



Pharmacy Policy
Non-Sterile Compounded Medication

Line of Business: Medicare

P & T Approval Date: December 21, 2021

Effective Date: January 1, 2022

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, and are 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 at least one prescription ingredient that is 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
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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)

- **Department of Health Care Services (DHCS)**
 - Requires the use of FDA-approved and nationally marketed drugs unless a compounded alternative is established to be medically necessary
 - Compounded drug may be dispensed only when
 - FDA-approved therapeutic equivalent does not exist, OR FDA-approved drug does not meet patient's medical need AND
 - Compounded alternative is determined to be medically necessary

- **Food and Drug Administration (FDA): Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance**

A. Conditions of Section 503A

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:

- 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).
- 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).
- 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.

- 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).
 - 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).
 - 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).
 - 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.
 - 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).
 - 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.
 - 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). See section III.B.4 below for the interim policy for this provision.
- **Medicare Manual Chapter 6:**
"[FAQ] Q22. Does Medicare Part D cover drugs that are compounded?
Answer: No. This depends on the components of the compounded medication. A compounded prescription drug product may be covered if it contains at least one FDA approved drug component, although reimbursement is limited to the compounding fees and FDA approved component(s) only. Bulk powders are not FDA approved drug products and therefore are not covered under Part D. A compounded drug must also be prescribed for a 'medically accepted

indication'." [emphasis added] (see <http://www.medicarepartdappeals.com/content/frequently-asked-question#Q22>)

References

1. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research. Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. July 2014. Retrieved September 19, 2014, from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf>.
2. H.R.3204 – Drug Quality and Security Act. Retrieved September 22, 2014, from <http://beta.congress.gov/bill/113th/house-bill/3204>.
3. Compounding Quality Act: Title I of the Drug Quality and Security Act of 2013. Retrieved September 22, 2014, from <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/>.
4. 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)
5. Pharmacy Compounding of Human Drug Products Under Section 503A Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act Guidance. Retrieved July 25, 2016, from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf>
6. Compounded drugs under Medicare Part B: Payment and Oversight. Department of Health And Human Services. Office of Inspector General. April 2014.
7. Medicare Manual Chapter 6

Change Control		
Date	Change	Author
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