Louisiana ~~Fee-for-Service~~ Medicaid
~~Granulocyte C~~Colony Stimulating Factor~~s (GCSF) Agents~~
~~Filgrastim (Neupogen®), Filgrastim-aafi (Nivestym®), Filgrastim-sndz (Zarxio®),~~
~~Pegfilgrastim (Neulasta®),~~ Pegfilgrastim-cbqv (Udenyca®), ~~Pegfilgrastim-jmdb (Fulphila®),~~
~~Sargramostim (Leukine®), and Tbo-filgrastim (Granix®)~~

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

Additional Point-of-Sale edits may apply.

A~~uthorization a~~pproval criteria ~~– all of the following are required:~~

- There is no preferred alternative that is:
  - ~~the~~ The exact same chemical entity, formulation, strength, etc.; **OR**
  - FDA-approved biosimilar to the requested medication; **AND**
- 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 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 ~~inappropriate~~ concomitant drug therapies or disease states that limit the use of the requested ~~medication, and~~medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.~~.~~

Reauthorization ~~approval~~ criteria ~~– both of the following are required:~~

- 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 as indicated by improvement in signs, symptoms, and/or lab results compared to baseline.

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Duration of initial and reauthorization approval~~, both initial and reauthorization~~: 12~~6~~ months

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

Covered Diagnoses/Indications	Filgrastim (Neupogen®)	Filgrastim-aafi (Nivestym®)	Filgrastim-sndz (Zarxio®)	Pegfilgrastim (Neulasta®)	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
Patients with acute myeloid leukemia (AML) receiving induction and/or consolidation chemotherapy	X	X	X				X[1]	
Bone marrow transplantation in cancer patients	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[2]							X	
Severe chronic neutropenia (congenital, cyclic, or idiopathic)	X	X	X					
~~Medication~~Radiation-induced neutropenia (severe)	X			X			X	

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

~~Requests must include the name of the offending medication and the condition being treated with the medication.~~

References

Fulphila (Pegfilgrastim-jmdb) [package insert]. Rockford, IL: Mylan Institutional LLC; May ~~2018~~2019. ~~Retrieved from~~ https://www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3ea915d7-2feb-4e75-91f7-913c965b7d8a&type=display~~https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=3ea915d7-2feb-4e75-91f7-913c965b7d8a&type=pdf&name=3ea915d7-2feb-4e75-91f7-913c965b7d8a~~

~~Granix~~GRANIX (tbo-filgrastim) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March ~~2018~~2019. https://www.granixhcp.com/globalassets/granix-hcp/prescribing-information.pdf~~Retrieved from http://www.granixhcp.com/prescribing-information.pdf~~http://www.granixhcp.com/Pdf/prescribing-information.pdf

Leukine (sargramostim) [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2018. ~~Retrieved from~~ https://www.leukine.com/wp-content/uploads/2020/02/Prescribing_Information.pdf~~http://www.leukine.com/pi~~

Neulasta (pegfilgrastim) [package insert]. Thousand Oaks, CA: Amgen Inc.; April ~~2018~~2019. ~~Retrieved from~~ https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-

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Neupogen (filgrastim) [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2018. ~~Retrieved from~~ https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neupogen/neupogen_pi_hcp_english.pdf

~~Nivestym~~NIVESTYM (filgrastim-aafi) [package insert]. New York, NY: Pfizer Inc.; July 2018. ~~Retrieved from~~ http://labeling.pfizer.com/ShowLabeling.aspx?id=10899

Udenyca (pegfilgrastim-cbqv) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2019. ~~Retrieved from~~ https://udenyca.com/wp-content/pdfs/udenyca-pi.pdf

Zarxio (filgrastim-sndz) [package insert]. Princeton, NJ: Sandoz Inc.; ~~2018~~August 2019. ~~Retrieved from~~ https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c0d1c22b-566b-4776-bdbf-00f96dad0cae&type=display~~https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=c0d1c22b-566b-4776-bdbf-00f96dad0cae&type=pdf&name=c0d1c22b-566b-4776-bdbf-00f96dad0cae~~

Revision	Date
Single PDL Implementation	May 2019
Added Udenyca	April 2020

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