Prior Authorization Review Panel

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PMN.22	**Effective Date: 01/2020** **Revision Date: 01/2021**
Policy Name: Brand Name Override of Medications Not on the Statewide PDL	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: added language to require use of preferred biosimilars if available; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Brand Name Override of Medications Not on the Statewide PDL

Reference Number: PA.CP.PMN.22
Effective Date: 09/06
Last Review Date: 01/2021

Revision Log

Description
The intent of the criteria is to ensure patients follow selection elements established by Pennsylvania Health and Wellness® medical policy for brand name drugs that are outside of the scope of the Pennsylvania Medical Assistance Program's Statewide PDL.

FDA Approved Indication(s)
Varies by drug product.

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

I. Initial Approval Criteria

A. Request for Brand Name Drug that is outside the scope of the Statewide PDL in Lieu of Generic Formulation (must meet 1, 2, 4, 5, and 6; OR must meet 1, 3 and 6)**:**

1. Prescribed indication is FDA-approved;*
   **Requests for off-label use should also be reviewed against PA.CP.PMN.53*
2. Failure of an adequate trial of or clinically significant adverse effects to two generics* (each from a different manufacturer) or the preferred biosimilar(s) of the requested brand name drug, unless member has contraindications to the excipients in all generics/biosimilars;
   **If a second generic of the requested brand name drug is not available, member must try a formulary alternative 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 (*see appendix D for examples*), 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 (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Request for Brand Name Drug that is <u>outside of the scope of the Statewide PDL</u> when a Generic Equivalent Does Not Exist:
Refer to Requests for Medically Necessary Drug Not on the Statewide 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 (*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

- Note: if the requested medication appears on the Pennsylvania Medical Assistance Program's Statewide PDL, whether preferred or non-preferred status, a coverage determination must be made using the corresponding State-directed prior authorization policy. This policy is only relevant to requests for brand name medications that are not included on the Statewide PDL.
- 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.
- Examples of Narrow Therapeutic Window drugs include, but are not limited to: amiodarone, digoxin, disopyramide, flecainide, procainamide, propafenone, and theophylline)

IV. References

1. FDA Center for Drug Evaluation and Research (CDER) Orange Book Preface at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed November 17, 2020.
2. FDA Electronic Orange Book at http://www.fda.gov/cder/ob/. Accessed November 17, 2020.
3. FDA MedWatch Reporting Forms at http://www.fda.gov/Safety/MedWatch/HowToReport. Accessed November 17, 2020.

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	
1Q 2020 annual review: revised for use with only medications outside of the scope of Statewide PDL; revised to limit indications to FDA-approved uses and added reference to off-label use policy	01/2020	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2021 annual review: added language to require use of preferred biosimilars if available; references reviewed and updated.	01/2021	