Louisiana Medicaid
Colony Stimulating Factors

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for all granulocyte colony stimulating factor (GCSF) agents (preferred and non-preferred).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria for Initiation of Therapy

- If the request is for a non-preferred agent, there is no preferred alternative that is:
  - The exact same chemical entity, formulation, strength, etc.; **OR**
  - An FDA-approved biosimilar to the requested medication that is indicated for the condition being treated; **AND**
- For non-preferred filgrastim formulation requests – there has been a treatment failure or intolerable side effect with or contraindication to any preferred filgrastim formulation that is appropriate for the condition being treated; **AND**
- For non-preferred pegfilgrastim formulation requests – there has been a treatment failure or intolerable side effect with or contraindication to any preferred pegfilgrastim formulation that is appropriate for the condition being treated; **AND**
- If request is for a non-preferred agent - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the recipient is currently using the requested medication; **AND**
- **ONE** of the following is required:
  - The recipient has an approved diagnosis (or indication) for the agent requested (See Table 1); **OR**
  - For requests that do not include diagnoses/indications listed in the table below, support for use of the requested medication is noted on the request with references cited**.**

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy 12 months

Table 1. Diagnoses/Indications for Granulocyte Colony Stimulating Factor Agents

Covered Diagnoses/Indications	Eflapegrastim-xnst (Rolvedon™)	Filgrastim (Neupogen®)	Filgrastim-aafi (Nivestym®)	Filgrastim-ayow(Releuko®)	Filgrastim-sndz (Zarxio®)	Pegfilgrastim (Neulasta®)	Pegfilgrastim – apgf (Nyvepria™)	Pegfilgrastim- bmez (Ziextenzo™)	Pegfilgrastim- cbqv (Udenyca®)	Pegfilgrastim-fpgk (Stimufend®)	Pegfilgrastim-jmdb (Fulphila®)	Pegfilgrastim-pbbk (Fylnetra®)	Sargramostim (Leukine®)	Tbo-filgrastim (Granix®)
Prophylaxis of febrile neutropenia in cancer patients receiving myelosuppressive chemotherapy for non-myeloid malignancies	X	X	X	X	X	X	X	X	X	X	X	X		X
Patients with acute myeloid leukemia (AML) receiving induction and/or consolidation chemotherapy		X	X	X	X								X[1]	
Bone marrow transplantation in cancer patients		X	X	X	X								X	
Mobilization and engraftment of peripheral blood progenitor cell collection and therapy in cancer patients		X	X		X								X	
Bone marrow transplant failure or engraftment													X[2]	
Severe chronic neutropenia (congenital, cyclic, or idiopathic)		X	X	X	X									
Hematopoietic Subsyndrome of Acute Radiation Syndrome		X			X	X		X	X	X			X	

1. Safety and efficacy of Leukine® have not been assessed in AML patients younger than 55 years of age.
2. For patients 2 years of age or older.

References

Fulphila (Pegfilgrastim-jmdb) [package insert]. Rockford, IL: Mylan Institutional LLC; October 2021. https://www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3ea915d7-2feb-4e75-91f7- 913c965b7d8a&type=display

Fylnetra (pegfilgrastim-pbbk) [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761084s000lbl.pdf

Granix (tbo-filgrastim) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023. https://www.granixhcp.com/globalassets/granix-hcp/prescribing-information.pdf

Leukine (sargramostim) [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2018. https://www.leukine.com/wp-content/uploads/2020/06/Prescribing_Information.pdf

Neulasta (pegfilgrastim) [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neulasta/neulasta_pi_hcp_english.ashx

Neupogen (filgrastim) [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neupogen/neupogen_pi_hcp_english.pdf

Nivestym (filgrastim-aafi) [package insert]. New York, NY: Pfizer Inc.; February 2024. http://labeling.pfizer.com/ShowLabeling.aspx?id=10899

Nyvepria (pegfilgrastim-apgf) [package insert]. New York, NY: Pfizer Inc; March 2023. http://labeling.pfizer.com/ShowLabeling.aspx?id=13622

Releuko (filgrastim-ayow) [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022. https://www.amneal.com/wp-content/uploads/2022/03/Releuko-Prescribing-Information.pdf

Rolvedon (eflapegrastim-xnst) [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc; November 2023. https://www.rolvedon.com/pdf/rolvedon-prescribing-information.pdf

Stimufend (pegfilgrastim-fpgk) [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023. https://www.stimufendhcp.com/sites/default/files/documents/2024-02/stimufend_prescribinginfo_approved_2023.pdf

Udenyca (pegfilgrastim-cbqv) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023. https://udenyca.com/wp-content/pdfs/udenyca-pi.pdf

Zarxio (filgrastim-sndz) [package insert]. Princeton, NJ: Sandoz Inc.; OctoberJanuary 2024. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c0d1c22b-566b-4776-bdbf-00f96dad0cae&type=display

Ziextenzo (pegfilgrastim-bmez) [package insert]. Princeton, NJ: Sandoz Inc.; February 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761045Orig1s014lbl.pdf

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Added Udenyca®, formatting changes / April 2020	August 2020
Added Ziextenzo®, updated references / July 2020	August 2020
Added Nyvepria™, updated references, formatting changes / May 2021	July 2021
Formatting changes; updated references / September 2021	January 2022
Combined Releuko® with Colony Stimulating Factors criteria, updated references / November 2022	January 2023
Added indication of Hematopoietic Subsyndrome of Acute Radiation Syndrome to Udenyca®, previous use policy clarification, updated references / December 2022	April 2023
Combined Fylnetra®, Rolvedon™, and Stimufend® with Colony Stimulating Factors criteria, modified 'preferred alternative' statement, updated references / May 2023	July 2023
Added pegfilgrastim criterion, added indication of Hematopoietic Subsyndrome of Acute Radiation Syndrome to Stimufend® and Ziextenzo®, formatting changes, updated references / March 2024	October 2024
Added indication of Hematopoietic Subsyndrome of Acute Radiation Syndrome to Zarxio®, updated references / November 2024	March 2025