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

Reference Number: CP.PMN.255
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Medicaid

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 PDL 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-PDL drugs, under the pharmacy benefit, should be reviewed against CP.PMN.16 Request for Medically Necessary Drug Not on the PDL 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 PDL* 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-PDL drugs, under the pharmacy benefit, should be reviewed against CP.PMN.16 Request for Medically Necessary Drug Not on the PDL 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*

A. Pharmacy Benefit: Labeled Use without Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes (must meet all)**:**

1. Request is for a PDL drug;*
   All requests for non-PDL drugs, under the pharmacy benefit, should be reviewed against CP.PMN.16 - Request for Medically Necessary Drug Not on the PDL.
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 the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;
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*
   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 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):
   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 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. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   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 6 months (whichever is less)

B. Medical Benefit: Labeled Use without 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 the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;
4. 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*
   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 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):
   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 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. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   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 6 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*

A. Pharmacy or Medical Benefit: Labeled Use without 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. New dose does not exceed the FDA-approved maximum recommended dose for the relevant indication;
   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 policies – CP.PMN.53 for Medicaid 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
HIV: human immunodeficiency virus
PDL: preferred drug list

Appendix B: Therapeutic Alternatives
Varies by drug product

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.

State	Step Therapy Prohibited?	Notes
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.
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
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

Appendix F: States with Limitations against Redirections in Certain 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.
NV	No	For typical or atypical antipsychotic or anticonvulsant medications, step therapy is limited to one PDL drug.

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 19, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy CP.PMN.53; no significant changes from previously approved policy; references reviewed and updated.	07.13.20	11.20
4Q 2021 annual review: added requirement for diagnoses; added requirement that request is for a formulary drug; added notation that generic alternatives are preferred; modified dosing requirements to allow off-label dosing; references reviewed and updated.	07.22.21	11.21
Removed HIM-Medical Benefit line of business (criteria from this policy added to HIM.PA.33 for medical benefit requests); added redirection bypass for states with regulations against redirections in cancer along with Appendix E; created separate criteria set for	01.06.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
medical benefit requests to distinguish that formulary/PDL verbiage is not applicable; revised references from "formulary" to "PDL".		
4Q 2022 annual review: clarified and expanded criteria to apply to recent label changes pending clinical policy updates; references reviewed and updated.	06.29.22	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 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 F, which includes Arkansas.	07.05.23	
Added Nevada to Appendix F with the following step therapy limits: For typical or atypical antipsychotic or anticonvulsant medications, step therapy is limited to one PDL drug.	08.31.23	
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.	05.28.24	
4Q 2024 annual review: added depression and transplant to list of continuity of care programs per current Centene standard approach; references reviewed and updated.	07.29.24	11.24

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.