Clinical Policy: Compounded Medications

Reference Number: CP.PMN.280
Effective Date: 09.01.22
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy applies to requests for compounded medications.

FDA Approved Indication

Varies by drug product.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that compounded medications are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**For Medicaid requests, ensure compounded product is coverable per the Medicaid Benefit Master Grid.*

A. All FDA-Approved Indications (must meet all)**:**

1. Active ingredient(s) in compound are FDA-approved;
2. One of the following (a, b, or c):
   a. Medical justification supports inability to use commercially available FDA-approved products (e.g., allergy to a certain dye and need for a medication to be made without it, elderly patient who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form);
   b. Prescribed for pediatric dosing in the absence of commercially available products;
   c. Prescribed in the place of an FDA-approved product that is in shortage per the FDA or ASHP Drug Shortages list (*see Appendix E*);
3. Acceptable compendium supports efficacy and safety for the indicated treatment and route of administration (*see Appendix D*);
4. Prescribed dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration:
Prescribed for FDA-approved product in shortage – up to anticipated resolution date or 3 months for unknown resolution date
Prescribed for all other uses – 1 month

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**For Medicaid requests, ensure compounded product is coverable per the Medicaid Benefit Master Grid.*

A. All FDA-Approved Indications (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. For FDA-approved product in drug shortage, drug is still in shortage per the FDA or ASHP Drug Shortages list (*see Appendix E*);
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration:
Prescribed for FDA-approved product in shortage – up to anticipated resolution date or 6 months for unknown resolution date
Prescribed for all other uses – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: Acceptable Compendia

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Truven Health Analytics Micromedex DrugDEX (DrugDEX), with strength of recommendation Class I or IIa
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, level of evidence 1, 2A, or 2B
- Elsevier/Gold Standard Clinical Pharmacology

Appendix E: Drug Shortage Resources

- The FDA's Drug Shortages Index can be found at: https://dps.fda.gov/drugshortages
- ASHP's Drug Shortages List can be found at: https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; adopted from CP.PCH 27 (to be retired); added Medicaid line of business (WCG.CP.PCH.27 to be retired); for legacy WCG Medicaid, initial approval duration revised from "based on submitted request" to "1 month."	05.11.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.18.22	
3Q 2023 annual review: no significant changes.	04.24.23	08.23
Clarified that active ingredient(s) in compound are FDA-approved.	03.05.24	
3Q 2024 annual review: no significant changes.	05.06.24	08.24
For initial therapy, added criteria option that compounded drug is prescribed in the place of an FDA-approved product that is in shortage per the FDA or ASHP Drug Shortages list and respective approval duration as "up to anticipated resolution date or 3 months for unknown resolution date;" for continued therapy for FDA-approved product in shortage, added requirement that product is still in shortage and approval duration as "up to anticipated resolution date or 6 months for unknown resolution date."	01.28.25	
Added criterion to check benefit master grid to ensure coverability for Medicaid members.	03.06.25	
3Q 2025 annual review: added route of administration, in addition to the indication, for requirement that acceptable compendium supports efficacy and safety.	04.14.25	08.25
3Q 2026 annual review: no significant changes; added ICHRA line of business.	04.15.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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