

SENTARA COMMUNITY PLAN (MEDICAID)

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 1-800-750-9692. 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 (Pharmacy)

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

Short-acting Granulocyte Colony-Stimulating Factors (G-CSFs)		
<input type="checkbox"/> Granix [®] (tbo-filgrastim)	<input type="checkbox"/> Neupogen [®] (filgrastim)	<input type="checkbox"/> Nivestym [™] (filgrastim-aafi)
<input type="checkbox"/> Releuko [®] (filgrastim-ayow)	<input type="checkbox"/> Zarxio [®] (filgrastim-sndz)	

Granulocyte-macrophage Colony-Stimulating Factor (GM-CSF)
<input type="checkbox"/> Leukine [®] (sargramostim)

Long-acting Granulocyte Colony-Stimulating Factors (G-CSFs)	
<input type="checkbox"/> Fulphila [™] (pegfilgrastim-jmdb)	<input type="checkbox"/> Rolvedon [™] (eflapeggrastim-xnst)
<input type="checkbox"/> Fylnetra [™] (pegfilgrastim-pbbk)	<input type="checkbox"/> Stimufend [®] (pegfilgrastim-fpgk)
<input type="checkbox"/> Neulasta [®] (pegfilgrastim)	<input type="checkbox"/> Udenyca [®] (pegfilgrastim-cbqv)
<input type="checkbox"/> Nyvepria [™] (pegfilgrastim-apgf)	<input type="checkbox"/> Ziextenzo [™] (pegfilgrastim-bmez)

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

Member Name: _____

Member Sentara #: _____ 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, if applicable: _____

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%

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- ☐ 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
 - ☐ 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

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- ❑ 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 0.1×10^9)
 - ❑ 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 $> 38.3^{\circ}\text{C}$ (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 ($0.5 \times 10^9/\text{L}$) 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]
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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

- ☐ 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]**

<input type="checkbox"/> 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 ($ANC \leq 1000/mm^3$)
 - ☐ 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

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- ☐ 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

- ☐ 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 0.1×10^9)
 - ☐ 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 $> 38.3^{\circ}\text{C}$ (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 ($0.5 \times 10^9/\text{L}$) 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]**

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- ☐ 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:

Medication being provided by Specialty Pharmacy – Proprium Rx

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

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

*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; 3/9/2023; 3/13/2024; 4/26/2024~~