

Drug Policy

Policy:	General Oncology Prior Authorization	Annual Review Date: 07/18/2024 Last Revised Date: 10/17/2024
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OVERVIEW

Prior authorization is required to ensure that oncology medications are being used safely and that they will be effective for the prescribed indication.

POLICY STATEMENT

This policy involves the use of oncology medications. This policy **does not** apply to products used for supportive care purposes (e.g. anti-emetics, filgrastim, epoetin alfa, etc.). Prior authorization is recommended for pharmacy benefit coverage of oncology medications. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with oncology medications as well as the monitoring required for adverse events and long-term efficacy, initial approval requires oncology medications be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, oncology medications must be prescribed by or in consultation with a hematologist, oncologist, or a specialist with experience in treating the cancer for which the drug is being requested. All approvals for initial therapy are provided for the initial approval duration noted below.

Select oncology products may be subject to additional criteria requirements. Refer to the Oncology Care Value Preferred Specialty Management policy for details.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of oncology medications is recommended in those who meet the following criteria:

1. **Requests for an FDA-labeled indication (per the most recent package insert)**
Criteria. *Patient must meet the following criteria*
 - A. If the indication in the product’s most recent FDA-approved labeling (package insert) specifies the prior use of another treatment or medication, the patient has had a prior trial on the agent specified *; AND
 - B. Diagnostic or confirmatory testing has been conducted to support the use of this medication for this particular indication, including any specifically mentioned diagnostics or testing, as noted in the most recent FDA-approved labeling (package insert) [NOTE: this includes testing for targeted mutations or gene expression] *; AND

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- C. The requested drug will only be used for the recommended duration for the indication; AND
- D. The requested dose follows the dosing guidelines outlined in the product's most recent FDA-approved labeling (package insert); AND
- E. The patient does not have any contraindications to the requested medication; AND
- F. If the indication in the product's most recent FDA-approved labeling (package insert) specifies that the requested agent be used in combination with additional antineoplastic therapy, the patient will use the recommended medication regimen for treatment; AND
- G. If the request is for a brand product with an AA- or AB-rated generic product available, the patient must meet one of the following:
 - a. The patient has tried the generic product *; OR
 - b. The patient cannot take the generic product due to a formulation difference in the inactive ingredients [e.g. difference in dyes, fillers, preservatives] between the brand and generic product which would result in a significant allergy or adverse reaction per the prescriber *

2. Patients with an indication that is cited in the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium as a category 1, 2A, or 2B recommendation

Criteria. *Patient must meet the following criteria*

- A. If the NCCN recommended use for the requested agent in the most recent version of the NCCN Drugs & Biologics Compendium specifies the prior use of another treatment or medication, the patient has had a prior trial with the agent specified *; AND
- B. Diagnostic or confirmatory testing has been conducted to support the use of this medication for the specific NCCN recommended use, including any specifically mentioned diagnostics or testing, as noted in the most recent version of the NCCN Drugs & Biologics Compendium [NOTE: this includes testing for targeted mutations or gene expression] *; AND
- C. The requested drug will only be used for the recommended duration for the condition per the most recent version of the NCCN Drugs & Biologics Compendium; AND
- D. The patient does not have any contraindications to the requested medication; AND
- E. If the NCCN recommended use for the requested agent in the most recent version of the NCCN Drugs & Biologics Compendium specifies that the requested agent be used in combination with additional antineoplastic therapy, the patient will use the recommended regimen for treatment; AND
- F. If the request is for a brand product with an AA- or AB-rated generic product available, the patient must meet one of the following:
 - a. The patient has tried the generic product *; OR
 - b. The patient cannot take the generic product due to a formulation difference in the inactive ingredients [e.g. difference in dyes, fillers, preservatives] between the brand and generic product which would result in a significant allergy or adverse reaction per the prescriber *

3. Patient has been started on the requested oncology medication

Criteria. *Approve for an indication or condition addressed as an approval in this document. Prescriber will provide evidence of beneficial response warranting continuation of therapy.*

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 6 months

B) *Extended Approval:* 1 year

*** Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.