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: 11/01/2020**
Policy Number: PA.CP.PMN.16	**Effective Date: 01/2020** **Revision Date: 10/2020**
Policy Name: Request for Medically Necessary Drug Not on the Statewide Preferred Drug List	

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:

Added bypass of required preferred agent trials if clinically significant adverse effects are experienced or all are contraindicated; dose requirements and positive response added

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

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

Reference Number: PA.CP.PMN.16
Effective Date: 01.18
Last Review Date: 11.20

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and 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®", 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):

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 Pennsylvania Health and 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;
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018: replacing retired policy PA.CP.PST.16	10/18	
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	09/01/2019	
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	07.20	11.20