Clinical Policy: Brand Name Override and Non-Formulary Medications

Reference Number: HIM.PA.103
Effective Date: 12.01.14
Last Review Date: 11.25
Line of Business: HIM

Revision Log

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

Description

Brand name drugs and non-formulary drugs require review prior to approval. For non-formulary medications, this policy is to be used when there are no drug specific guidelines or coverage criteria. A generic drug is identical and bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic substitution is mandatory for Centene health plans when A-rated generic equivalents are available. In addition, non-formulary drugs are generally drugs that have been reviewed by the Centene Pharmacy and Therapeutics Committee and believed to be either second-line therapy or of parity compared to formulary drugs.

FDA Approved Indication(s)

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 brand name drugs and non-formulary drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

For members in **Nevada, medical management techniques, including quantity management, beyond step therapy is not allowed for medication-assisted treatment (MAT)/withdrawal, HIV, and hepatitis C drugs*

A. Request for Brand Name or Non-Formulary Drug (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   Requests for **off-label use should also be reviewed against **HIM.PA.154** – Off-Label Drug Use*
   Requests for **non-formulary contraceptives should be reviewed against **HIM.PA.100** Non-Formulary and Formulary Contraceptives*
   Requests for **non-formulary blood glucose test strips should be reviewed against **HIM.PA.34** Non-Formulary Test Strips*
2. Request is not for a benefit excluded use (e.g., cosmetic, non-formulary weight loss drugs);
3. Failure of 2 formulary agents as described below (a, b, or c), each used for at least 30 days unless clinically significant adverse effects are experienced, all are contraindicated, or request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix E*) or for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix F*):*

**For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

a. Agents must be within the same therapeutic class as the prescribed agent;
b. If there is only 1 formulary agent within the same therapeutic class as the prescribed agent, member must use at least one additional agent that is recognized as a standard of care for the treatment of the relevant diagnosis, provided that such agent exists;
c. If there are no formulary agents within the same therapeutic class, member must use 2 formulary alternatives that are recognized as standards of care for the treatment of the relevant diagnosis, provided that 2 such agents exist;

4. If request is for a brand name drug, one of the following (a or b), unless member has contraindications to the excipients in all generics/biosimilars:
   a. Member must use generic version of the brand name drug, if available;
   b. If a biosimilar is available, member must use all preferred biosimilar(s);*^
      **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395, unless biosimilar is interchangeable per FDA Purple Book*
      ^For New York requests, the step therapy requirements above do not apply, unless biosimilar is interchangeable per FDA Purple Book
5. For combination product or alternative dosage form or strength of existing drugs, one of the following (a, b, or c):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
   b. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix E*);
   c. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix F*);
   **Use of a copay card or discount card does not constitute medical necessity*
6. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 12 months

II. Continued Therapy*

** For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed for medication-assisted treatment (MAT)/withdrawal, HIV, and Hepatitis C drugs*

A. Request for Brand Name or Non-Formulary Drug (must meet all)**:**

1. Member meets one of the following (a, b, or c):
   a. Currently receiving medication via Centene benefit;
   b. Member has previously met initial approval criteria;
   c. State or Health plan continuity of care programs apply to the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology, depression, transplant) with documentation that supports that member has received this

medication for at least 30 days (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. New dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 12 months

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

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information
- Examples of failure of a generic drug include:
  - Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug
  - Increase or worsening in symptoms (e.g., increase in seizure activity) when switched to a generic drug that is not attributed to progression of the disease state, increase in member age or weight, or member non-compliance

Appendix E: States with Limitations against Redirections in Certain Mental Health Settings

State	Step Therapy Prohibited?	Notes
AR	Yes	For the treatment of psychosis and serious mental illness through antipsychotic prescription drugs, no step therapies allowed.
TX	No	For the treatment of psychosis and serious mental illness (e.g., depression), step therapy is limited to one drug (excluding the generic or pharmaceutical equivalent of the prescribed drug).

Appendix F: States with Regulations against Redirections in Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.

State	Step Therapy Prohibited?	Notes
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
IN	Yes	For advanced, metastatic cancer and associated conditions
LA	Yes[≠]	For stage 4 advanced, metastatic cancer or associated conditions. [≠]Exception if clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
MS	Yes	For advanced metastatic cancer and associated conditions
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	For stage 4 metastatic cancer and associated conditions
OK	Yes	For advanced metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes^	For stage 4 advanced metastatic cancer, metastatic blood cancer, and associated conditions ^Exception if step therapy is for AB-rated generic equivalent, interchangeable biological product, or biosimilar product to the equivalent brand drug
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface Annual Addition:V44 at Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA. Accessed August 21, 2025.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed July 10, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.22.21	11.21
Added clarification in section I.A.1 that non-formulary contraceptives should be reviewed against HIM.PA.100 Non-formulary and Formulary contraceptives	06.09.22	
4Q 2022 annual review: no significant changes; references reviewed and updated.	08.02.22	11.22
Added the following approval pathway for continuation of therapy requests: State or Health plan continuity of care programs apply to	02.06.23	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
the requested drug and indication (e.g., seizures, heart failure, human immunodeficiency virus infection, and psychotic disorders [e.g., schizophrenia, bipolar disorder], oncology) with documentation that supports that member has received this medication for at least 30 days (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*		
Added bypass of formulary agent and combination products redirection if request is for treatment of a member in a State with limitations on step therapy in certain mental health settings along with Appendix E, which includes Arkansas.	07.05.23	
Added Texas to Appendix E with requirements for single drug redirection.	07.19.23	
4Q 2023 annual review: added requirement that request is not for a benefit excluded use; references reviewed and updated.	08.02.23	11.23
Added non-formulary weight loss drugs as an example of a benefit excluded use.	05.15.24	
Added disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439. Added allowance for continuation of care for depression and transplant.	05.28.24	
4Q 2024 annual review: added bypass of formulary agent and combination products redirection if request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings along with Appendix F; references reviewed and updated.	07.29.24	11.24
Clarified for brand name drug requests, member must use generic or all preferred biosimilar(s), if available.	03.31.25	
4Q 2025 annual review: no significant changes; for brand requests, clarified generic must be used if available; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395 and New York per plan request.	10.06.25	11.25
For Appendix F, added state IN.	03.30.26	

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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