

Clinical Policy: Brand Name Override

Reference Number: CP.PMN.22

Effective Date: 09.01.06

Last Review Date: 02.18

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, or 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)

Not applicable

Policy/Criteria

Provider must submit documentation (including 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. Failure of an adequate trial of or clinically significant adverse effects to 2 generics* of the requested brand name drug, each from a different manufacturer, unless member is contraindicated to the excipients in all generics;
**If a second generic of the requested brand name drug is not available, member must try a preferred generic drug from a similar therapeutic class (e.g., meloxicam for Naprosyn), provided that such agent exists*
2. If clinically significant adverse effects were experienced, provider submits a copy of the MedWatch form(s) submitted to the FDA (*see Appendix C*);
3. 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;
4. Dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months**B. Other diagnoses/indications:** Not applicable**II. Continued Therapy****A. Request for Brand Name Drug in Lieu of Generic Formulation (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, new dose does not exceed the FDA approved maximum recommended dose.

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
Not applicable

Appendix C: 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.
- MedWatch forms can be obtained and completed online at the FDA website. They can also be requested by contacting Envolve Pharmacy Solutions via phone (1-800-460-8988) or fax (1-866-399-0929). Sections A, B, D, and G are to be completed by the prescriber.

V. Dosage and Administration

Not applicable

VI. Product Availability

Not applicable

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 14, 2017.
2. FDA Electronic Orange Book at <http://www.fda.gov/cder/ob/>. Accessed November 14, 2017.
3. FDA MedWatch Reporting Forms at <http://www.fda.gov/Safety/MedWatch/HowToReport>. Accessed November 14, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added requirement for a generic medication from a similar therapeutic class as Part C under therapeutic failure criteria.		02.13
Added that MedWatch form can be completed online to MedWatch form paragraph; added specific form sections to be completed.		02.13
Updated reference section to reflect current literature search.		02.13
Removed the list of medications may be prescribed as a brand name without obtaining a prior authorization override.		02.14
Converted to new template.	08.15	08.15
Streamlined criteria. Moved “A trial of a preferred generic drug from a similar therapeutic class may also be required prior to brand name drug approval” from both approval criteria sets to the additional notes section as it is not a definitive requirement. Removed reference to exempt drug list from notes section because such list does not exist in the document. Updated background and references.	06.16	08.16
N/A	03.17	08.17
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

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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