

Title: Compounded Products

Policy #: Rx.01.134

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for compounded products, consistent with Pharmacy Compounding of Human Drug Products Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, where at least one ingredient is a prescription drug, as provided under the member's prescription drug benefit.

This policy will also be used to review requests for ingredients which are not considered standard coverage under the prescription drug benefit that are used in compounded products. This includes requests for injectable medications that are used as part of a compound for a route of administration other than injectable.

Description:

The Food and Drug Administration (FDA) defines pharmacy compounding as the practice in which pharmacists combine, mix, or alter ingredients to create unique medications that meet the specific needs of an individual patient. Generally, drugs are compounded for patients that have allergic reactions to inactive ingredients in FDA approved products or for those patients who require a different formulation of a medication that is not commercially available.

Compounding pharmacies are regulated by State Boards of Pharmacy and the FDA (if they are outsourcing facilities). For non-outsourcing facilities, drugs can be compounded only if certain conditions are met, such as, valid prescription requirement for an identified individual patient; or in limited quantities before obtaining the actual prescription by the pharmacy. Moreover, FDA restricts the production of essential copies of approved and unapproved non-prescription drugs.

A compounded product is not considered medically necessary when it replicates a commercially available product (unless the commercially available product is temporarily unavailable), contains a drug product or component that has been removed from the market because it is unsafe or not effective or contains a drug product or component that is excluded from the member's benefit.

Policy:

A compounded product, including a commercially available compounding kit, is considered medically necessary when ALL of the follow inclusion criteria are met:

- A. The active prescription ingredient(s) of the compound is FDA approved or supported by accepted compendium as stated in the Off-Label Use policy for the indication and route of administration; AND
- B. The product as compounded is not commercially available. This may include a current short supply* of the commercially available product or the member has a medical need for a dosage form, strength or formulation other than what can be accomplished with a commercially available product; AND
- C. Member had an inadequate response or inability to tolerate all commercially available therapeutic alternatives to treat the condition for which the compound has been requested; AND
- D. The compound does not contain any product(s) that were withdrawn or removed from the market due to safety reasons; AND
- E. The compound is not used for, nor does it contain, a product that is indicated for an excluded benefit (e.g., cosmetic)

Additionally, authorization may be placed to allow access to the prescription benefit for products that are not considered standard coverage (e.g. drugs administered intravenously) when all the following criteria are met:

- A. All of the above criteria are for medically necessary are met for the compounded product; AND

- B. The product is being used in a compound that will be administered through a route that is considered standard coverage for the prescription benefit (e.g., oral, topical, inhalation, etc.). Bladder installation may be considered if the above criteria are met.

Authorization length for short supply of the commercially available product will be six months.

All other authorizations: 2 years

* <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

* <http://www.ashp.org/Drug-Shortages/Current-Shortages>

Black Box Warning as shown in the drug Prescribing Information:

See labeling for specific ingredients used in a compound.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

American Pharmacists Association. Frequently Asked Questions About Pharmaceutical Compounding. Available from: <http://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding>. Accessed July 21, 2021.

ASHP Guidelines on Outsourcing Sterile Compounding Services. January 2014. Available from: <http://www.aihp.org/content/71/2/145?sso-checked=true>. July 21, 2021.

International Academy of Compounding Pharmacist. Available from: <http://www.iacprx.org/>. Accessed July 21, 2021.

Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act. December 2016. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>. Accessed July 21, 2021..

Pharmacy Compounding of Human Drug Products Under Section 503B of the Federal Food, Drug and Cosmetic Act. January 2018. Available from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf>. Accessed July 21, 2021..

Report: Limited FDA Survey of Compounded Drug Products. June 2018. Available from: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm>, Accessed July 21, 2021..

USP Compounding Standards and Resources. Available from: http://www.usp.org/usp-healthcare-professionals/compounding?gclid=CJfWt97qmsECFedzMgodCzqA_w. Accessed July 21, 2021..

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Note: All routes of administration listed may not be covered under the pharmacy benefit, e.g. intravenous, intramuscular.

Product	Description
Compound claims greater than \$75	compound where the submitted claim cost is greater than or equal to \$75
Various	Compounding kit

Cross References:

Off Label Use Policy (Rx.01.33)

Policy Version Number:	10.00
P&T Approval Date:	June 10, 2021
Policy Effective Date:	October 01, 2021
Next Required Review Date:	June 10, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

