

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

Reference Number: PA.CP.PMN.22

Effective Date: 09/2006

Last Review Date: 01/2023

[Revision Log](#)

Description

The intent of the criteria is to ensure patients follow selection elements established by PA Health & 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 PA Health & 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 to alternative therapies required in criterion 2 above, provider submits chart note documentation;
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

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- 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 outside of the scope of the Statewide PDL 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 PA Health & 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:

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- 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 October 27, 2022.
2. FDA Electronic Orange Book at <http://www.fda.gov/cder/ob/>. Accessed October 27, 2022.
3. FDA MedWatch Reporting Forms at <http://www.fda.gov/Safety/MedWatch/HowToReport>. Accessed October 27, 2022.

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.	01/2019	
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	

CLINICAL POLICY

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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	
1Q 2022 annual review: references reviewed and updated.	01/2022	
1Q 2023 annual review: no significant changes; added the following clarification to chart note requirements of adverse effects: If clinically significant adverse effects were experienced <i>to alternative therapies required in criterion 2 above</i> , provider submits chart note documentation; references reviewed and updated.	01/2023	