Medical Policy:
Colony Stimulating Factors (CSF)

Last review date: 7/1/2026

Applicable Products:	
Fulphila (pegfilgrastim-jmdb)	Releuko (filgrastim)
Fylnetra (pegfilgrastim)	Rolvedon (eflapegrastim-xnst)
Granix (tbo-filgrastim)	Ryzneuta (efbemalenograstim alfa-vuxw)
Neulasta (pegfilgrastim)	Stimufend (pegflilgrastim-fpgk)
Neupogen (filgrastim)	Udenyca (pegfilgrastim-cbqv)
Nivestym (filgrastim-aafi)	Zarxio (filgrastim-sndz)
Nypozi (filgrastim-txid)	Ziextenzo (pegfilgrastim-bmez)
Nyvepria (pegfilgrastim-apgf)	

Initial Approval Criteria:
Coverage may be approved if all of the following are met:
- Diagnosis-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Primary prophylaxis of febrile neutropenia (FN):
- Must be receiving a chemotherapy regimen with a dosing regimen of once every 2 weeks or greater; **AND**
- Must have one of the following:
    - Must be receiving dose-dense chemotherapy (refer to chemotherapy regimens within NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors); **OR**
    - Must be receiving myelosuppressive chemotherapy which has a greater than 20% risk of FN, as calculated in current ASCO and NCCN guidelines for myeloid growth factors; **OR**
    - Must be receiving non-myelosuppressive chemotherapy which has ≤20% risk of FN and be considered to be at high risk for chemotherapy-induced febrile neutropenia or infection due to at least one of the following:
        - Previous chemotherapy or radiation therapy
        - Persistent neutropenia
        - Bone marrow involvement by tumor
        - Recent surgery and/or open wounds
        - Liver dysfunction, bilirubin >2mg/dL
        - Renal dysfunction, CrCl <50mL/min
        - Age >65 years receiving full chemotherapy dose intensity
        - Advanced cancer
        - Preexisting neutropenia
        - Infection
        - Poor performance status or nutritional status
        - Cardiovascular disease
        - Multiple co-morbid conditions
        - HIV infection

Secondary prophylaxis of febrile neutropenia (FN)

- Must be receiving a chemotherapy regimen with a dosing regimen of once every 2 weeks or greater; **AND**
- Must have experienced a neutropenic complication from a prior cycle of chemotherapy for which primary prophylaxis was not received, in which a reduced dose may compromise disease-free or overall survival or treatment outcome

Treatment of febrile neutropenia (FN)

- Must have fever and neutropenia and be at high-risk for infection-related complications or have prognostic factors that are predictive of poor clinical outcomes. Must have at least one of the following high-risk features:
    - Sepsis syndrome
    - Age greater than 65 years
    - Absolute neutrophil count (ANC) <100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - Prior episode of febrile neutropenia; **AND**
- Must NOT have received long-lasting prophylactic pegfilgrastim during current chemotherapy cycle

Bone marrow transplant:

- Must have one of the following:
    - Must require administration after autologous (not allogeneic) peripheral blood progenitor cell (PBPC) or bone marrow transplantation for non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma (HL); **OR**
    - Must require mobilization of progenitor cells into peripheral blood, often in conjunction with chemotherapy, for collection by leukapheresis; **OR**
    - Must have undergone allogeneic bone marrow transplant from HLA matched related donor; **OR**
    - Must have undergone allogeneic or autologous bone marrow transplantation where engraftment is delayed or has failed

Acute Myeloid Leukemia (AML)

- Must be an adult with a diagnosis of AML receiving induction or consolidation therapy

Myelodysplastic Syndromes (MDS)

- Must have a diagnosis of MDS, neutropenia, and recurrent or resistant infections; **AND**
- Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate]); **AND**
- Used for treatment of symptomatic anemia with no del(5q) mutation; **AND**
- Patient is receiving concurrent therapy with Erythropoiesis Stimulating Agents (ESAs)

Patients receiving radiation:

- Must be receiving radiation therapy, without concomitant chemotherapy, and have expected prolonged delays secondary to neutropenia

Older lymphoma patients

- Must be age 65 years and older with a diagnosis of acute aggressive lymphoma treated with curative chemotherapy (CHOP-R)

Congenital, cyclic, or idiopathic neutropenia

- Must have a diagnosis of congenital, cyclic, or idiopathic neutropenia with symptomatic neutropenia

Drug-induced agranulocytosis

- Must have severe neutropenia associated with fever or evidence of serious infection as a result of myelosuppressive medication

Hematopoietic Syndrome of Acute Radiation Syndrome:

- Must have acute exposure to myelosuppressive doses of radiation

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

3 months