Clinical Policy: Brand Name Override and Non-Formulary Medications

Reference Number: HIM.PA.103
Effective Date: 12.01.14
Last Review Date: 02.21
Line of Business: HIM

Revision Log

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

Description

Brand name drugs and non-formulary drugs require review prior to approval. For non-formulary medications, this policy is to be used when there are no drug specific guidelines or coverage criteria. A generic drug is identical and bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic substitution is mandatory for Centene health plans when A-rated generic equivalents are available. In addition, non-formulary drugs are generally drugs that have been reviewed by the Centene Pharmacy and Therapeutics Committee and believed to be either second-line therapy or of parity compared to formulary drugs.

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 brand name drugs and non-formulary drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Brand Name or Non-Formulary Drug (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against HIM.PA.154 – Off-Label Drug Use*
2. Failure of 2 formulary agents as described below (a, b, or c), each used for at least 30 days unless contraindicated or clinically significant adverse effects are experienced:
   a. Agents must be within the same therapeutic class as the prescribed agent;
   b. If there is only 1 formulary agent within the same therapeutic class as the prescribed agent, member must use at least one additional agent that is recognized as a standard of care for the treatment of the relevant diagnosis, provided that such agent exists;
   c. If there are no formulary agents within the same therapeutic class, member must use 2 formulary alternatives that are recognized as standards of care for the treatment of the relevant diagnosis, provided that 2 such agents exist;
3. If request is for a brand name drug, one of the following (a or b), unless member has contraindications to the excipients in all generics/biosimilars:

a. At least one of the previously tried agents was the generic version of the brand name drug;
b. If a biosimilar is available, member has failed all preferred biosimilar(s);

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 indication and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable.

II. Continued Therapy

A. Request for Brand Name or Non-Formulary Drug (must meet all)**:**

1. Currently receiving medication via Centene benefit or 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 and health plan approved daily quantity limit;
   b. New dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable.

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

Appendix D: General Information

- Examples of failure of a generic drug include:

- Suboptimal drug plasma levels while taking the generic drug as compared to drug plasma levels while taking the brand name drug
- Increase or worsening in symptoms (e.g., increase in seizure activity) when switched to a generic drug that is not attributed to progression of the disease state, increase in member age or weight, or member non-compliance

V. Dosage and Administration

Varies by drug product

VI. Product Availability

Varies by drug product

VII. References

1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed November 17, 2020.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed November 17, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format.	08.16	08.16
Converted to new template, added maximum dose criteria	04.17	08.17
1Q18 annual review - No significant changes. - References added.	12.04.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	12.06.18	02.19
Clarified trial/failure requirement to ensure agents that are within the same therapeutic class as the requested agent are used if available.	01.28.19	
1Q 2020 annual review: added requirement that request is for an FDA-approved indication or off-label use policy is satisfied; revised dosing requirements to include health plan quantity limit or dosing supported by guidelines; references reviewed and updated.	10.31.19	02.20
Added criteria for combinations products and alternative dosage forms or strengths of existing drugs.	03.03.20	05.20
1Q 2021 annual review: added language to require use of preferred biosimilars if available; references to HIM.PHAR.21 revised to HIM.PA.154; added to policy description "For non-formulary medications, this policy is to be used when there are no drug specific guidelines or coverage criteria"; references reviewed and updated.	11.17.20	02.21

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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