Neulasta and pegfilgrastim biosimilars

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4**.**

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 (POS Code 24)*
❑ *Home (POS Code 12)*
❑ *Off Campus Outpatient Hospital (POS Code 19)*
❑ *On Campus Outpatient Hospital (POS Code 22)*
❑ *Office (POS Code 11)*

Drug Information:

Strength/Measure _____*Units* ❑ ml ❑ Gm ❑ mg ❑ ea ❑ Un

Directions (sig) _____*Route of administration*_____

Dosing frequency _____

What is the ICD-10 code? _____

Exception Criteria Questions:

A. What is the prescribed drug?
❑ Neulasta (Including Onpro kit). *Skip to Clinical Criteria Questions*
❑ Fulphila, *Skip to Clinical Criteria Questions*
❑ Udenyca
❑ Ziextenzo
❑ Nyvepria
❑ Fylnetra, *skip to Clinical Criteria Questions*

Send completed form to: Priority Partners Fax: 1-866-212-4756

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Priority Partners ● 7231 Parkway Drive Suite 100 ● Hanover, MD 21076
Phone: 888-819-1043 ● Fax: 1-866-212-4756 ● www.hopkinshealthplans.org

❑ Stimufend*, skip to Clinical Criteria Questions*
❑ Other_____*, skip to Clinical Criteria Questions*

B. The preferred products for your patient's health plan are Fulphila and Neulasta (including Onpro kit). Can the patient's treatment be switched to a preferred product?
❑ Yes*, Skip to Clinical Criteria Questions*
❑ No

C. Does the patient have a documented intolerable adverse event to treatment with all of the preferred products (Fulphila, Neulasta (including Onpro kit))? ***Action Required: If 'Yes', Attach supporting chart note(s)***.

❑ Yes*, If Yes, skip to Clinical Criteria Questions* ❑ No

D. 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 products)?
ACTION REQUIRED: If 'No', attach supporting chart note(s). ❑ Yes ❑ No

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. ***ACTION REQUIRED***: Submit supporting documentation
[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. ***ACTION REQUIRED***: Submit supporting documentation
[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. ***ACTION REQUIRED***: Submit supporting documentation
❒ 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.

[Please verify at least two risk factors are indicated. Refer to policy "APPENDIX C: Patient 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, *Continue to 14*

14. Please indicate the patient's second risk factor: ***ACTION REQUIRED***: Please submit documentation confirming the patient's risk factors.
[Please verify at least two different risk factors are indicated (see answers to question 12 and 14). Refer to policy "APPENDIX C: Patient 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

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. **Soft Tissue Sarcoma:**
    i. MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
    ii. Doxorubicin
    iii. Ifosfamide/doxorubicin
15. **Small Cell Lung Cancer:**
    i. Top (topotecan)
    ii. CAV (cyclophosphamide, doxorubicin, vincristine)
16. **Testicular Cancer:**
    i. VelP (vinblastine, ifosfamide, cisplatin)
    ii. VIP (etoposide, ifosfamide, cisplatin)
    iii. TIP (paclitaxel, ifosfamide, cisplatin)
17. Gestational Trophoblastic Neoplasia:
    i. EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
    ii. EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
    iii. EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
    iv. TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)
    v. BEP (bleomycin, etoposide, cisplatin)
    vi. VIP (etoposide, ifosfamide, cisplatin)
    vii. ICE (ifosfamide, carboplatin, etoposide)

18. Wilms Tumor:
    i. Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
    ii. Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

*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)
   iv. FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
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. **Pancreatic Cancer:**
   FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
10. **Prostate Cancer:**
    Cabazitaxel
11. **Small Cell Lung Cancer:**
    Etoposide/carboplatin
12. **Testicular Cancer:**
    i. BEP (bleomycin, etoposide, cisplatin)
    ii. Etoposide/cisplatin
13. **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.

C. APPENDIX C: Patient Risk Factors*

1. Active infections, open wounds, or recent surgery
2. Age greater than or equal to 65 years
3. Bone marrow involvement by tumor producing cytopenias
4. Previous chemotherapy or radiation therapy
5. Poor nutritional status
6. Poor performance status
7. Previous episodes of FN
8. Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
9. Persistent neutropenia

*This list is not all-inclusive.

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by Priority Partners.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Priority Partners Fax: 1-866-212-4756