

**Granulocyte Stimulating Agents**  
**Granix (TBO-filgrastim)**  
**Nivestym (filgrastim-aafi)**  
**Zarxio (filgrastim-sndz)**  
**Effective 1/1/2021**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when filled via that pharmacy benefit.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

No PA	PA Required
Fulphila® (pegfilgrastim-jmdb)	Granix® (TBO-filgrastim)
Leukine® (sargramostim)	Nivestym® (filgrastim-aafi)
Neulasta® (pegfilgrastim)	Zarxio® (filgrastim-sndz)
Neupogen® (filgrastim)	
Udenyca® (pegfilgrastim-cbqv)	
Ziextenzo® (pegfilgrastim-bmez)	

**Approvable Diagnosis:**

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever (Granix®, Nivestym®, Zarxio®)
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (Nivestym®, Zarxio®)



- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (Nivestym<sup>®</sup>, Zarxio<sup>®</sup>)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (Nivestym<sup>®</sup>, Zarxio<sup>®</sup>)
- Reduce the incidence and duration of sequelae of severe neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (Nivestym<sup>®</sup>, Zarxio<sup>®</sup>)

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when the following criteria are met, and documentation is provided:

**Granix<sup>®</sup>** (TBO-filgrastim), **Nivestym<sup>®</sup>** (filgrastim-aafi), **Zarxio<sup>®</sup>** (filgrastim-sndz)

Prescriber provides documentation of the following:

1. Medical records documenting an inadequate response, adverse reaction or contraindication to Neupogen<sup>®</sup> (filgrastim)

### Continuation Criteria

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

### Limitations

1. Initial authorizations and reauthorizations will be granted for 12 months

### References

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; March 2019.
2. Leukine (sargramostim) [prescribing information]. Lexington, MA: Partner Therapeutics; May 2018.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen; June 2018
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira Inc; July 2018
5. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc; August 2019
6. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc; September 2020.
7. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc; September 2019.
8. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; January 2020.
9. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; June 2020.

### Review History

10/20/2020- Switched from SGM to Custom; Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021



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