Clinical Policy: Brand Name Override

Reference Number: PA.CP.PMN.22
Effective Date: 09/06
Last Review Date: 01/19

Revision Log

Description
The intent of the criteria is to ensure patients follow selection elements established by Pennsylvania Health and Wellness®", medical policy for non-PDL brand name drugs.

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness", that non-PDL brand name drugs are **medically necessary** for members meeting the following criteria:

I. Initial Approval Criteria

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

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex);
2. Failure of an adequate trial of or clinically significant adverse effects to two generics* of the requested brand name drug, each from a different manufacturer, unless member has contraindications 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), that is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex) for the requested indication, provided that such agent exists*
3. If currently taking and stabilized on a brand name drug with a narrow therapeutic window, the request will be approved;
4. If clinically significant adverse effects were experienced, provider submits a copy of the MedWatch form(s) submitted to the FDA (*see Appendix D*);
5. 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*

6. 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;
      i. Refer to policy PA.CP.PMN.59 quantity Limit Override for quantities exceeding limits
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Request for Brand Name Drug When a Generic Equivalent Does Not Exist: Refer to Requests for Medically Necessary Drug Not on the PDL policy, PA.CP.PMN.16.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (see PA.LTSS.PHAR.01);
2. Member is responding positively to therapy.
3. If request is for a dose increase, new dose does not exceed 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;
      i. Refer to policy PA.CP.PMN.59 quantity Limit Override for quantities exceeding limits
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:
N/A

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list

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.

- 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.

Background

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 Pennsylvania Health and Wellness when A-rated generic equivalents are available; however, brand name drugs may be approved in certain circumstances where there is an adverse reaction to or therapeutic failure of generic drugs.

References (or Bibliography)

1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed May 9, 2018.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed May 9, 2018.
3. FDA MedWatch Reporting Forms at http://www.fda.gov/Safety/MedWatch/HowToReport. Accessed May 9, 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
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.		
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.	01/19	