral dosage forms and may require liquid forms to continue their therapy.

Unlike FDA-approved medications, compounded medications are not clinically evaluated for safety or efficacy. Compounding pharmacies are not subject to statutes governing good manufacturing practices. They are required to comply with United States Pharmacopeia Chapters 795 and 797 which specifies conditions for safe compounding practices for non-sterile and sterile compounded medications. The FDA generally defers to state boards of pharmacy to enforce these guidelines.

Coverage is subject to the coverage limitations and exclusions of the member's contract. Medical necessity of covered medications is governed by approved FDA indications as well as related guidelines and policies (see **Related Guidelines / Policies**).

2018 Update

Annual review – no changes required.

2019 Update

Reviewed Food and Drug Administration information on Human Drug Compounding and no changes were made to medical necessity criteria. Updated references.

2020 Update

Added tables for Length of Approval and Documentation Requirements to standardize policy format.

2021 Update

Annual review with no changes to policy statements.

2022 Update

Added a note that this policy does not apply to infused admixtures.

2023 Update

Annual review with no changes to policy statements.

2024 Update

Annual review with no changes to policy statements.

2025 Update

Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

References

1. Food and Drug Administration Human Drug Compounding. **https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding** Accessed February 10, 2025.
2. Lyon J, Drug shortage compounding: the only safe medication source in a time of crisis Int J Pharm Compd. 2012 Nov-Dec;16(6):456-60.
3. Lam MS, Extemporaneous compounding of oral liquid dosage formulations and alternative drug delivery methods for anticancer drugs Pharmacotherapy. 2011 Feb;31(2):164-92.
4. Gudeman J, Jozwiakowski M et al. Potential Risks of Pharmacy Compounding Drugs R D 2013;13(1)1-8.

History

Date	Comments
10/09/12	New policy added to Prescription Drug section. Policy approved with 90-day provide notification hold. The policy is effective February 11, 2013.
01/22/13	Policy effective date delayed and is now April 1, 2013.
03/11/13	Replace policy. Policy updated within the Policy Guidelines, clarifying criteria added, removed and rearranged; Description section removed; Rationale section significantly updated; references added, removed, renumbered and updated. Policy effective date remains 4/1/13.
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
11/10/14	Annual review. Covered to Benefit Coverage Guideline template. Coverage information added to address hormone pellets; considered investigational. Notation in header section removed indicating coverage is managed by the pharmacy benefit.
10/13/15	Annual Review. Policy reviewed; no change in policy statements.
01/19/16	Coding update. New CPT code J7999, effective 1/1/16, added to policy.

Date	Comments
01/01/17	Annual Review, approved December 13, 2016. Policy reviewed; no change in policy statements.
09/01/17	Annual Review, approved August 22, 2017. No changes to policy statements. Statement added to intro "This policy is not intended to apply to infused admixtures."
11/01/18	Annual Review, approved October 26, 2018. No changes to policy statements.
01/01/20	Annual Review, approved December 10, 2019. No changes to policy statements.
12/01/20	Annual Review, approved November 19, 2020. No changes to policy statements. Added tables for Length of Approval and Documentation Requirements.
10/01/21	Annual Review, approved September 23, 2021. No changes to policy statements.
11/01/22	Annual Review, approved October 24, 2022. Added a note that this policy does not apply to infused admixtures. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 20, 2023. No changes to policy statements.
08/01/24	Annual Review, approved July 22, 2024. No changes to policy statements.
03/01/25	Annual Review, approved February 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.