AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: COLONY STIMULATING FACTORS

[Form to be completed ONLY if the member is self-administering]

Short-acting Granulocyte Colony-Stimulating Factors (G-CSFs)		
❑ **Granix®** (tbo-filgrastim)	❑ **Neupogen®** (filgrastim)	❑ **Nivestym™** (filgrastim-aafi)
❑ **Releuko®** (filgrastim-ayow)	❑ **Zarxio®** (filgrastim-sndz)	

Granulocyte-macrophage Colony-Stimulating Factor (GM-CSF)
❑ **Leukine®** (sargramostim)

Long-acting Granulocyte Colony-Stimulating Factors (G-CSFs)	
❑ **Fulphila™** (pegfilgrastim-jmdb)	❑ **Rolvedon™** (eflapegrastim-xnst)
❑ **Fylnetra™** (pegfilgrastim-pbbk)	❑ **Stimufend®** (pegfilgrastim-fpgk)
❑ **Neulasta®** (pegfilgrastim)	❑ **Udenyca®** (pegfilgrastim-cbqv)
❑ **Nyvepria™** (pegfilgrastim-apgf)	❑ **Ziextenzo™** (pegfilgrastim-bmez)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

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Maximum Daily Dose:

Fulphila 6 mg prefilled syringe: 1 syringe/14 days	Nivestym 480 mcg prefilled syringe: 3 syringes/1 day
Fylnetra 6 mg prefilled syringe: 1 syringe/14 days	Nyvepria 6 mg prefilled syringe: 1 syringe/14 days
Granix 300 mcg prefilled syringe: 4 syringes/1 day	Releuko 300 mcg vial: 3 vials/1 day
Granix 300 mcg single-dose vial: 4 vials/1 day	Releuko 300 mcg prefilled syringe: 3 syringes/1 day
Granix 480 mcg prefilled syringe: 3 syringes/1 day	Releuko 480 mcg vial: 3 vials/1 day
Granix 480 mcg single-dose vial: 3 vials/1 day	Releuko 480 mcg prefilled syringe: 3 syringes/1 day
Leukine 250 mcg vial: 28 vials/14 days	Rolvedon 13.2 mg prefilled syringe: 1 syringe/14 days
Neulasta 6 mg prefilled syringe: 1 syringe/14 days	Stimufend 6 mg prefilled syringe: 1 syringe/14 days
Neulasta 6 mg prefilled syringe kit: 1 kit/14 days	Udenyca 6 mg prefilled syringe: 1 syringe/14 days
Neupogen 300 mcg vial: 3 vials/1 day	Udenyca 6 mg auto-injector: 1 injection/14 days
Neupogen 300 mcg SingleJect: 3 syringes/1 day	Udenyca 6 mg onbody (syringe, with wearable injector): 1 syringe/14 days
Neupogen 480 mcg vial: 3 vials/1 day	Zarxio 300 mcg prefilled syringe: 3 syringes/1 day
Nivestym 300 mcg prefilled syringe: 3 syringes/1 day	Zarxio 480 mcg prefilled syringe: 3 syringes/1 day
Nivestym 480 mcg vial: 3 vials/1 day	Ziextenzo 6 mg prefilled syringe: 1 syringe/14 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

PROVIDER PLEASE NOTE: SUBMISSION OF APPLICABLE DOCUMENTATION IS NECESSARY (I.E. CHART NOTES, DISEASE HISTORY, CURRENT/PAST THERAPY RECORD, COMPLETE BLOOD COUNT OR OTHER LABORATORY RESULTS) FOR COMPLETION OF REQUEST

❑ Short-acting Granulocyte Colony-Stimulating Factors (G-CSFs)

PLEASE SELECT ONE OF THE FOLLOWING INDICATIONS FOR USE:

- ❑ Medication will be used as primary prevention of febrile neutropenia in members with non-myeloid malignancy meeting **ONE** of the following **[Length of authorization = 6 months]**:
  - ❑ Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia greater than 20%
  - ❑ Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to < 20% **AND one or more** of the following co-morbidities (select all that apply):
    - ❑ Age >65 years receiving full dose intensity chemotherapy
    - ❑ Extensive prior exposure to chemotherapy
    - ❑ Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - ❑ Persistent neutropenia (ANC $\leq 1000/mm^3$)
    - ❑ Bone marrow involvement by tumor

