Clinical Policy: Oncology Agents, Oral

Reference Number: PHW.PDL.239
Effective Date: 01/01/2020
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health and Wellness® that Oral Oncology Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Oncology Agents, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for Oncology Agents, Oral must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the Oncology Agent, Oral for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling or nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. The prescribed Oncology Agent, Oral is prescribed by or in consultation with an oncologist or hematologist; **AND**

4. For a non-preferred Oncology Agent, Oral, **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Oncology Agents, Oral approved or medically accepted for the member's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Oncology Agent, Oral l (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

AND

5. If the prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ONCOLOGY AGENTS, ORAL: The determination of medical necessity of a request for renewal of a prior authorization for an Oncology Agent, Oral that was previously approved will take into account whether the member:

1. Has documentation of a positive clinical response to the medication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed the Oncology Agent, Oral by or in consultation with an oncologist or hematologist; **AND**

4. For a non-preferred Oncology Agent, Oral with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested medication.

AND

5. If a prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Oncology Agent, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization

request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. **Approval Duration:**
   - **New request: duration of request or 6 months (whichever is less)**
   - **Renewal request: duration of request or 12 months (whichever is less)**

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025: policy revised according to DHS revisions effective 01/06/2025	11/2024