

## Clinical Policy: Request for Medically Necessary Drug Not on the Statewide Preferred Drug List

Reference Number: PA.CP.PMN.16

Effective Date: 01/2018

Last Review Date: 07/2023

[Coding Implications](#)[Revision Log](#)

### Description

The intent of the criteria is to ensure that patients follow selection elements established by PA Health & Wellness medical policy for drugs that are not on the Statewide preferred drug list (PDL).

### FDA approved indication

N/A

### Policy/Criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup>, that drugs that are not listed on the Statewide PDL are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

*\*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria\**

##### A. Request for a Drug NOT on the Statewide PDL where Custom Coverage Criteria

**Exist:** *Please refer to the custom coverage criteria policy corresponding to the medication and the indicated use*

##### B. Request for a Drug NOT on the Statewide PDL for a Labeled Use without Coverage Criteria (must meet all):

1. Request is for a drug without custom coverage criteria;
2. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at maximum indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
3. If request is for combination product or alternative dosage form or strength of existing drugs (except combination HIV antiretrovirals), medical justification\* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);  
*\*Use of a copay card or discount card does not constitute medical necessity*
4. Member has no contraindications to prescribed agent per the product information label;
5. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
6. Treatment is not for a benefit-excluded purpose (e.g., cosmetic);
7. Request meets one of the following (a or b):

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- a. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: duration of request or 6 months (whichever is less)**

- C. Request for a Drug NOT on the Statewide PDL for an Off-label Use (i.e. utilization of an FDA-approved drug for uses other than those listed in the FDA-approved labeling or in treatment regimens or populations that are not included in approved labeling) where No Custom Coverage Criteria Exist: Please refer to PA.CP.PMN.53 Off-Label Use of Drugs Not on the Statewide Preferred Drug List**

**II. Continued Therapy**

- A. Request for a Drug NOT on the Statewide PDL where Custom Coverage Criteria Exist: Please refer to the custom coverage criteria policy corresponding to the medication and the indicated use**

- B. Request for a Drug NOT on the Statewide PDL for a Labeled Use without Coverage Criteria (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit, or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHARM.01) applies;
2. Member is responding positively to therapy or provider feels necessary to continue requested medication;
3. If request is for a dose increase, request meets 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;
  - 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**

- C. Request for a Drug NOT on the Statewide PDL for an Off-label Use (i.e. utilization of an FDA-approved drug for uses other than those listed in the FDA-approved labeling or in treatment regimens or populations that are not included in approved labeling) where No Custom Coverage Criteria Exist: Please refer to PA.CP.PMN.53 Off-Label Use of Drugs Not on the Statewide Preferred Drug List**

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

PDL: preferred drug list

## CLINICAL POLICY

### Request for Medically Necessary Drug not on the PDL



Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018: replacing retired policy PA.CP.PST.16	10/2018	
09/01/2019 submission for statewide PDL implementation 01/01/2020: Policy Name revised to reflect its use only for drugs NOT listed on the statewide PDL	09/2019	
4Q 2020 annual review: added bypass of required preferred agent trials if clinically significant adverse effects are experienced or all are contraindicated; dose requirements and positive response added	07/2020	
4Q 2021 annual review: no significant changes	10/2021	
4Q 2022 annual review: no significant changes.	10/2022	
Added renewal criteria provider feels necessary to continue	07/2023	