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- ❑ Member has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- ❑ Recent surgery and/or open wounds
- ❑ Poor performance status
- ❑ Renal dysfunction (creatinine clearance <50 mL/min)
- ❑ Liver dysfunction (elevated bilirubin >2.0 mg/dL)
- ❑ Chronic immunosuppression in the post-transplant setting, including organ transplant

OR

❑ Member is 18 years of age or older, has a diagnosis of acute myeloid leukemia, **AND** filgrastim therapy is needed shortly following completion of induction or consolidation chemotherapy **[Length of authorization = 6 months]**

OR

❑ Member has been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]) **[Length of authorization = Date of service only]**

OR

❑ Member has been diagnosed with a non-myeloid malignancy, **AND** will be receiving myeloablative chemotherapy following a bone marrow transplant **[Length of authorization = Date of service only]**

OR

❑ Medication will be used in apheresis collection of autologous hematopoietic progenitor cells **[Length of authorization = Date of service only]**

OR

❑ Member has been diagnosed with congenital, cyclic, or idiopathic neutropenia, **AND** is currently showing symptoms and incidence of complications (e.g., fever, infections, oropharyngeal ulcers) **[Length of authorization = 12 months]**

OR

❑ Treatment with filgrastim is needed as adjunctive treatment of febrile neutropenia when primary prophylaxis with a long-acting granulocyte colony stimulating factor is not given **[Length of authorization = 6 months]**

OR

❑ Adjunctive treatment of febrile neutropenia is considered clinically appropriate when at least **ONE** of the following risk factors are present (in the absence of prior growth factor use within the same chemotherapy cycle of treatment) **(select all that apply)** **[Length of authorization = 6 months]**:

- ❑ Age > 65 years
- ❑ Neutrophil recovery is expected to be delayed (greater than 10 days)
- ❑ Neutropenia is profound (less than 0.1 x 10^9)
- ❑ Active pneumonia
- ❑ Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)

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- ❑ Invasive fungal or opportunistic infection
- ❑ Onset of fever during inpatient stay

NOTE: Febrile neutropenia is defined as an oral temperature > 38.3°C (101.0°F) or 2 consecutive readings of 38.0°C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/µL (0.5 x 10^9/L) or less than 1000 cells/µL and expected to fall below 500 cells/µL over the next 48 hours.

OR

- ❑ Member has a diagnosis of primary myelodysplastic syndrome, **AND** filgrastim therapy will be used in combination with epoetin to treat anemia **[Length of authorization = 6 months]**

OR

- ❑ Member has a diagnosis of non-Hodgkin lymphoma or multiple myeloma, **AND** filgrastim therapy will be used in combination with plerixafor for the collection of progenitor cells leading to subsequent autologous transplantation. **[Length of authorization = Date of service only]**

  NOTE: Mozobil (plerixafor) requires prior authorization

❑ Granulocyte-macrophage Colony-Stimulating Factor (GM-CSF) [Leukine]

PLEASE SELECT ONE OF THE FOLLOWING INDICATIONS FOR USE:

- ❑ Member is 55 years of age or older, has a diagnosis of acute myeloid leukemia, **AND** sargramostim therapy is needed shortly after the completion of induction or repeat induction of chemotherapy **[Length of authorization = 6 months]**

OR

- ❑ Member is 2 years of age or older, **AND** sargramostim therapy is needed for faster reconstitution of myeloid to prepare for allogeneic bone marrow transplant **(NOTE: confirmation of HLA-matched donor status is required) [Length of authorization = 6 months]**

OR

- ❑ Member is 2 years of age or older, has undergone bone marrow transplant (allogeneic or autologous), **AND** sargramostim therapy is needed because there is delayed or failed neutrophil recovery **[Length of authorization = 6 months]**

OR

- ❑ Medication will be used in apheresis collection of autologous hematopoietic progenitor cells **[Length of authorization = Date of service only]**

OR

- ❑ Member is 2 years of age or older, has a diagnosis of acute lymphoblastic leukemia (ALL), Hodgkin lymphoma (HL), or non-Hodgkin lymphoma (NHL), **AND** sargramostim therapy is needed for faster reconstitution of myeloid following an autologous peripheral blood progenitor cell transplant or bone marrow transplant **[Length of authorization = 6 months]**

