



# nh healthy families™

## MEDICAL NECESSITY GUIDELINE

<b>DEPARTMENT:</b> Pharmacy	<b>DOCUMENT NAME:</b> Off-Label Use
<b>PAGE:</b> 1 of 3	<b>REFERENCE NUMBER:</b> NH.PMN.53
<b>EFFECTIVE DATE:</b> 11/12	<b>REPLACES DOCUMENT:</b>
<b>RETIRED:</b>	<b>REVIEWED:</b> 11/12, 12/14, 08/16, 07/17
<b>PRODUCT TYPE:</b> All	<b>REVISED:</b> 11/13

### **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:** This guideline is designed for drugs being requested for use other than the indication, treatment regimen, or patient population as approved by the U.S. Food and Drug Administration (FDA).

**Brand:** Various drug products.

**FDA Labeled Indications:** Varies among drug product. Refer to the drug’s FDA approved indication(s) and labeling.

**Criteria for Approval:**

- A. Use must be for a specific diagnosis, for appropriate disease stage, and disease duration.
- B. Use must be supported by Phase 3 study or high quality, large controlled research studies published in a well-respected drug reference book, reputable peer-reviewed medical journals or other respected sources that support the off-label use. In addition, recognized clinical treatment guidelines may be considered. Treatment guidelines must be based on information from medical literature, including clinical trials, and recommend current standard of care.
- C. Use must have a specified dosage regimen and duration of

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treatment supported by the referenced study or clinical practice guideline.

- D. The patient for whom the medication is requested must be similar to the patients in the study and meet inclusion/exclusion criteria. Criteria, such as age, and co-morbidities, must be similar to the referenced study population.
- E. Use shows clear and significant clinical or economic advantage over current standard of care treatment, including approved drug regimen(s). Trial and failure, or contraindication, of Preferred Drug List (PDL) medications must be considered prior to approval of off-label medications.
- F. Clinically unacceptable risk with a change in therapy to the preferred agent

**Approval:** Initial Approval: 12 months or the requested length of therapy, whichever is less.  
Continued Approval: 12 months.

### Special Instructions

Varies among drug products.

### Revision Log

Revision	Date
Edited Description of Plan criteria.	11/13
Added "labeling" to FDA labeled indications section.	11/13
Edited Criteria for approval Section B.	11/13
"Standard of care" recommendation moved to Section B.	11/13
Added "current standard of care treatment" in Section E.	11/13
Reviewed.	12/14
Added Clinically unacceptable risk with a change in therapy to the preferred agent.	07/15
Annual Review, No Changes	08/16
Annual Review, No Changes	07/17



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### 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

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