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.

*These agents may have a **Black Box Warning(s)** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- There is no preferred alternative that is:
  - The exact same chemical entity, formulation, strength, etc.; **OR**
  - FDA-approved biosimilar to the requested medication; **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**
- If request is for a non-preferred agent - **ONE** of the following is required~~Previous use of a preferred product - **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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information, including absolute neutrophil count (ANC), have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

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

Covered Diagnoses/Indications	Filgrastim (Neupogen®)	Filgrastim-aafi (Nivestym®)	Filgrastim-ayow (Releuko®)	Filgrastim-sndz (Zarxio®)	Pegfilgrastim (Neulasta®)	Pegfilgrastim – apgf (Nyvepria™)	Pegfilgrastim- bmez (Ziextenzo™)	Pegfilgrastim- cbqv (Udenyca®)	Pegfilgrastim-jmdb (Fulphila®)	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
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							
Radiation-induced neutropenia (severe)	X				X					X	
Hematopoietic Subsyndrome of Acute Radiation Syndrome								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; March 2021. https://www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3ea915d7-2feb-4e75-91f7-

913c965b7d8a&type=display

Granix (tbo-filgrastim) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019. 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.; February 2021. 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.; April 2021.http://labeling.pfizer.com/ShowLabeling.aspx?id=10899

Nyvepria (pegfilgrastim-apgf) [package insert]. New York, NY: Pfizer Inc; June 2020. http://labeling.pfizer.com/ShowLabeling.aspx?id=13622

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

Udenyca (pegfilgrastim-cbqv) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022~~June 2021~~. https://udenyca.com/wp-content/pdfs/udenyca-pi.pdf

Zarxio (filgrastim-sndz) [package insert]. Princeton, NJ: Sandoz Inc.; August 2019. 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.; March 2021. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7dada041-6528-4acf-809c-62d271538c9a&type=display

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