Clinical Policy: Global Biopharm

Reference Number: CP.PHAR.57
Effective Date:03/11
Last Review Date: 08/17 Revision Log
Line of Business: Medicaid, Medicare Part B or C

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

Description
This policy is to be used to determine medical necessity of existing or newly approved drug therapy where no custom coverage criteria are available, including off-label requests for an indication, treatment regimen, or patient population not approved by the U.S. FDA (Food and Drug Administration).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) 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 drug therapy without Centene® custom coverage criteria or for off-label uses 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 Custom Criteria (must meet all):

1. The drug is prescribed for an FDA (Food and Drug Administration)- approved indication;
2. Requested dosage regimen and duration is within dosing guidelines recommended for the specific indication according to the product information label of the drug;
3. Failure of adequate trials of two formulary agents considered standard of care for the relevant diagnosis, when such agents exist, unless member experiences clinically significant adverse effect or has contraindication(s);
4. Member has no contraindications to prescribed agent per the product information label;
5. If applicable, prescriber have taken necessary measures to minimize any risk associated with a boxed warning in the product information label.

Approval duration: duration of request or 3 months (whichever is less)

B. Off-label Use (must meet all)**:**

1. Request meets one of the following (a or b):
   a. Use is supported by the National Comprehensive Cancer Network Drug Information and Biologics Compendium level of evidence 1 & 2a;
   b. The use is supported by evidence from two high quality published studies in peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following:

i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
ii. Adequate representation of the prescribed drug regimen;
iii. Clinically meaningful outcomes as a result of the drug therapy in question;
iv. Appropriate experimental design method to address research questions (see Appendix C for additional information);

2. Treatment is not for a cosmetic purpose;
3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of adequate trials of two FDA approved drug(s) that are considered the standard of care, when such agent exists, at maximum indicated doses, unless member experiences clinically significant adverse effect or has contraindication(s);
5. Requested dosage regimen and duration is within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: duration of request or 3 months (whichever is less)

II. Continued Therapy

A. All requests (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation supports positive response to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed dosing guidelines recommended by clinical practice guidelines and/or medical literature.

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

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

A. 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

Appendix B: General Information

- The U.S. FDA approves drugs for specific indications included in the drug's product information label. The approval by the FDA means that the company can include the information in their package insert. Omission of uses for a specific age group or a specific disorder from the approved label means that the evidence required by law to allow their inclusion in the label has not been submitted to the FDA. Off-label, or "unlabeled," drug use is the utilization of an FDA-approved drug for indications, treatment regimens, or populations other than those listed in the FDA-approved labeling. Many off-label uses are effective and well-documented in the peer-reviewed literature, and they are widely used even though the manufacturer has not pursued the additional indications. Refer to the drug's FDA approved indication(s) and labeling (varies among drug products).

Appendix C: Appropriate Experimental Design Methods

Randomized, controlled trials are generally considered the gold standard; however:

- In some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover.
- Case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- Non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.

V. Dosage and Administration

Not applicable

VI. Product Availability

Not applicable

VII. References

A. 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 July 14, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
No changes	04/13	05/13
Added #7 in criteria for consultation with medical expert	04/14	05/14
No changes	05/15	05/15
Updated off-label use criteria Added new compendia approved by CMS Removed drug shortage criteria Converted into new template	08/15	08/15
Converted to new template. CMS Medicare Benefit Policy Manual and Medicare Prescription Drug Benefit Manual inform compendial and peer-reviewed literature requirements with the exception of NCCN compendial LOE 2b.	07/16	08/16
Converted to new template. Description is modified so policy doesn't apply to just specialty drugs. Criteria set created for labeled and off-label uses.Limited acceptable off-label uses to primary literature and evidenced based clinical practice guidelines and NCCN 1 & 2a recommended uses in place of the recommendation in the CMS Medicare Benefit Policy Manual and Medicare Prescription Drug Benefit Manual since this policy will not apply to Medicare.	08/17	08/17
Added Medicare Part B or C to line of business. Added the disclaimer note for Medicare members.	11/17	11/17

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.