Clinical Policy: No Coverage Criteria, Recent Label Changes Pending Clinical Policy Update

Reference Number: HIM.PA.33
Effective Date: 05.01.16
Last Review Date: 11.26
Line of Business: HIM/ICHRA

Revision Log

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

Description

This policy is to be used for formulary drugs that:*

- Require prior authorization where there are no specific guidelines or coverage criteria.
- Have drug specific clinical policies that are pending updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens).

All requests for non-formulary drugs, under the pharmacy benefit, should be reviewed against HIM.PA.103 – Brand Name Override and Non-Formulary Medications or medication specific prior authorization criteria when available

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 all medical necessity determinations for formulary* drug therapy without Centene® coverage criteria or pending clinical policy updates as a result of recent label changes be considered on a case-by-case basis by a physician, pharmacist, or ad hoc committee, using the guidance provided within this policy.

All requests for non-formulary drugs, under the pharmacy benefit, should be reviewed against HIM.PA.103 – Brand Name Override and Non-Formulary Medications or medication specific prior authorization criteria when available

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 per NRS 695C.1743*

A. Pharmacy Benefit: No Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all)**:**

1. Request is for a drug on the formulary*;
   *Requests for **formulary contraceptives** should be reviewed against **HIM.PA.100** Non-formulary and Formulary contraceptives*

Requests for **non-formulary drugs, under the pharmacy benefit, should be reviewed against **medication-specific prior authorization criteria** when available; if there are no medication-specific criteria, refer to **HIM.PA.103** – Brand Name Override and Non-Formulary Medications*

2. Request is not for a benefit excluded use (e.g., cosmetic);
3. One of the following (a or b):
   a. Requested drug does not have a drug-specific clinical policy or custom coverage criteria;
   b. Requested drug has a drug-specific clinical policy that is pending clinical policy updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens);
4. Diagnosis of one of the following (a or b):
   a. A condition for which the product is FDA-indicated and -approved;
   b. A condition supported by one of the following (i, ii, iii, or iv):
      i. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B (*see Appendix D*);
      ii. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (1 – 4):
         1) Adequate representation of the member's clinical characteristics, age, and diagnosis;
         2) Adequate representation of the prescribed drug regimen;
         3) Clinically meaningful outcomes as a result of the drug therapy in question;
         4) Appropriate experimental design and method to address research questions (*see Appendix F for additional information*);
      iii. Micromedex DrugDex® with strength of recommendation Class I or IIa (*see Appendix D*);
      iv. For state(s) with state-specific regulations for supportive evidence for requests in pediatrics where member's age is beyond the FDA labeled indication and prescribing information, refer to *Appendix G* for supportive references by State;
5. Failure of an adequate trial of at least two preferred* FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at maximum indicated doses, unless one of the following (a, b, or c):^
   **Generic is preferred, if available generically*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   a. Clinically significant adverse effects are experienced or all are contraindicated;
   b. Request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
   c. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix F*);
6. 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);
**Use of a copay card or discount card does not constitute medical necessity*
b. Request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
c. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix F*);

7. Member has no contraindications to the prescribed agent per the prescribing information;
8. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
9. Request meets one of the following (a or b):
   a. Both of the following (i and ii):
      i. Dose does not exceed the FDA-approved maximum recommended dose for the relevant product and indication;
      ii. Request does not exceed health plan-approved quantity limit, if applicable;*
      **Requests exceeding the health plan-approved quantity limit should also be reviewed against CP.PMN.59 Quantity Limit Override and Dose Optimization*
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months, whichever is less

B. Medical Benefit: No Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all)**:**

1. Request is not for a benefit excluded use (e.g., cosmetic);
2. One of the following (a or b):
   a. Requested drug does not have a drug-specific clinical policy or custom coverage criteria;
   b. Requested drug has a drug-specific clinical policy that is pending clinical policy updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens);
3. Diagnosis of one of the following (a or b):
   a. A condition for which the product is FDA-indicated and -approved;
   b. A condition supported by one of the following (i, ii, iii, or iv):
      i. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B (*see Appendix D*);
      ii. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (1 – 4):
         1) Adequate representation of the member's clinical characteristics, age, and diagnosis;
         2) Adequate representation of the prescribed drug regimen;
         3) Clinically meaningful outcomes as a result of the drug therapy in question;

