

DRUG DETERMINATION POLICY

Title: DDP-52 Oncology Products

Effective Date: 12/13/2021



Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

This policy was developed to provide general guidance on ensuring appropriate usage of all oncology products.

3.0 Clinical Determination Guidelines:

A. Prescriber: oncologist.

B. Diagnosis and severity [must meet both listed below]:

1. Genetic testing: diagnosis is confirmed by appropriate genetic testing (if applicable) for medications with Food and Drug Administration (FDA) specified mutational target.
2. Tumor type/stage: clinically diagnosed with cancer stage and tumor type consistent with FDA approved indication for the requested medication.

C. Appropriate medication use [must meet both listed below]:

1. FDA approval status [must meet one listed below]:

- a. FDA-approved: product, indication, and/or dosage regimen.
- b. Non-FDA-approved: compendium support (Lexicomp™, NCCN) for use of a drug for a non-FDA-approved indication or dosage regimen.

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies [must meet one listed below]:

- a. Oncology: National Comprehensive Cancer Network (NCCN) category of evidence and consensus 2A (based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate).

D. Other therapies: contraindicated, inadequate response or experienced significant adverse effects to prior line of therapy based on NCCN clinical practice guidelines.

E. Dose rounding [if applicable must meet one listed below]:

- 1. Medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturer's strength of the requested medication for patients weighing above 10Kg.
- 2. Medications with rounding otherwise specified per Health Plan Benefit Coverage Policies (BCPs) and/or Drug Determination Policies (DDPs).

F. Wastage [if applicable must meet both listed below]:

- 1. Indication: if a drug or biological is only available in a single-use vial or single-use package that remains after rounding (if applicable) and administering a dose and/or quantity.
- 2. Prior authorization/approval unit calculation: separately identify wastage and/or dose as well as duration of the prior authorization.
 - a. Billing: bill the wastage separately using the JW modifier.

G. Approval:

- 1. Initial: six months duration.
- 2. Re-approval: six months duration [must meet all listed below]:
 - a. Patient must continue to meet the criteria required for initial approval.
 - b. Patient has experienced a positive clinical response from continuous treatment with the requested therapy.
 - c. Patient has been able to tolerate the therapy.

4.0 Coding:

None.

5.0 References, Citations, Resources & Associated Documents:

- 1. Treatment by Cancer Type. NCCN Guidelines. http://www.nccn.org/guidelines/category_1. Accessed August 1, 2021.
- 2. Drugs@FDA: FDA-Approved Drugs. [Accessdata.fda.gov. http://www.accessdata.fda.gov/scripts/cder/daf/](https://www.accessdata.fda.gov/scripts/cder/daf/). Accessed August 1, 2021.

6.0 Appendices:

None.

7.0 Revision History:

Original Effective Date: 12/13/2021

Next Review Date: 12/13/2022

Revision Date	Reason for Revision

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