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Colony Stimulating Factors (CSF) Prior Authorization

Drug(s) Applied:	**Nivestym** (filgrastim-aafi), short-acting CSF **Fulphila** (pegfilgrastim-jmdb), long-acting CSF

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for a compendia-supported indication and all of the following criteria are met:

Compendia Allowed: AHFS-DI supportive; Clinical Pharmacology supportive; DrugDex Class I, IIa or IIb level of evidence; Lexi-Drugs evidence level A; NCCN category 1 or 2A recommended use

I. Initial Therapy Criteria
   A. **Short-acting CSF agent** as indicated by chart notes within past 90 days
      1. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
      2. ONE of the following:
         a) Patient has undergone an allogeneic or autologous hematopoietic stem cell transplant **or**
         b) Patient has acute myeloid leukemia (AML) AND is receiving or has had induction or consolidation chemotherapy **or**
         c) Patient has a non-myeloid malignancy AND is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplantation (BMT) **or**
         d) Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) AND the requested agent will be used to increase survival **or**
         e) Requested agent is being used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis **or**
         f) Requested agent is being used for therapeutic use for febrile neutropenia (FN) AND the patient has at least one risk factor for infection-related complications or poor clinical outcome [e.g., greater than 65 years of age, sepsis syndrome, absolute neutrophil count (ANC) less than 100 neutrophils/mcL, anticipated prolonged (greater than 10 days) neutropenia, pneumonia, invasive fungal infections or clinically

documented infections, hospitalization, or prior episode of FN] **or**

g) Requested agent will be used as primary prophylaxis for the prevention of febrile neutropenia (FN) in patients receiving a chemotherapy regimen who have an overall risk of greater than 20% **or**

h) Requested agent will be used as primary prophylaxis for prevention of FN in patients receiving a chemotherapy regimen who have an overall risk of 10 to 20% AND the prescriber has assessed the patient risk factors and determined that the patient has at least 1 risk factor [e.g., prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2.0 mg/dL), renal dysfunction (creatinine clearance less than 50 mL/min), age greater than 65 years receiving full chemotherapy dose intensity, poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4), HIV infection with low CD4 counts (450 cells/mm3 or less)), **or**

i) Requested agent will be used as primary prophylaxis for prevention of FN in patients receiving a chemotherapy regimen who have an overall risk of less than 10% AND the prescriber has assessed the patient risk factors and determined that the patient has at least 2 risk factors [e.g., prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2.0 mg/dL), renal dysfunction (creatinine clearance less than 50 mL/min), age greater than 65 years receiving full chemotherapy dose intensity, poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4), HIV infection with low CD4 counts (450 cells/mm3 or less)) **or**

j) Requested agent will be used as secondary prophylaxis in patients who had a febrile neutropenic episode or dose-limiting neutropenic event from a prior chemotherapy cycle **or**

k) Patient has a diagnosis of myelodysplastic syndrome (MDS) and ONE of the following:
    (1) Patient has an ANC less than or equal to 500/mm^3 AND a history of recurrent or resistant bacterial infections **or**
    (2) Requested agent will be used for enhancement of erythropoietic activity for the treatment of refractory anemia and ALL of the following:
        (a) Requested agent will be used concurrently with an erythropoietin stimulating agent (ESA) **and**
        (b) Patient has a serum erythropoietin level less than or equal

to 500 mU/mL **and**

(c) Patient currently has adequate iron stores (i.e., greater than or equal to 20% transferrin saturation or serum ferritin greater than or equal to 100 ng/ml) **or**

l) Patient has a diagnosis of severe chronic neutropenia (i.e., congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia) and ALL of the following:

(1) Patient has at least one symptom (e.g., fever, infections, oropharyngeal ulcers) **and**

(2) Diagnostic labs have been evaluated (e.g., CBC with differential showing ANC less than 500 cells/μL on at least 2 separate occasions, assessment of platelet counts, bone marrow morphology, and karyotype analysis) **or**

m) Patient has another FDA labeled indication or compendia-supported indication for the requested agent **and**

3. Prescriber is a specialist in the area of the patient's diagnosis (e.g., hematology, oncology)

Approval Duration: 3 months

B. **Long-acting CSF agent** as indicated by chart notes within past 90 days

1. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
2. ONE of the following:

a) Requested agent will be used for secondary prophylaxis in patients who had a febrile neutropenic episode or dose-limiting neutropenic event from a prior chemotherapy cycle and patient's chemotherapy is NOT being used on a weekly basis **or**

b) Requested agent will be used for primary prophylaxis for the prevention of febrile neutropenia (FN) in patients receiving a chemotherapy regimen who have an overall risk of greater than 20% and the patient's chemotherapy is NOT being used on a weekly basis **or**

c) Requested agent will be used for primary prophylaxis for prevention of FN in patients receiving a chemotherapy regimen who have an overall risk of 10 to 20% and BOTH of the following:

(1) Prescriber has assessed the patient risk factors and determined that the patient has at least 1 risk factor (e.g., prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver

dysfunction [bilirubin greater than 2.0 mg/dL], renal dysfunction [creatinine clearance less than 50 mL/min], age greater than 65 years receiving full chemotherapy dose intensity, poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4), HIV infection with low CD4 counts (450 cells/mm3 or less)) **and**

(2) Patient's chemotherapy is NOT being used on a weekly basis **or**

d) Requested agent will be used for primary prophylaxis for prevention of FN in patients receiving a chemotherapy regimen who have an overall risk of less than 10% and ALL of the following:

(1) Prescriber has assessed the patient risk factors and determined that the patient has at least 2 risk factors (e.g., prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction [bilirubin greater than 2.0 mg/dL], renal dysfunction [creatinine clearance less than 50 mL/min], age greater than 65 years receiving full chemotherapy dose intensity, poor performance status (Eastern Cooperative Oncology Group [ECOG] Performance Status 3–4), HIV infection with low CD4 counts (450 cells/mm3 or less)) **and**

(2) Patient's chemotherapy is NOT being used on a weekly basis **or**

e) Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) and the requested agent will be used to increase survival **or**

f) Patient has another FDA labeled indication or compendia-supported indication for the requested agent **and**

3. Prescriber is a specialist in the area of the patient's diagnosis (e.g., hematology, oncology)

Approval Duration: 3 months

II. Continued Therapy Criteria

A. **Severe chronic neutropenia, MDS, or secondary prophylaxis in chemotherapy** as indicated by chart notes within past 90 days

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Chart notes indicate patient has been treated with the requested agent within the past 90 days and is a continuation of therapy (starting on samples is not approvable)

Approval Duration: 3 months

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Policy Owned by: Curative PBM team