Colony Stimulating Factors
Utilization Management Criteria

Therapeutic Class:	Colony Stimulating Factors
Non-Preferred Agents:	**Pegfilgrastim Products** Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), Stimufend (pegfilgrastim-fpgk, Udenyca (pegfilgrastim-cbqv), Ziextenzo (Pegfilgrastim-bmez), Nyvepria (pegfilgrastim-apgf) **Filgrastim Products** Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), Nypozi (filgrastim-txid), Releuko (filgrastim-ayow) **Other** Leukine (sargramostim), Rolvedon (eflapegrastim-xnst), Ryzneuta (efbemalenograstim alfa-vuxw)
Preferred Agents:	Fylnetra (pegfilgrastim-pbbk), Neupogen (filgrastim)
Implementation Date:	1/1/2026
Prepared For:	CT
PDL Status:	Non-Preferred
Purpose:	Colony-stimulating factor (CSF) agents serve a vital role in oncology, particularly for patients undergoing treatments that impact the immune system. These agents are pivotal in treating and preventing neutropenia, a condition characterized by a dangerously low level of neutrophils. Neutropenia often affects patients receiving myelosuppressive chemotherapy or those undergoing bone marrow transplantation, both of which can significantly reduce the body's ability to fight infections. In addition to managing neutropenia, CSF agents are also employed to mobilize peripheral blood stem cells. This process is crucial for collecting these cells from the blood for use in autologous stem cell transplantation, offering an alternative to traditional bone marrow transplantation. Furthermore, certain CSF agents have a role in treating the effects of acute radiation syndrome, a serious condition that occurs after a high dose of radiation exposure, impacting bone marrow function and, consequently, blood cell production. Through these diverse applications, CSF agents provide essential support in mitigating the side effects of cancer treatments and enhancing patient outcomes.

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Table 1. Colony Stimulating Factors

Generic Name	Brand Name	Approved Indications*	Route of Administration	Biosimilar Availability
Efbemalenograstim alfa-vuxw	Ryzneuta®	Myelosuppression	SC	N
Eflapegrastim	Rolvedon®	Myelosuppression	SC	N
Filgrastim	Neupogen®	Myelosuppression, AML, BMT, H-ARS, PBPC, SCN	SC, IV	Y
Filgrastim-aafi	Nivestym™	Myelosuppression, AML, BMT, PBPC, SCN	SC, IV	N/A
Filgrastim-txid	Nypozi™	Myelosuppression, AML, BMT, PBPC, SCN, H-ARS		
Filgrastim-ayow	Releuko®	Myelosuppression, AML, BMT, PBPC, SCN, H-ARS		
Filgrastim-sndz	Zarxio®	Myelosuppression, AML, BMT, PBPC, SCN, H-ARS		
Pegfilgrastim	Neulasta® (Onpro®, Syringe)	Myelosuppression, H-ARS	SC	Y
Pegfilgrastim-apgf	Nyvepria™	Myelosuppression	SC	N/A
Pegfilgrastim-bmez	Ziextenzo®	Myelosuppression		
Pegfilgrastim-cbqv	Udenyca® (Autoinjector, OnBody, Syringe)	Myelosuppression, H-ARS		
Pegfilgrastim-fpgk	Stimufend®	Myelosuppression, H-ARS		
Pegfilgrastim-jmbd	Fulphila®	Myelosuppression		
Pegfilgrastim-pbbk	Fylnetra®	Myelosuppression, H-ARS		
Sargramostim	Leukine®	AML, BMT, H-ARS, PBPC	SC, IV	N
Tbo-filgrastim	Granix®	Myelosuppression	SC	N

*Abbreviations: AML, acute myeloid leukemia; BMT, bone marrow transplant; H-ARS, Hematopoietic Syndrome of Acute Radiation Syndrome; IV, intravenous; PBPC, peripheral blood progenitor cell collection and therapy; SC, subcutaneous; SCN, severe chronic neutropenia.*For indication details, reference appendix A*

Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes

General Approval Criteria:

- Claim is for a preferred agent **OR**

Initial Therapy:

- Prescribed by or in consultation with a hematologist, oncologist, or other specialist familiar with the treated disease state **AND one of the following:**

- Failure to achieve desired therapeutic outcome with **ONE** preferred agent (Fylnetra, Neupogen) **OR** documented adverse reaction/adverse event or contraindication to Fylnetra and Neupogen

  OR

- For Leukine being requested as initial therapy: Leukine is being requested for a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (GM-CSF) **OR** documented medical reason a preferred product (Fylnetra, Neupogen) cannot be utilized (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, preferred drug is not approved for patient age/weight/indication). Submission of clinical evidence for uses supported by compendia required.

Initial PA length: 1 year

Exclusion Criteria: Approval criteria not met

Continuation Therapy: Documented continued clinical benefit **AND** Documented compliance on current therapy regimen *(Exceptions: Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred filgrastim and pegfilgrastim formulations*

Continuation Length: 1 year

References:

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Revision History

Date	Version	Revisions
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