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: 10/2024

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 PA Health & 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 preferred* 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 one of the following (a or b):
   a. Clinically significant adverse effects are experienced or all are contraindicated;
   b. Request is for Stage IV or metastatic cancer;
   **Where there is an available preferred agent on the Statewide PDL or supplemental formulary*
3. If request is for combination product or alternative dosage form or strength of existing drugs (except combination HIV antiretrovirals), one of the following:
   a. 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);
   b. Request is for Stage IV or metastatic cancer;
   **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 PA Health & Wellness benefit, or member has previously met all initial approval criteria or the Continuity of Care policy (PA.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

Reviews, Revisions, and Approvals	Date
4Q 2018: replacing retired policy PA.CP.PST.16	10/2018
4Q 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
4Q 2023 annual review: addition of preferred agent, when present	10/2023
4Q 2024 annual review: added bypass for stage IV and metastatic cancer	10/2024