OR

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OR

- ❑ Member has been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]) **[Length of authorization = Date of service only]**

OR

- ❑ Member has a diagnosis of high-risk neuroblastoma, **AND** sargramostim is needed for combination therapy with a with GD2-binding monoclonal antibody (i.e., dinutiximab or naxitamab) **[Length of authorization = 6 months]**

❑ Long-acting Granulocyte Colony-Stimulating Factors (G-CSFs)

PLEASE SELECT ONE OF THE FOLLOWING INDICATIONS FOR USE:

- ❑ Medication will be used as primary prevention of febrile neutropenia in members with non-myeloid malignancy meeting **ONE** of the following **[Length of authorization = 6 months]**:
  - ❑ Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia greater than 20%
  - ❑ Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to < 20% **AND one or more** of the following co-morbidities (select all that apply):
    - ❑ Age >65 years receiving full dose intensity chemotherapy
    - ❑ Extensive prior exposure to chemotherapy
    - ❑ Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - ❑ Previous/persistent neutropenia (ANC ≤ 1000/mm3)
    - ❑ Bone marrow involvement by tumor
    - ❑ Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
    - ❑ Recent surgery and/or open wounds
    - ❑ Poor performance status
    - ❑ Renal dysfunction (creatinine clearance <50 mL/min)
    - ❑ Liver dysfunction (elevated bilirubin >2.0 mg/dL)
    - ❑ Chronic immunosuppression in the post-transplant setting, including organ transplant

OR

- ❑ Member has been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS]) **[Length of authorization = Date of service only]**

OR

- ❑ Medication will be used as secondary prevention of febrile neutropenia in members with non-myeloid malignancy, **AND** having experienced a neutropenic complication from a prior cycle of the same chemotherapy **[Length of authorization = 6 months]**

OR

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- ❑ Treatment with requested medication is needed as adjunctive treatment of febrile neutropenia when primary prophylaxis is not given **[Length of authorization = 6 months]**

OR

- ❑ Adjunctive treatment of febrile neutropenia is considered clinically appropriate when at least **ONE** of the following risk factors are present (in the absence of prior growth factor use within the same chemotherapy cycle of treatment) (select all that apply) **[Length of authorization = 6 months]**:
  - ❑ Age > 65 years
  - ❑ Neutrophil recovery is expected to be delayed (greater than 10 days)
  - ❑ Neutropenia is profound (less than 0.1 x 10^9)
  - ❑ Active pneumonia
  - ❑ Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)
  - ❑ Invasive fungal or opportunistic infection
  - ❑ Onset of fever during inpatient stay

  NOTE: Febrile neutropenia is defined as an oral temperature > 38.3°C (101.0°F) or 2 consecutive readings of 38.0°C (100.4°F) for 1 hour, with an absolute neutrophil count less than 500 cells/µL (0.5 x 10^9/L) or less than 1000 cells/µL and expected to fall below 500 cells/µL over the next 48 hours

OR

- ❑ Treatment with requested medication is needed after bone marrow transplantation (BMT) failure or engraftment delay **[Length of authorization = 6 months]**

OR

- ❑ Medication will be used in apheresis collection of autologous hematopoietic progenitor cells **[Length of authorization = Date of service only]**

- ❑ **For medical necessity on a treatment purpose not listed, please provide clinical rationale and submit any chart notes/literature you feel would be pertinent in support of medical necessity:**

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Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

*<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u> *

***Approved by Pharmacy and Therapeutics Committee:** ~~2/16/2023;~~ **3/21/2024**
REVISED/UPDATED/REFORMATTED: ~~2/9/2009; 6/14/2011; 8/19/2011; 1/23/2012; 1/14/2014; 4/9/2014; 5/7/2014; 5/28/2014; 8/13/2014; 10/31/2014; 5/21/2015; 12/27/2015; 6/9/2016; 8/19/2016; 9/22/2016; 12/11/2016; 8/3/2017; 5/14/2019; 8/6/2019; 12/20/2021; 1/12/2022; 2/23/2022; 3/23/2022;03/09/2023; 10/26/2023;~~ **4/26/2024**