



Neupogen, Granix, Nivestym, Zarxio

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?
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - 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 – Zarxio, *skip to criteria questions*
 Yes – Nivestym, *skip to criteria questions*
 No
- C. Does the patient have a documented latex allergy and the prescriber has stated that the patient must use latex-free vials? **ACTION REQUIRED: If Yes, attach supporting chart note(s)** Yes, *skip to letter E* No
- D. Are Neupogen or Granix being requested for doses less than 180 mcg? Yes No, *skip to letter F*
- E. Did the patient have a documented inadequate response or intolerable adverse event to treatment with Nivestym? **ACTION REQUIRED: If Yes, attach supporting chart note(s).** Yes No *If Yes or No, skip to Criteria Questions*
- F. Has the patient failed treatment with Zarxio and Nivestym due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? **ACTION REQUIRED: If Yes, attach supporting chart note(s).** Yes No
- G. Was the intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference products and biosimilar products)? **ACTION REQUIRED: If No, attach supporting chart note(s)** Yes No

Criteria Questions:

1. Which drug is being prescribed?
- Neupogen Granix Zarxio Nivestym Other _____
2. What is the patient's diagnosis?
- | | |
|---|---|
| <input type="checkbox"/> Agranulocytosis (non-chemotherapy drug induced) | <input type="checkbox"/> Stem cell transplantation related indications |
| <input type="checkbox"/> Anemia in myelodysplastic syndrome | <input type="checkbox"/> Neutropenia in myelodysplastic syndrome |
| <input type="checkbox"/> Acute myeloid leukemia | <input type="checkbox"/> Neutropenia associated with HIV/AIDS |
| <input type="checkbox"/> Neutropenia related to renal transplantation | <input type="checkbox"/> Aplastic anemia |
| <input type="checkbox"/> Severe chronic neutropenia – Congenital neutropenia | <input type="checkbox"/> Hematopoietic syndrome of acute radiation syndrome |
| <input type="checkbox"/> Severe chronic neutropenia – Cyclic neutropenia | <input type="checkbox"/> CAR-T cell related toxicities |
| <input type="checkbox"/> Severe chronic neutropenia – Idiopathic neutropenia | <input type="checkbox"/> Hairy cell leukemia |
| <input type="checkbox"/> Chronic myeloid leukemia | <input type="checkbox"/> Glycogen storage disease (GSD) Type 1 |
| <input type="checkbox"/> Neutropenia (prevention or treatment) associated with myelosuppressive anti-cancer therapy | |
| <input type="checkbox"/> Other _____ | |
3. 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

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

Section B: CAR-T Cell Related Toxicities

5. Will the requested medication be used as supportive care for neutropenia? Yes No

Section C: Hairy Cell Leukemia

6. Will the requested medication be used for treatment of neutropenic fever following chemotherapy?
 Yes No

Section D: Chronic Myeloid Leukemia (CML)

7. Will the requested medication be used to treat persistent neutropenia due to tyrosine kinase inhibitor therapy?
 Yes No

Section E: Glycogen Storage Disease (GSD) Type 1

8. Will the requested medication be used for the treatment of low neutrophil counts? Yes No

Section F: Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy

9. Will the requested medication be used in combination with any other colony stimulating factor products within any chemotherapy cycle? Yes No
10. Will the patient be receiving chemotherapy and radiation therapy at the same time? Yes No
11. 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 #15
 Treatment of high risk febrile neutropenia, skip to #17
 No
12. 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.**
 Yes No
13. 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
14. 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.**
- 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
- Yes No *No further questions*
15. Has the patient experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy?
 Yes No

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16. 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*
17. 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
- Yes No

Step Therapy Override: Complete if Applicable for the state of Maryland	Please Circle	
	Yes	No
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

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Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical 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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