

## 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; **AND/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 (Fynetra®)	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 <sup>1</sup>	
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 <sup>2</sup>	
Severe chronic neutropenia (congenital, cyclic, or idiopathic)		X	X	X	X									
Hematopoietic Subsyndrome of Acute Radiation Syndrome		X			X	X		X	X	X		<u>X</u>	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>

Fynetra (pegfilgrastim-pbbk) [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; ~~April~~ May 2025. <https://fynetra.us/full-prescribing-info/#important-safety-information>  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761084s000lbl.pdf](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](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](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](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 (eflapregastim-xnst) [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc; November

2023. <https://www.rolvedon.com/pdf/rovedon-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](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.; October 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761045Orig1s014lbl.pdf)

<b>Revision / Date</b>	<b>Implementation Date</b>
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 Flyneta®, 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
<u>Added indication of Hematopoietic Subsyndrome of Acute Radiation Syndrome to Flyneta®, updated references / June 2025</u>	<u>January 2026</u>