# Neulasta and pegfilgrastim biosimilars

## 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* |

What is the ICD-10 code? _____

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

 CareFirst MR C26684-A Neulasta and pegfilgrastim biosimilars SGM 1931-A – 01/2025.

**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?

- ❑ Neulasta, *Continue to Question B*
- ❑ Neulasta Onpro kit, *Continue to Question B*
- ❑ Fulphila, *Skip to Clinical Criteria Questions*
- ❑ Fylnetra *Continue to Question B*
- ❑ Nyvepria, *Skip to Clinical Criteria Questions.*
- ❑ Udenyca, *Continue to Question B*
- ❑ Udenyca on-body injector, *Continue to Question B*
- ❑ Ziextenzo, *Continue to Question B*
- ❑ Stimufend, *Continue to Question B*

B. Is the product being requested for the treatment of neutropenia associated with myelosuppressive anti-cancer therapy?

❒ Yes, *Continue to Question C*

❒ No, *Skip to Clinical Criteria Questions*

C. The preferred products for your patient's health plan are Fulphila and Nyvepria.

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

❒ Yes, Fulphila, *Skip to Clinical Criteria Questions*
❒ Yes, Nyvepria, *Skip to Clinical Criteria Questions*

❒ No, *Continue to Question D*

D. Does the patient have an inadequate response, or contraindication to BOTH preferred products (Fulphila and Nyvepria)? ***Action Required***: If 'Yes', attach supporting chart note(s)

❒ Yes, *Skip to Clinical Criteria Questions*

❒ No, *Continue to Question E*

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

❒ Yes, *Continue to Question F*

❒ No, *Continue to Question F*

F. 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, *Continue to Clinical Criteria Questions*
❒ No, *Continue to Clinical Criteria Questions*

**Clinical Criteria Questions:**

1. What is the patient's diagnosis?

❒ Neutropenia associated with myelosuppressive anti-cancer therapy, *Continue to 4*

❒ Stem cell transplantation-related indication, *No further questions*

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

❒ Hairy cell leukemia, *Continue to 3*

❒ Other, please specify. _____, *No further questions*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

3. Will the requested drug be used for treatment of neutropenic fever following chemotherapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Yes, *Continue to 5*

❒ No, *Continue to 5*

5. Will the patient be receiving chemotherapy at the same time as they receive radiation therapy?

❒ Yes, *Continue to 6*

❒ No, *Continue to 6*

6. Will the requested drug be administered with a weekly chemotherapy regimen?

❒ Yes, *Continue to 7*

❒ No, *Continue to 7*

7. For which of the following indications is the requested drug being prescribed?

❒ Primary prophylaxis (i.e., to be given 24 hours after first cycle of chemotherapy) of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancy, *Continue to 8*

❒ Secondary prophylaxis of febrile neutropenia in a patient with a solid tumor or non-myeloid malignancies, *Continue to 15*

❒ Other, please specify. _____, *No further questions*

8. 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.
[Refer to policy "APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher"]

❒ Yes, *No Further Questions*

❒ No, *Continue to 9*

9. 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.
[Refer to policy "APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%"]
❒ Yes, *Continue to 11*
❒ No, *Continue to 10*

10. Has the patient received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy that is expected to result in less than 10% risk incidence of febrile neutropenia? ***ACTION REQUIRED***: If Yes, please submit documentation confirming the patient's diagnosis and the chemotherapeutic regimen.
❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

11. Is the patient considered to be at high risk for febrile neutropenia because of bone marrow compromise, co-morbidities, or other patient specific risk factors including any of the following? ***ACTION REQUIRED***: If Yes, please submit documentation confirming the patient's risk factors.
❒ Yes, active infections, open wounds, or recent surgery ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, age greater than or equal to 65 years ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, bone marrow involvement by tumor producing cytopenias ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, previous chemotherapy or radiation therapy ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, poor nutritional status ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, poor performance status ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, previous episodes of FN ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease. Please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, persistent neutropenia ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, other bone marrow compromise, comorbidities, or patient specific risk factors not listed above. Please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ No, the patient does not have any risk factors, *No further questions*

