Leukine

CareFirst 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

 CareFirst MR C26683-A Leukine SGM 1929-A - 1/2024.

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. Is the product being requested for the treatment of one of the following indications?

- Neutropenia associated with myelosuppressive anti-cancer therapy
- Neutropenia due to chemotherapy for acute myeloid leukemia
- Neutropenia associated with myeloablative chemotherapy after a bone marrow transplant for a non-myeloid cancer
- Autologous stem cell mobilization
- Severe chronic congenital neutropenia, severe chronic cyclic neutropenia, or severe chronic idiopathic neutropenia

❒ Yes, *Continue to Question B*

❒ No, *Skip to Clinical Criteria Questions*

B. The preferred products for your patient's health plan are Nivestym and Zarxio

Can the patient's treatment be switched to one of the preferred products?

❒ Yes, *Please obtain form for preferred product and submit a corresponding PA*

❒ No, *Continue to Question C*

C. Did the patient have an inadequate response or contraindication to both preferred products (Nivestym and Zarxio)? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Skip to Clinical Criteria Questions*

❒ No, *Continue to Question D*

D. Has the patient failed treatment with both of the preferred products (Nivestym and Zarxio) due to an intolerable adverse event (e.g., rash, nausea, vomiting)? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Continue to Question E*

❒ No, *Continue to Question F*

E. 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 product and biosimilar product)? ***Action Required***: If 'No', Attach supporting chart note(s)

❒ Yes, *Skip to Clinical Criteria Questions*

❒ No, *Skip to Clinical Criteria Questions*

F. Does the patient have a documented latex allergy? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Continue to Question G*

❒ No, *Continue to Question G*

G. Did the patient have an inadequate response or contraindication to Nivestym? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Skip to Clinical Criteria Questions*

❒ No, *Continue to Question H*

H. Has the patient failed treatment with Nivestym due to an intolerable adverse event (e.g., rash, nausea, vomiting)? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Continue to Question I*

❒ No, *Continue to Question I*

I. 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 product and biosimilar product)? ***Action Required***: If 'No', Attach supporting chart note(s)

❒ Yes

❒ No

Criteria Questions:

1. What is the patient's diagnosis?

❒ Neutropenia (prevention or treatment) associated with myelosuppressive anti-cancer therapy, *Continue to #10*

❒ Agranulocytosis (non-chemotherapy drug induced), *No Further Questions*

❒ Stem cell transplantation-related indication, *No Further Questions*

❒ Myelodysplastic syndrome (anemia or neutropenia), *No Further Questions*

❒ Acute myeloid leukemia, *No Further Questions*

❒ Neutropenia associated with HIV/AIDS, *No Further Questions*

❒ Aplastic anemia, *No Further Questions*

❒ Severe chronic neutropenia – Congenital neutropenia, *No Further Questions*

❒ Severe chronic neutropenia – Cyclic neutropenia, *No Further Questions*

❒ Severe chronic neutropenia – Idiopathic neutropenia, *No Further Questions*

❒ Hematopoietic syndrome of acute radiation syndrome, *Continue to #2*

❒ Neuroblastoma, *Continue to #3*

❒ Other, *No Further Questions*

Hematopoietic syndrome of acute radiation syndrome

2. Will the requested medication be used for the treatment of radiation-induced myelosuppression following a radiological/nuclear incident?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Neuroblastoma

3. Is the patient's disease considered high-risk?

❒ Yes, *Continue to #4*

❒ No, *Continue to #4*

4. Will the requested medication be used in combination with ALL of the following medications?

i. Dinutuxin (Unituxin)
ii. Interleukin-2 (aldesleukin)[Proleukin]
iii. isotretinoin (13-cis-retinoic acid)

❒ Yes, *No Further Questions*

❒ No, *Continue to #5*

5. Will the requested medication be used in combination with naxitamab-gqgk (Danyelza)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Neutropenia in cancer patients receiving myelosuppressive chemotherapy

10. Will the requested medication be used in combination with any other colony stimulating factor products within any chemotherapy cycle?

❒ Yes, *Continue to #11*

❒ No, *Continue to #11*

11. Will the patient be receiving chemotherapy and radiation therapy at the same time?

❒ Yes, *Continue to #12*

❒ No, *Continue to #12*

12. 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, *Continue to #13*
❒ Secondary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy, *Continue to #16*

❒ Treatment of high risk febrile neutropenia, *Continue to #18*

❒ Other, *No Further Questions*

Primary prophylaxis

13. 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*

❒ Yes, *No Further Questions*

❒ No, *Continue to #14*

14. 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, *Continue to #15*

❒ No, *Continue to #15*

5. 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 Further Questions*

❒ No, *No Further Questions*

Secondary prophylaxis

16. 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, *Continue to #17*

❒ No, *Continue to #17*

17. 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 Further Questions*

❒ No, *No Further Questions*

Treatment of High Risk Febrile Neutropenia

18. 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 0.1×10^9/L) neutropenia
- Prior episodes of febrile neutropenia

