Clinical Policy: Brand Name Override

Reference Number: PA.CP.PMN.22
Effective Date: 09/06
Last Review Date: 07/18

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)
Not applicable

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. 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

II. Continued Therapy

A. Request for Non-PDL Brand Name Drug (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. Documentation of positive response to therapy.
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose.
4.

Approval duration: Initial approval: 12 months
Continued approval: 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: MedWatch Forms
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.

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.

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 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	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		

Reviews, Revisions, and Approvals	Date	Approval Date
be expected to benefit the patient when the generics did not. References reviewed and updated.		