12. Please indicate which risk factor applies to the patient: ***ACTION REQUIRED***: Please submit documentation confirming the patient's risk factors.
❒ Active infections, open wounds, or recent surgery ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Age greater than or equal to 65 years ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Bone marrow involvement by tumor producing cytopenias ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Previous chemotherapy or radiation therapy ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Poor nutritional status ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Poor performance status ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*

❒ Previous episodes of FN ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*

❒ Persistent neutropenia ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*

❒ None of the above*, Continue to 13*

13. Does the patient have a second risk factor?
❒ Yes*, Continue to 14*
❒ No*, No Further Questions*

14. Please indicate the patient's second risk factor: ***ACTION REQUIRED***: Please submit documentation confirming the patient's risk factors.
❒ Active infections, open wounds, or recent surgery ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Age greater than or equal to 65 years ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Bone marrow involvement by tumor producing cytopenias ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Previous chemotherapy or radiation therapy ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ Poor nutritional status ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ Poor performance status ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ Previous episodes of FN ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease. Please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ Persistent neutropenia ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ The patient does not have a second risk factor*, 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*, Continue to 16*
❒ No*, Continue to 16*

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 Further Questions*
❒ No*, No Further Questions*

## Appendix

**APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher**
This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.
Acute Lymphoblastic Leukemia
Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)
Bladder Cancer
Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer
- VAIA (vincristine, doxorubicin, ifosfamide, and dactinomycin)
- VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
- Cisplatin/doxorubicin
- VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
- VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)

Breast Cancer
- Dose-dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel
- TAC (docetaxel, doxorubicin, cyclophosphamide)
- TC (docetaxel, cyclophosphamide)
- TCH (docetaxel, carboplatin, trastuzumab)

Head and Neck Squamous Cell Carcinoma
TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma
- Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
- Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)

Kidney Cancer
Doxorubicin/gemcitabine
Non-Hodgkin's Lymphoma
- CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) ± rituximab
- ICE (ifosfamide, carboplatin, etoposide) ± rituximab
- Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
- MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± rituximab
- DHAP (dexamethasone, cisplatin, cytarabine) ± rituximab
- ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) ± rituximab
- HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
- Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone)

Melanoma
Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma
- VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
- DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)

Ovarian Cancer
- Topotecan ± bevacizumab
- Docetaxel

Soft Tissue Sarcoma
- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
- Doxorubicin
- Ifosfamide/doxorubicin

Small Cell Lung Cancer
Topotecan
Testicular Cancer
- VelP (vinblastine, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)

Gestational Trophoblastic Neoplasia
- EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
- EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
- EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
- TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)
- BEP (bleomycin, etoposide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- ICE (ifosfamide, carboplatin, etoposide)

Wilms Tumor
- Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
- Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

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

**APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%**
This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.
Occult Primary – Adenocarcinoma
Gemcitabine/docetaxel
Breast Cancer
- Docetaxel ± trastuzumab
- AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
- AC + sequential docetaxel + trastuzumab
- Paclitaxel every 21 days ± trastuzumab
- TC (docetaxel, cyclophosphamide)

Cervical Cancer
- Irinotecan
- Cisplatin/topotecan
- Paclitaxel/cisplatin ± bevacizumab
- Topotecan

Colorectal Cancer
FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Esophageal and Gastric Cancers
Irinotecan/cisplatin
Non-Hodgkin's Lymphomas
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
- CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
- Bendamustine

Non-Small Cell Lung Cancer
- Cisplatin/paclitaxel
- Cisplatin/vinorelbine
- Cisplatin/docetaxel
- Cisplatin/etoposide
- Carboplatin/paclitaxel
- Docetaxel

Ovarian Cancer
Carboplatin/docetaxel
Pancreatic Cancer
FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Prostate Cancer
Cabazitaxel
Small Cell Lung Cancer
Etoposide/carboplatin
Testicular Cancer
- BEP (bleomycin, etoposide, cisplatin)
- Etoposide/cisplatin

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

| **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**