Clinical Policy: Formulary Medications Without Specific Guidelines
Reference Number: HIM.PA.33
Effective Date: 05.01.16
Last Review Date: 11.20
Line of Business: HIM

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.

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 formulary medications without specific guidelines are medically necessary when the following criteria are met:

I. Initial Approval Criteria
    A. Formulary Medications without Specific Guidelines (must meet all):
        1. Request is for a drug on the formulary;
           *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
        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 contraindicated or clinically significant adverse effect are experienced;
           *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);
           *Use of a copay card or discount card does not constitute medical necessity
        5. Request meets one of the following (a or b):
           a. Dose does not exceed the FDA-approved maximum recommended dose for the relevant product and indication;
II. Continued Therapy
   A. Formulary Medications without Specific Guidelines (must meet all):
      1. One of the following (a, b, or c):
         a. Currently receiving medication via Centene benefit;
         b. Member has previously met initial approval criteria;
         c. Health plan 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, 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 policy –
      HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

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.

V. Dosage and Administration
   Varies by drug product.

VI. Product Availability
   Varies by drug product.

VII. References
   Not applicable.
Reviews, Revisions, and Approvals

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<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Converted to new template</td>
<td>01.17</td>
<td>05.17</td>
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<tr>
<td>2Q 2018 annual review: no significant changes</td>
<td>02.23.18</td>
<td>05.18</td>
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<td>Revised to include NCCN Compendium category 1, 2A, and 2B supported uses;</td>
<td>12.06.18</td>
<td>02.19</td>
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<td>added continuation of care language.</td>
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<td>2Q 2019 annual review: added requirement to ensure requested product is</td>
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<td>on the formulary with reference to HIM.PA.103 if product is non-formulary.</td>
<td>02.19.19</td>
<td>05.19</td>
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<tr>
<td>2Q 2020 annual review: Section IA, 2b removed NCCN category 2B recommendation</td>
<td>02.17.20</td>
<td>05.20</td>
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<td>from approvable off-label uses; clarified reference for non-formulary</td>
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<td>medications that may be reviewed using medication specific prior authorization</td>
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<td>4Q 2020 annual review: added NCCN 2B as an acceptable level of evidence for</td>
<td>08.06.20</td>
<td>11.20</td>
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<td>off-label use per Compliance; added criteria for combinations products and</td>
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<td>alternative dosage forms or strengths of existing drugs; added requirement</td>
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<td>for redirection to two preferred FDA-approved drugs; delete reference to</td>
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<td>off-label use policy in Section I and II.</td>
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**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
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