

Clinical Policy Title:	filgrastim
Policy Number:	RxA.157
Drug(s) Applied:	Neupogen, Granix, Releuko, Nivestym, Zarxio
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Febrile Neutropenia (Neupogen, Granix, Releuko, Nivestym, Zarxio):

1. Diagnosis of febrile neutropenia prophylaxis with nonmyeloid malignancies;
2. Patient is receiving myelosuppressive anti-cancer drugs with significant incidence of severe neutropenia with fever;
3. Patient has had a failure to Nivestym™ or Zarxio®, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Chemotherapy-Induced Neutropenia (Neupogen, Releuko, Nivestym, Zarxio):

1. Diagnosis of acute myeloid leukemia (AML);
2. Prescribed for use following induction or consolidation chemotherapy;
3. Patient has had a failure to Nivestym™ or Zarxio®, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Bone Marrow Transplantation (BMT)/Stem Cell Transplant (Neupogen, Releuko, Nivestym, Zarxio):

1. Patient meets one the following (a, b, or c):
 - a. Diagnosis of non-myeloid malignancy undergoing myeloablative chemotherapy following BMT;
 - b. Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy;
2. Patient has had a failure to Nivestym™ or Zarxio®, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

D. Peripheral Blood Progenitor Cell Collection (Neupogen, Nivestym, Zarxio):

1. Prescribed for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

2. Patient has had a failure to Nivestym™ or Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 6 months

E. Chronic Neutropenia (Neupogen, Releuko, Nivestym, Zarxio):

1. Prescribed for use in symptomatic severe chronic neutropenia caused by congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia;
2. Patient has had a failure to Nivestym™ or Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 6 months

F. Acute Radiation Syndrome (Neupogen):

1. Prescribed for use following suspected or confirmed acute exposure to myelosuppressive doses of radiation;

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 6 months

References

1. National Comprehensive Cancer Network. Acute Myeloid Leukemia. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed: March 20, 2025.
2. National Comprehensive Cancer Network. Wilms Tumor. Version 2,2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/wilms_tumor.pdf. Accessed: March 20, 2025.
3. National Comprehensive Cancer Network. Myelodysplastic Syndromes Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed March 20, 2025.
4. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed: March 20, 2025.
5. National Comprehensive Cancer Network. Hematopoietic Growth Factors - Management of Neutropenia. Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed: March 20, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy description table updated 2. Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by	07/31/2020	09/14/2020

<p>RxAdvance or the member has met initial approval criteria listed in this policy”</p> <ol style="list-style-type: none"> 3. Initial therapy and continued therapy approval duration updated 4. References were updated 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were updated. 2. Initial approval criteria I.E.1 was added “Request is for Neupogen®”. 	02/19/2021	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Releuko®. 2. Initial Approval Criteria, I.A.3, I.B.3, I.D.2, I.F.3: Updated to include trial and failure criteria For Releuko® member has had a failure with Zarxio® or Nivestym™, unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.C.2, I.E.3: Updated to include new drug criteria Request is for Neupogen®, Zarxio®, Nivestym™, Granix®. 4. Initial Approval Criteria, I.H: Updated to include approval criteria for indication, Wilms Tumor (Nephroblastoma). 5. References were reviewed and updated. 	03/14/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4, I.B.4, I.C.5, I.D.3, I.E.4, I.F.4 and I.G.4: Updated to include new prescribing criteria The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., pegfilgrastim, Leukine®) within any chemotherapy cycle. 2. Initial Approval Criteria, I.F.3: Updated trial and failure criteria from For Neupogen®, Releuko®, Granix® requests, member has had a failure with Nivestym™ or Zarxio®*, unless contraindicated or clinically significant adverse effects are experienced to For Neupogen®, Releuko®, Granix® requests, member has had a failure with Nivestym™ or Zarxio®*, unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.G.3: Updated trial and failure criteria from Member has had a 	11/02/2022	01/17/2023

<p>failure with Zarxio® or Nivestym™, unless contraindicated or clinically significant adverse effects are experienced to For Neupogen® or Releuko® request, member has had a failure with Zarxio® or Nivestym™, unless contraindicated or clinically significant adverse effects are experienced;</p> <p>4. Continued Therapy Approval, II.A.3 : Updated to include new prescribing criteria The requested medication will not be prescribed concurrently with other colony stimulating factors (e.g., pegfilgrastim, Leukine®) within any chemotherapy cycle.</p> <p>5. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed.	2/28/2024	2/28/2024
<p>Policy was reviewed.</p> <p>1. Updated Continuation of therapy language.</p> <p>2. References were updated.</p>	03/20/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025