Neupogen, Granix, Zarxio, Nivestym, Releuko

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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

 Neupogen, Granix, Nivestym, Zarxio, Releuko MR Biosimilar SGM – 09/2022.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Exception Criteria Questions

A. What drug is being prescribed?
- ❑ Neupogen
- ❑ Granix
- ❑ Nivestym, *Skip to Clinical Criteria Questions*
- ❑ Zarxio, *Skip to Clinical Criteria Questions*
- ❑ Releuko, *Skip to Clinical Criteria Questions*

B. 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*

C. 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

D. 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 F* ❑ No

E. Are Neupogen or Granix being requested for doses less than 180 mcg? ❑ Yes ❑ No, *skip to letter G*

F. 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*

G. 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

H. 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 ❑ Releuko ❑ Other _____

2. What is the patient's diagnosis?
   ❑ Agranulocytosis (non-chemotherapy drug induced)
   ❑ Anemia in myelodysplastic syndrome
   ❑ Acute myeloid leukemia
   ❑ Neutropenia related to renal transplantation
   ❑ Hematopoietic subsyndrome of acute radiation syndrome
   ❑ Severe chronic neutropenia – Congenital neutropenia
   ❑ Severe chronic neutropenia – Cyclic neutropenia
   ❑ Severe chronic neutropenia – Idiopathic neutropenia
   ❑ Chronic myeloid leukemia
   ❑ Stem cell transplantation related indications
   ❑ Neutropenia in myelodysplastic syndrome
   ❑ Neutropenia associated with HIV/AIDS
   ❑ Aplastic anemia
   ❑ CAR-T cell related toxicities
   ❑ Hairy cell leukemia
   ❑ Glycogen storage disease (GSD) Type 1
   ❑ Neutropenia (prevention or treatment) associated with myelosuppressive anti-cancer therapy
   ❑ Other _____

3. What is the ICD-10 code? _____

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

Section A: Hematopoietic Subsyndrome of Acute Radiation Syndrome

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 (Prevention or Treatment) Associated with Myelosuppressive Anti-Cancer Therapy

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*
    ❑ None of the above.

Section G: Primary Prophylaxis

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 and no further questions.***
    - ❑ Yes - Active infections, open wounds, or recent surgery
    - ❑ Yes - Poor nutritional status
    - ❑ Yes - Age greater than or equal to 65 years
    - ❑ Yes - Poor performance status
    - ❑ Yes - Previous chemotherapy or radiation therapy
    - ❑ Yes - Previous episodes of FN
    - ❑ Yes - Bone marrow involvement by tumor producing cytopenias
    - ❑ Yes - Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
    - ❑ Yes - Persistent neutropenia
    - ❑ Yes - Other bone marrow compromise or comorbidity not listed above
    - ❑ No - None of the above

Section H: Secondary Prophylaxis

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

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.*

Section I: Treatment of High Risk Febrile Neutropenia

17. Does the patient have any of the following prognostic factors that are predictive of clinical deterioration?
    - ❑ Yes - Age greater than 65 years
    - ❑ Yes - Sepsis syndrome
    - ❑ Yes - Invasive fungal infection
    - ❑ Yes - Prior episodes of febrile neutropenia
    - ❑ Yes - Being hospitalized at the time of the development of fever
    - ❑ Yes - Pneumonia or other clinically documented infection
    - ❑ Yes - Prolonged (neutropenia expected to last greater than 10 days) or profound (absolute neutrophil count less than 1 x 10^9/L) neutropenia
    - ❑ No - None of the above

Step Therapy Override: Complete if Applicable for the state of Maryland	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

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)**

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