4) Appropriate experimental design and method to address research questions (*see Appendix F for additional information*);

iii. Micromedex DrugDex® with strength of recommendation Class I or IIa (*see Appendix D*);

iv. For state(s) with state-specific regulations for supportive evidence for requests in pediatrics where member's age is beyond the FDA labeled indication and prescribing information, refer to *Appendix G* for supportive references by State;

4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at maximum indicated doses, unless one of the following (a, b, or c);*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   a. Clinically significant adverse effects are experienced or all are contraindicated;
   b. Request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
   c. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix F*);
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);
      **Use of a copay card or discount card does not constitute medical necessity*
   b. Request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*) ;
   c. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix F*);
6. Member has no contraindications to the prescribed agent per the prescribing information;
7. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
8. Request meets one of the following (a or b):
   a. Both of the following (i and ii):
      i. Dose does not exceed the FDA-approved maximum recommended dose for the relevant product and indication;
      ii. Request does not exceed health plan-approved quantity limit, if applicable;*
      **Requests exceeding the health plan-approved quantity limit should also be reviewed against CP.PMN.59 Quantity Limit Override and Dose Optimization*
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months, whichever is less

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 per NRS 695C.1743*

A. Pharmacy or Medical Benefit: No Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (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. Both of the following (i and ii):
      i. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
      ii. Request does not exceed health plan-approved quantity limit, if applicable;*
      **Requests exceeding the health plan-approved quantity limit should also be reviewed against CP.PMN.59 Quantity Limit Override and Dose Optimization*
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months, whichever is less

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 – HIM.PA.154 for health insurance marketplace/ICHRA or evidence of coverage documents;

B. Indications or diagnoses in which the drug has been shown to be unsafe or ineffective.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies by drug product.

Appendix D: General Information
These criteria are to be used only when specific prior authorization criteria do not exist.

Appendix E: 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.
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 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

Appendix F: 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 G: Supportive References by State in Pediatrics Where Request is for a Member with Age Beyond the FDA Labeled Indication and Prescribing Information

State	Supportive References
LA	The drug has been recognized for the treatment of the disease or condition in pediatric application by one of the following: • The American Medical Association Drug Evaluations • The American Hospital Formulary Service (AHFS) Drug Information

State	Supportive References
	• The United States Pharmacopeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional" • Recognized in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed journal

V. Dosage and Administration

Varies by drug product.

VI. Product Availability

Varies by drug product.

VII. References

1. Food and Drug Administration: Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses - Recommended Practices. October 2023. Available at: https://www.fda.gov/media/173172/download. Accessed July 13, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: clarified and expanded criteria to apply to recent label changes pending clinical policy updates; references reviewed and updated.	08.02.22	11.22
Added reference to CC.PHARM.03A and CC.PHARM.03B to Section II for state or health plan continuity of care programs.	02.06.23	
Added bypass of preferred drugs 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 F, which includes Arkansas.	07.05.23	
Updated Appendix E to include Oklahoma; Added Texas to Appendix F 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 disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439. Updated Appendix E to include Mississippi. Added allowance for continuation of care for depression and transplant.	06.05.24	
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.29.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2025 annual review: expanded diagnosis requirements to include off-label uses consistent with HIM.PA.154 Off-Label Drug Use; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395.	07.10.25	11.25
For Appendix E, added state IN.	03.30.26	
4Q 2026 annual review: for FDA-approved doses, added requirement that request does not exceed health plan-approved quantity limit per CDPA request; updated Appendix E with revised language for Tennessee; added Nevada to Appendix F; added ICHRA line of business; references reviewed and updated. Added reference to NRS 695C.1743 to disclaimer that medical management techniques beyond step therapy is not allowed for MAT/withdrawal, HIV, and hepatitis C for members in NV per VPRP request. Removed Nevada from Appendix F per VPRP request and Compliance.	10.27.26	11.26

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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