

# SENTARA HEALTH PLANS

## 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 may 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)               |   |   |
|--|---|---|
| <input type="checkbox"/> <b>Granix</b> <sup>®</sup> (tbo-filgrastim)       | <input type="checkbox"/> <b>Neupogen</b> <sup>®</sup> (filgrastim)                  | <input type="checkbox"/> <b>Nivestym</b> <sup>™</sup> (filgrastim-aafi) |
| <input type="checkbox"/> <b>Releuko</b> <sup>®</sup> (filgrastim-ayow)     | <input type="checkbox"/> <b>Zarxio</b> <sup>®</sup> (filgrastim-sndz)               |   |
| Granulocyte-macrophage Colony-Stimulating Factor (GM-CSF)                  |   |   |
| <input type="checkbox"/> <b>Leukine</b> <sup>®</sup> (sargramostim)        |   |   |
| Long-acting Granulocyte Colony-Stimulating Factors (G-CSFs)                |   |   |
| <input type="checkbox"/> <b>Fulphila</b> <sup>™</sup> (pegfilgrastim-jmdb) | <input type="checkbox"/> <b>Ryzneuta</b> <sup>®</sup> (efbemalenograstim alfa-vuxw) |   |
| <input type="checkbox"/> <b>Fylnetra</b> <sup>™</sup> (pegfilgrastim-pbbk) | <input type="checkbox"/> <b>Stimufend</b> <sup>®</sup> (pegfilgrastim-fpgk)         |   |
| <input type="checkbox"/> <b>Neulasta</b> <sup>®</sup> (pegfilgrastim)      | <input type="checkbox"/> <b>Udenyca</b> <sup>®</sup> (pegfilgrastim-cbqv)           |   |
| <input type="checkbox"/> <b>Nyvepria</b> <sup>™</sup> (pegfilgrastim-apgf) | <input type="checkbox"/> <b>Ziextenzo</b> <sup>™</sup> (pegfilgrastim-bmez)         |   |
| <input type="checkbox"/> <b>Rolvedon</b> <sup>™</sup> (eflapegrastim-xnst) |   |   |

**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: \_\_\_\_\_

Weight: \_\_\_\_\_ Date: \_\_\_\_\_

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**Maximum Daily Dose:**

|  |  |
|--|--|
| Fulphila 6 mg prefilled syringe: 1 syringe/14 days   | Nyvepria 6 mg prefilled syringe: 1 syringe/14 days                       |
| Fylnetra 6 mg prefilled syringe: 1 syringe/14 days   | Releuko 300 mcg vial: 3 vials/1 day                                      |
| Granix 300 mcg prefilled syringe: 4 syringes/1 day   | Releuko 300 mcg prefilled syringe: 3 syringes/1 day                      |
| Granix 300 mcg single-dose vial: 4 vials/1 day       | Releuko 480 mcg vial: 3 vials/1 day                                      |
| Granix 480 mcg prefilled syringe: 3 syringes/1 day   | Releuko 480 mcg prefilled syringe: 3 syringes/1 day                      |
| Granix 480 mcg single-dose vial: 3 vials/1 day       | Rolvedon 13.2 mg prefilled syringe: 1 syringe/14 days                    |
| Leukine 250 mcg vial: 28 vials/14 days               | Ryzneuta 20 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                      |
| Nivestym 480 mcg prefilled syringe: 3 syringes/1 day |  |

**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 ≤ 1000/mm<sup>3</sup>)

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- 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**

- 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  $0.1 \times 10^9$ )
  - Active pneumonia

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- ❑ 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<sup>9</sup>/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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- 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  $\leq$  1000/mm<sup>3</sup>)
    - 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**

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

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**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  $0.1 \times 10^9$ )
  - ❑ 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 ( $0.5 \times 10^9/L$ ) 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.\*\****  
***\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\****