nh healthy families

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Brand Name Override
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PMN.22
EFFECTIVE DATE: 09/06	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/10, 08/16, 3/17
PRODUCT TYPE: All	**REVISED:** 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 02/14, 06/15

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Generic Drug Products:

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 prescription plans when an A-rated generic equivalent is available.

Brand Vs AB-rated Generic:

AB-rated generic drugs are products that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products (i.e. Brand name) and actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence.

Brand: A prescriber's indication of dispense as written (DAW) or brand medically necessary will require a prior authorization (PA)

override for the pharmacy to be reimbursed for the Brand Name medication if the patient is already tolerating a generic form of the drug they will continue to receive the generic. Divalproex sodium formulations can be approved as "brand medically necessary" for treatment of epilepsy with documentation of a diagnosis.

FDA Labeled Indications: Various drug products.

Criteria for Approval:

Criteria for Brand Name approval due to allergic reaction/adverse reaction:

A. The patient has demonstrated a documented adverse reaction to the generic product and the adverse reaction caused by the generic meets one of the following criteria:
   1. life threatening
   2. hospitalization
   3. disability
   4. required intervention to prevent impairment

B. **AND** an FDA MedWatch form has been completed and submitted to the FDA for review (NOTE: A copy of the completed FDA MedWatch form must also accompany the PA request)

C. **OR** if the allergic reaction does not meet one of the criteria above **AND** generic drugs are available a history of recent trial and failure of two generic drugs from two different manufacturers (when available) must be documented in the pharmacy claims history, one of which must be within the previous 90 days. A trial of a preferred generic medication from the same or similar drug class may also be required prior to brand name approval (e.g. meloxicam for naproxen) **AND** an FDA MedWatch form has been completed (Sections

A, B, D, and G) and submitted to the FDA for review. A copy of the completed FDA MedWatch form must also accompany the PA request.

D. **OR** Clinically unacceptable risk with a change in therapy to a preferred drug

Criteria for Brand Name approval due to therapeutic failure:

A. The patient has demonstrated therapeutic failure to two generic drugs from two different manufacturers (when available) **AND** the two generics must be documented in the pharmacy claims history. The provider must document the clinical failure due to suboptimal drug plasma concentrations, if applicable, while taking the generic drug as compared to drug plasma levels while on brand name medication, and provide this information for review.

B. OR the member experiences an increase or worsening in symptoms (i.e.: an increase in seizure activity) when switched to generic medication **AND** the increase in symptoms is not attributed to progression of the disease state, increase in patient age or weight, or patient non-compliance. The provider must document the clinical failure and provide this information for review.

C. A trial of a preferred generic medication from a similar therapeutic class may also be required.

D. OR Clinically unacceptable risk with a change in therapy to a preferred drug

NOTE: A brand name medication will not be approved for members who have not been tried on generic medication unless the medication is listed as exempt above. MedWatch forms can be obtained or completed on-line on the FDA website, by calling US Script at 1-800-460-8988 or requested

by fax to 1-866-399-0929. Sections A, B, D, and G to be completed by the prescriber.

Approval: Initial Approval: 12 months Continued Approval: 12 months

Special Instructions
Patient requests for brand name drugs will not be approved.

References:

1. FDA Center for Drug Evaluation and Research Office of Generic Drugs. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/
2. CDERFDA Electronic Orange Book at http://www.fda.gov/cder/ob/
3. FDA MedWatch Reporting Forms http://www.fda.gov/Safety/MedWatch/HowToReport
4. Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease *JAMA.* 2008; 300(21):2514-2526.

Revision Log	
Revision	**Date**
Add the following medications to those that may be prescribed as a Brand Name without obtaining a medical necessity override: "aminophylline, disopyramide, levothyroxine, amiodarone, propafenone, valproate Na, and theophylline".	02/08
Add the following item under "Criteria for Approval" "Criteria for Brand Name approval due to therapeutic failure": "c. If multiple generics are available, a history of trials of generics from multiple companies must be documented in the claims processing system."	02/08

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This Guideline was rewritten to reflect the current Centene Health Plan process, aligning with the Pharmacy Benefit Manager's process and NCQA requirements.	02/09
Updated the drug listing in the "Criteria for Approval" section.	02/10
Added link to MedWatch forms in the "Criteria for Approval" section.	02/10
Updated reference section to reflect current literature search.	02/10
Added 12 month "Continued Approval" notation.	02/11
Added requirement for recent trial and failure of a generic. Added requirement of 'documented' adverse reaction to the generic product.	02/12
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
NO Changes	02/14
Added clinically unacceptable risk with a change in therapy to a preferred drug	06/15
Annual Review. No changes	08/16
Annual Review. No changes	03/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

NOTE: The electronic approval is retained in Compliance 360.