Clinical Policy: No Coverage Criteria

Reference Number: LA.PMN.255
Effective Date: 04.28.23
Last Review Date: 06.26.23~~01.21~~
Line of Business: Medicaid

Revision Log

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

Please note: This policy is for medical benefit

Description
This policy is to be used to determine medical necessity of formulary, existing or newly approved drug therapy where there are no coverage criteria.

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
~~*Prior authorization is required.*~~ *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 Louisiana Healthcare Connections that all medical necessity determinations for drug therapy without Louisiana Healthcare Connections coverage criteria be considered on a case-by-case basis by a physician, pharmacist or ad hoc committee, using the guidance provided within this policy.

I. Initial Approval Criteria

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

1. 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);
2. 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;
3. 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 clinically significant adverse effect are experienced, all are contraindicated, or request is for a product for treatment associated with cancer.

a. 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.

**Generic is preferred, if available generically*

4. For combination product or alternative dosage form or strength of existing drugs, 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), unless request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings. 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.

**Use of a copay card or discount card does not constitute medical necessity*

5. Member has no contraindications to the prescribed agent per the prescribing information;
6. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
7. 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*).

~~1.~~
~~2. Request is for a drug without custom coverage criteria;~~
~~3. Member meets the following (a):~~
~~a. For Medicaid pharmacy requests: 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 clinically significant adverse effect are experienced or all are contraindicated;~~
~~4. If request is for combination product or alternative dosage form or strength of existing drugs, 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*~~

~~5. Member has no contraindications to the prescribed agent per the prescribing information;~~
~~6. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;~~
~~7. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.~~

Approval duration: Duration of request or 6 months (whichever is less)

II. Continued Therapy

A. Labeled Use without 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 LHCC benefit;

b. Member has previously met initial approval criteria;
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*).

~~**A.** Labeled Use without Coverage Criteria (must meet all):~~
~~1. Member meets one of the following (a, b, or c):~~
~~a. Currently receiving medication via Louisiana Healthcare Connections benefit;~~
~~b. Member has previously met initial approval criteria;~~
~~c. Louisiana Healthcare Connections continuity of care programs apply to 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;~~
~~2. Member is responding positively to therapy;~~
~~3. If request is for a dose increase (quantity or frequency), member has been titrated up from the lower dose with documentation of partial improvement, and the new dose does not exceed dosing guidelines recommended by the product information label or clinical practice guidelines and/or medical literature.~~
~~Approval duration: Duration of request or 12 months (whichever is less)~~

~~II.~~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 – LA.PMN.53 for Medicaid or evidence of coverage documents;

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

~~III.~~IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus

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.

~~IV.~~V. Dosage and Administration

Varies by drug product

~~V.~~VI. Product Availability
Varies by drug product

~~VI.~~ Referencess
VII.

1. Food and Drug Administration: Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses - Recommended Practices. February 2014. Available at: https://www.fda.gov/media/88031/download. Accessed June 29, 2022.
~~1. Food and Drug Administration. Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. January 2009. Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm. Accessed August 3, 2020.~~

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	01.21	04.28.21
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; Clarified and expanded criteria to apply to recent label changes pending clinical policy updates; References reviewed and updated. Added redirection bypass due to regulations against redirections in cancer Added blurb this policy is for medical benefit only.	06.26.23	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. 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.