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

APPENDIX

A. APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher*†

1. Acute Lymphoblastic Leukemia:
   Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)

2. Bladder Cancer:
   i. Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
   ii. CBDCa/Pac (carboplatin, paclitaxel)
3. Bone Cancer:
   i. VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)
   ii. VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with
   ifosfamide and etoposide)
   iii. Cisplatin/doxorubicin
   iv. VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
   v. VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
4. Breast Cancer:
   i. Docetaxel + trastuzumab
   ii. Dose-dense AC (doxorubicin, cyclophosphamide) + paclitaxel (or dose dense paclitaxel)
   iii. TAC (docetaxel, doxorubicin, cyclophosphamide)
   iv. AT (doxorubicin, docetaxel)
   v. Doc (docetaxel)
   vi. TC (docetaxel, cyclophosphamide)
   vii. TCH (docetaxel, carboplatin, trastuzumab)
5. Colorectal Cancer:
   FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
6. Esophageal and Gastric Cancers:
   Docetaxel/cisplatin/fluorouracil
7. Head and Neck Squamous Cell Carcinoma:
   TPF (docetaxel, cisplatin, 5-fluorouracil)

8. Hodgkin Lymphoma:
   i. Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
   ii. Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
9. Kidney Cancer:
   Doxorubicin/gemcitabine
10. Non-Hodgkin's Lymphoma:
   i. CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
   ii. Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
   iii. ICE (ifosfamide, carboplatin, etoposide)
   iv. Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
   v. MINE (mesna, ifosfamide, mitoxantrone, etoposide)
   vi. DHAP (dexamethasone, cisplatin, cytarabine)
   vii. ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C))
   viii. HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
   ix. VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
11. Melanoma:
   Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
12. Multiple Myeloma:
   i. VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
   ii. DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)
13. Ovarian Cancer:
   i. Topotecan
   ii. Docetaxel
14. Pancreatic Cancer:
   FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
15. Soft Tissue Sarcoma:
   i. MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
   ii. Doxorubicin
   iii. Ifosfamide/doxorubicin
16. Small Cell Lung Cancer:
   i. Top (topotecan)
   ii. CAV (cyclophosphamide, doxorubicin, vincristine)
17. Testicular Cancer:
   i. VelP (vinblastine, ifosfamide, cisplatin)
   ii. VIP (etoposide, ifosfamide, cisplatin)
   iii. TIP (paclitaxel, ifosfamide, cisplatin)

*Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

† This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

B. APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%*†
   1. Occult Primary – Adenocarcinoma:

Gemcitabine/docetaxel

2. Breast Cancer:
   i. Docetaxel
   ii. CMF classic (cyclophosphamide, methotrexate, fluorouracil)
   iii. CA (doxorubicin, cyclophosphamide) (60 mg/m2) (hospitalized)
   iv. AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
   v. AC + sequential docetaxel + trastuzumab
   vi. A (doxorubicin) (75 mg/m2)
   vii. AC (doxorubicin, cyclophosphamide)
   viii. CapDoc (capecitabine, docetaxel)
   ix. Paclitaxel every 21 days
3. Cervical Cancer:
   i. Irinotecan
   ii. Cisplatin/topotecan
   iii. Paclitaxel/cisplatin
   iv. Topotecan
4. Colorectal Cancer:
   i. FL (fluorouracil, leucovorin)
   ii. CPT-11 (irinotecan) (350 mg/m2 q 3 wk)
   iii. FOLFOX (fluorouracil, leucovorin, oxaliplatin)
5. Esophageal and Gastric Cancers:
   i. Irinotecan/cisplatin
   ii. Epirubicin/cisplatin/5-fluorouracil
   iii. Epirubicin/cisplatin/capecitabine
6. Non-Hodgkin's Lymphomas:
   i. EPOCH-IT chemotherapy
   ii. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
   iii. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
   iv. FMR (fludarabine, mitoxantrone, rituximab)
   v. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
   vi. CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
   vii. Bendamustine
7. Non-Small Cell Lung Cancer:
   i. Cisplatin/paclitaxel
   ii. Cisplatin/vinorelbine
   iii. Cisplatin/docetaxel
   iv. Cisplatin/etoposide
   v. Carboplatin/paclitaxel
   vi. Docetaxel
8. Ovarian Cancer:
   Carboplatin/docetaxel
9. Prostate Cancer:
   Cabazitaxel
10. Small Cell Lung Cancer:
    Etoposide/carboplatin
11. Testicular Cancer:
    i. BEP (bleomycin, etoposide, cisplatin)
    ii. Etoposide/cisplatin
12. Uterine Sarcoma:
    Docetaxel

*Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

† This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

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