Clinical Policy: Brand Name Override

Reference Number: CP.PMN.22
Effective Date: 09.01.06
Last Review Date: 02.22
Line of Business: Medicaid

Revision Log

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

Description

Brand name drugs require review prior to approval. 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; however, brand name drugs may be approved in certain circumstances where there are adverse reactions to or therapeutic failure of generic 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 non-preferred brand name drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Brand Name Drug in Lieu of Generic Formulation (must meet all)**:**

1. Prescribed indication is FDA-approved;*
   ** Requests for off-label use should also be reviewed against CP.PMN.53 – Off-Label Use Policy*
2. Failure of an adequate trial of or clinically significant adverse effects to two generics* (each from a different manufacturer) or the preferred biosimilar(s) of the requested brand name drug, unless member has contraindications to the excipients in all generics/biosimilars;
   **If a second generic of the requested brand name drug is not available, member must try a formulary alternative that is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex) for the requested indication, provided that such agent exists*
3. If clinically significant adverse effects were experienced, provider submits chart note documentation;
4. Provider submits clinical rationale* supporting why the brand name drug will be more effective than the generic or will not produce the same adverse effects as the generic;
   **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. Request for Brand Name Drug When a Generic Equivalent Does Not Exist:

1. Refer to Requests for Medically Necessary Drug Not on the PDL policy, CP.PMN.16.

II. Continued Therapy

A. All Requests in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*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 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

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 October 19, 2021.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed October 19, 2021.
3. FDA MedWatch Reporting Forms at http://www.fda.gov/Safety/MedWatch/HowToReport. Accessed October 19, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review Modified to require trial of 2 generic drugs across the board, and moved examples of what constitutes failure to Appendix C. Added that drug trials must be of an adequate duration. Removed that one of the trials must have occurred in the last 90 days. Added maximum dosing requirement. Added requirement for clinical rationale as to why the brand name product would be expected to benefit the patient when the generics did not. References reviewed and updated.	11.30.17	02.18
1Q 2019 annual review: added requirement that request is for an FDA-approved indication or supported by standard pharmacopeias; added clarification that copay card or discount card does not constitute medical necessity for use of brand name product; added criteria set for brand name drugs when a generic equivalent is not available; added continuation of care language to section II; references reviewed and updated.	08.14.18	02.19
1Q 2020 annual review: revised to limit indications to FDA-approved uses and added reference to off-label use policy; removed 'for the relevant off-label use' from dosing limits; references reviewed and updated.	10.31.19	02.20
1Q 2021 annual review: added language to require use of preferred biosimilars if available; revised requirement for MedWatch form to "chart note documentation of clinically significant adverse effects experienced" based on feedback from PA Ops; references reviewed and updated.	11.17.20	02.21
1Q 2022 annual review; no significant changes; references reviewed and updated.	10.19.21	02.22
Template changes applied to continued therapy section.	09.20.22	

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.