



Leukine

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: Same as Referring Provider Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ kg

Patient Height: _____ cm

Please indicate the place of service for the requested drug:

- Ambulatory Surgical Home Off Campus Outpatient Hospital
 On Campus Outpatient Hospital Office Pharmacy

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Exception Criteria Questions

- A. Is the product being requested for the treatment of one of the following indications?
- Neutropenia due to myelosuppressive anti-cancer therapy
 - To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
 - To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
 - To mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
 - To reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- Yes No, *If No, skip to Criteria Questions*
- B. The preferred products for your patient's health plan are Zarxio and Nivestym. Can the patient's treatment be switched to a preferred product?
- Yes, *Please obtain Form for preferred product and submit for corresponding PA* No
- C. Did the patient have a documented inadequate response to Zarxio or Nivestym? **ACTION REQUIRED: If Yes, attach supporting chart note(s)** Yes, *skip to criteria questions* No
- D. Has the patient experienced a documented intolerable adverse event to Zarxio or Nivestym? **ACTION REQUIRED: If Yes, attach supporting chart note(s)** Yes No

Criteria Questions:

1. What is the patient's diagnosis?
- | | |
|---|--|
| <input type="checkbox"/> Agranulocytosis (non-chemotherapy drug induced) | <input type="checkbox"/> Severe chronic neutropenia - Congenital neutropenia |
| <input type="checkbox"/> Stem cell transplantation-related indication | <input type="checkbox"/> Severe chronic neutropenia - Cyclic neutropenia |
| <input type="checkbox"/> Myelodysplastic syndrome (anemia or neutropenia) | <input type="checkbox"/> Severe chronic neutropenia - Idiopathic neutropenia |
| <input type="checkbox"/> Acute myeloid leukemia | <input type="checkbox"/> Hematopoietic syndrome of acute radiation syndrome |
| <input type="checkbox"/> Neutropenia associated with HIV/AIDS | <input type="checkbox"/> Neuroblastoma |
| <input type="checkbox"/> Aplastic anemia | |
| <input type="checkbox"/> Neutropenia (prevention or treatment) associated with myelosuppressive anti-cancer therapy | |
| <input type="checkbox"/> Other _____ | |
2. What is the ICD-10 code? _____

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Hematopoietic syndrome of acute radiation syndrome

3. Will the requested medication be used for the treatment of radiation-induced myelosuppression following a radiological/nuclear incident? Yes No

Section B: Neuroblastoma

4. Is the patient's disease considered high-risk? Yes No
5. Will the requested medication be used in combination with ALL of the following medications? Yes No
- a) Dinutuxin (Unituxin)
 - b) Interleukin-2 (aldesleukin (Proleukin))
 - c) Isotretinoin (13-cis-retinoic acid)

Section C: Neutropenia (Prevention or Treatment) Associated with Myelosuppressive Anti-Cancer Therapy

6. Will the requested medication be used in combination with any other colony stimulating factor products within any chemotherapy cycle? Yes No
7. Will the patient be receiving concurrent chemotherapy and radiation therapy? Yes No

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8. For which of the following indications is the requested medication being prescribed?
- Primary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy
 - Secondary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy, *skip to #12*
 - Treatment of high risk febrile neutropenia, *skip to #14*
 - No
9. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia? ***ACTION REQUIRED: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen and no further questions. If yes, no further questions*** Yes No
10. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in 10-19% incidence of febrile neutropenia? ***ACTION REQUIRED: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen.*** Yes No
11. Is the patient considered to be at high risk for febrile neutropenia because of bone marrow compromise or co-morbidity, including any of the following? ***ACTION REQUIRED: If Yes, please submit documentation confirming the patient's risk factors. Indicate below and no further questions.***
- Active infections, open wounds, or recent surgery
 - Age greater than or equal to 65 years
 - Bone marrow involvement by tumor producing cytopenias
 - Previous chemotherapy or radiation therapy
 - Poor nutritional status
 - Poor performance status
 - Previous episodes of FN
 - Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
 - Persistent neutropenia
 - Other bone marrow compromise or comorbidity not listed above _____
 - None of the above
- No Further Questions*
12. Has the patient experienced a neutropenic complication from a prior cycle of similar chemotherapy? Yes No
13. For the planned chemotherapy cycle, will the patient receive the same dose and schedule of chemotherapy as the previous cycle (for which primary prophylaxis was not received)? Yes No *No further questions*
14. Does the patient have any of the following prognostic factors that are predictive of clinical deterioration?
- Age greater than 65 years
 - Being hospitalized at the time of the development of fever
 - Sepsis syndrome
 - Invasive fungal infection
 - Pneumonia or other clinically documented infection
 - Prolonged (neutropenia expected to last greater than 10 days) or profound (absolute neutrophil count less than $1 \times 10^9/L$) neutropenia
 - Prior episodes of febrile neutropenia

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Step Therapy Override: Complete if Applicable.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X _____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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