Pharmacy Policy
Non-Sterile Compounded Medication

Line of Business: Both Lines of Business
P & T Approval Date: August 21, 2019 Effective Date: October 1, 2019

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 include 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)

- **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:

  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 compounding using bulk drug substances, as defined in 21 CFR 207.13(a)(4), that comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists.
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
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)
7. Medicare Manual Chapter 6

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