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.

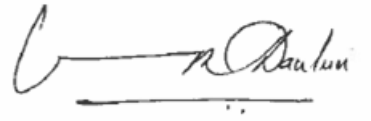
Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PMN.255	**Effective Date: 01/2020** **Revision Date: 10/2022**
Policy Name: No Coverage Criteria, Recent Label Changes Pending Clinical Policy Update for Drug Not on the Statewide Preferred Drug List	

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:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: No Coverage Criteria, Recent Label Changes Pending Clinical Policy Update for Drug Not on the Statewide Preferred Drug List

Reference Number: PA.CP.PMN.255
Effective Date: 01.2023
Last Review Date: 12/2022

Coding Implications
Revision Log

Description
This policy is to be used for drugs not on the Statewide Preferred Drug List (PDL) that:*

- Require prior authorization where there are no specific guidelines or coverage criteria.
- Have drug specific clinical policies that are pending updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens).

**All requests for non-PDL drugs, under the pharmacy benefit, should be reviewed against PA.CP.PMN.16 Request for Medically Necessary Drug Not on the Statewide Preferred Drug List or medication specific prior authorization criteria when available*

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
It is the policy of PA Health and Wellness®, that all medical necessity determinations for drugs NOT on the statewide PDL* drug therapy without coverage criteria or pending clinical policy updates as a result of recent label changes be considered on a case-by-case basis by a physician, pharmacist or ad hoc committee, using the guidance provided within this policy.
**All requests for non-PDL drugs, under the pharmacy benefit, should be reviewed against PA.CP.PMN.16 Request for Medically Necessary Drug Not on the Statewide Preferred Drug List or medication specific prior authorization criteria when available*

I. Initial Approval Criteria

A. Labeled Use without Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes for a Drug NOT on the Statewide PDL (must meet all)**:**

1. One of the following (a or b):
   a. Requested drug does not have a drug-specific clinical policy or custom coverage criteria;
   b. Requested drug has a drug-specific clinical policy that is pending clinical policy updates as a result of recent (within the last 6 months) label changes (e.g., newly approved indications, age expansions, new dosing regimens);
2. Diagnosis of one of the following (a or b):
   a. A condition for which the product is FDA-indicated and -approved;
   b. A condition supported by the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B;

3. 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 clinically significant adverse effect are experienced, all are contraindicated, or request is for a product for treatment is for Stage IV or metastatic cancer;
4. For combination product or alternative dosage form or strength of existing drugs, 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), unless request is for a product for treatment is for Stage IV or metastatic cancer;
5. Member has no contraindications to the prescribed agent per the prescribing information;
6. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
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;
    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)

B. 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. Labeled Use without Drug-specific Coverage Criteria or Pending Clinical Policy Updates as a Result of Recent Label Changes for a Drug NOT on the Statewide PDL (must meet all)**:**

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;
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;
    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: Duration of request or 12 months (whichever is less)

B. 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
PDL: preferred drug list

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy	12/2022	