



Pharmacy Policy
Non-Sterile Compounded Medication

Line of Business: All lines of business

P & T Approval Date: November 1, 2024

Effective Date: December 1, 2024

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and was approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Policy:

1. All compounded medications are subject to Prior Authorization
2. A request for compounded medications is considered medically necessary if all of the following are met:
 - a. A non-compounded version of the medicine is discontinued or generally unavailable
 - b. The compounded product contains prescription ingredients that are approved by the FDA for medical use.
 - c. The compounded product does not contain any bulk powder as an active ingredient, whereas bulk substance in the finished dosage form of the drug is acceptable.
 - d. The prescribed indication is supported by FDA-approval or adequate medical literature (e.g., USP Standards or National Formulary monograph, major peer-reviewed articles).
 - e. One of the following is met:
 - i. The patient is allergic to certain inactive ingredients in the commercially available FDA approved product.
 - ii. The patient has unique needs and requires tailored dosage strength or route (i.e.: pediatric)
 - iii. The patient has tried and failed an FDA approved alternative or no alternative exists
 - f. In addition to requiring all the necessary information on the prescription drug prior authorization request form, a coverage request for compound medications will also need to include all of the following:
 - i. All the ingredients in the compound. This includes both the active and inactive ingredients.
 - ii. The amount of each ingredient that is needed for the finished product.
 - iii. When possible, provide the National Drug Code (NDC) of the requested ingredients.

Clinical Justification:

- Compounded medications provide alternative route of administration for certain patient-specific conditions. Compounded drug product should be produced for a specific individual and not on a large scale.
- **United States Pharmacopoeia (USP)**
 - Drug should be compounded in compliance with the USP Chapter <795> using bulk drug substances as defined in 21 CFR 207.3(a)(4), that comply with applicable USP standards or National Formulary monograph if one exists. If no existing monograph, drug substance(s) must be a component of an FDA-approved human drug product or found on a list of bulk drug substances for use in compounding developed by FDA through regulation (Food, Drug and Cosmetic Act, section 510)
- **Food and Drug Administration (FDA): *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance***

Under section 503A of the FD&C Act, a compounded drug product is exempt from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act if it meets the conditions of section 503A of the FD&C Act. Specifically, the compounded drug product qualifies for the exemptions if:

1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&C Act).
2. The compounding of the drug product is performed:
 - By a licensed pharmacist in a state licensed pharmacy or a Federal facility, or by a licensed physician on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs; or
 - By a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient and:
 - Is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and
 - Those orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order (sections 503A(a)(1) and (2) of the FD&C Act).
3. The drug product is compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding⁸ using bulk drug substances, as defined in 21 CFR 207.3(a)(4), that comply with the standards of an applicable USP or National Formulary (NF) monograph if one exists.

If such a monograph does not exist, the drug substance(s) must be a component of an FDA-approved human drug product. If a monograph does not exist and the drug substance is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by FDA through regulation (section 503A(b)1(A)(i) of the FD&C Act). See section III.B.2 below for the interim policy for this provision.

4. The drug product is compounded using bulk drug substances that are manufactured by an establishment that is registered under section 510 of the FD&C Act (including a foreign establishment that is registered under 510(i) of the FD&C Act (section 503A(b)(1)(A)(ii) of the FD&C Act).
5. The drug product is compounded using bulk drug substances that are accompanied by valid certificates of analysis for each bulk drug substance (section 503A(b)(1)(A)(iii) of the FD&C Act).
6. The drug product is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapters on pharmacy compounding⁹ (section 503A(b)(1)(B) of the FD&C Act).
7. The drug product does not appear on the list, published at 21 CFR 216.24, that includes drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (section 503A(b)(1)(C) of the FD&C Act). See section III.B.1 below.
8. The licensed pharmacist or licensed physician does not compound regularly or in inordinate amounts any drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D) of the FD&C Act).
9. The drug product is not a drug product identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (section 503A(b)(3)(A) of the FD&C Act). See section III.B.3 below.
10. The drug product is compounded in a state that has entered into a memorandum of understanding (MOU) with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside such state; or, in states that have not entered into such an MOU with FDA, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the state in which they are compounded, more than 5% of the total prescription orders dispensed or distributed by such pharmacy or physician (sections 503A(b)(3)(B)(i) & (ii) of the FD&C Act).

- **Medicare Prescription Drug Benefit Manual Chapter 6**

- "... only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredients covered under Part B as prescribed and dispensed or administered, may be covered under Part D. Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug."
- "Bulk powders (i.e., Active Pharmaceutical Ingredients for compounding) do not satisfy the definition of a Part D drug and are not covered by Part D."
- "Section 1860D-2(e)(4) of the Act defines "medically-accepted indication," in part by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. ... Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications using the tools and data available to them to make such determinations."

References

1. US Pharmacopeia (USP). General Chapters 795. Pharmaceutical Compounding – Nonsterile Preparations. April 24, 2020. Accessed October 3, 2024. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-795-rb-notice-20200424.pdf
2. U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Drug Evaluation and Research. Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. June 2016. Accessed October 2, 2024. <https://www.fda.gov/media/94393/download>
3. Centers for Medicare and Medicaid Services (CMS). Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>
4. H.R.3204 – Drug Quality and Security Act. Accessed October 2, 2024. <https://www.congress.gov/bill/113th-congress/house-bill/3204>
5. Compounding Quality Act: Title I of the Drug Quality and Security Act of 2013. Accessed October 2, 2024. <https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>
6. FDA DHHS Subchapter C – Drugs: General Part 207 – Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution, 21 C.F.R. 207.3(a)(4) (revised as of April 1, 2014). Accessed October 2, 2024. [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-A/section-207.3#p-207.3\(a\)\(4\)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-A/section-207.3#p-207.3(a)(4))
7. Compounded drugs under Medicare Part B: Payment and Oversight. Department of Health And Human Services. Office of Inspector General. April 2014. Accessed October 2, 2024. <https://oig.hhs.gov/reports/all/2014/compounded-drugs-under-medicare-part-b-payment-and-oversight/>

Change Control		
Date	Change	Author
10/02/2024	<ul style="list-style-type: none"> Clinical justification section has been revised to ensure the content is up to date Minor format changes 	SV
10/05/2023	<ul style="list-style-type: none"> Updated LOB 	SV
10/07/2022	<ul style="list-style-type: none"> Removed DHCS regulations Updated P&T Approval Date and Effective Date 	CK
12/13/2021	<ul style="list-style-type: none"> Updated P&T Approval Date and Effective Date 	JM
11/24/2021	<ul style="list-style-type: none"> Updated document from “both lines of business” to “Medicare” Retyped “Conditions of Section 503A” and removed pasted images Change font color under “Medicare Manual Chapter 6” from gray to black 	NQ
04/16/2021	<ul style="list-style-type: none"> Renew with no changes 	JM
08/21/2019	<ul style="list-style-type: none"> Renewed with no updates/changes Updated P&T Approval and Effective Dates 	JM
07/19/2018	<ul style="list-style-type: none"> Update to exclude bulk powder, requiring ingredients list and qty Updated document to include both lines of business 	JT
07/02/2018	<ul style="list-style-type: none"> Changed Format 	IK
08/16/2017	<ul style="list-style-type: none"> Renewed with no updates/changes 	CT