
Medical Policy:

Colony Stimulating Factors (CSF)

Last Review Date: 10/01/2026

Prior review date: 01/01/2026

Applicable Products:	
Fulphila (pegfilgrastim-jmdb)	Releuko (filgrastim)
Fynetra (pegfilgrastim)	Rolvedon (eflapegrastim-xnst)
Granix (tbo-filgrastim)	Ryzneuta (efbemalenograstim alfa-vuxw)
Neulasta (pegfilgrastim)	Stimufend (pegfilgrastim-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 $\leq 20\%$ 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 $>2\text{mg/dL}$
 - Renal dysfunction, $\text{CrCl} < 50\text{mL/min}$
 - 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

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.