

MED RX POLICY

- POLICY:** Colony Stimulating Factors – Filgrastim Products Med Rx Policy
- Granix® (tbo-filgrastim subcutaneous injection – Teva)
 - Neupogen® (filgrastim intravenous or subcutaneous injection – Amgen)
 - Nivestym® (filgrastim-aafi intravenous or subcutaneous injection – Hospira/Pfizer)
 - Nypozi™ (filgrastim-txid intravenous or subcutaneous injection – Tanvex)
 - Releuko® (filgrastim-ayow intravenous or subcutaneous injection – Amneal)
 - Zarxio® (filgrastim-sndz intravenous or subcutaneous injection – Sandoz)

REVIEW DATE: 10/09/2024; selected revision 02/26/2025

OVERVIEW

Neupogen, Nivestym, Nypozi, Releuko, and Zarxio are indicated for the treatment/prevention of a variety of **neutropenia-related conditions**.¹⁻⁵ Nivestym, Nypozi, Releuko, and Zarxio were approved as biosimilars to Neupogen, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Neupogen. However, minor differences in clinically inactive components are allowed. At this time, Nivestym, Nypozi, Releuko, and Zarxio have only demonstrated biosimilarity, not interchangeability.

Granix is only indicated in patients ≥ 1 month of age to reduce the duration of **severe neutropenia** in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.⁶ Granix is not considered a biosimilar to Neupogen.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the respective standard *Colony Stimulating Factors Utilization Management Medical Policy* criteria. This program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the respective standard *Colony Stimulating Factors Utilization Management Medical Policy*.

Automation: None.

Preferred Products:	Nivestym, Zarxio
Non-Preferred Products:	Granix, Neupogen, Nypozi, Releuko

10/09/2024

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RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Granix	1. Approve if the patient meets BOTH of the following (A <u>and</u> B): A) Patient meets the standard <i>Colony Stimulating Factors – Granix Utilization Management Medical Policy</i> criteria; AND B) Patient meets BOTH of the following (i <u>and</u> ii): i. Patient has tried ONE of the following: Nivestym or Zarxio; AND ii. Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.
Neupogen, Nypozi, Releuko	1. Approve if the patient meets BOTH of the following (A <u>and</u> B): A) Patient meets the respective standard <i>Colony Stimulating Factors – Filgrastim Products Utilization Management Medical Policy</i> criteria; AND B) Patient meets BOTH of the following (i <u>and</u> ii): i. Patient has tried ONE of the following: Nivestym or Zarxio; AND ii. Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

REFERENCES

1. Neupogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2023.
2. Zarxio® intravenous or subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; August 2024.
3. Nivestym® intravenous or subcutaneous injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; February 2024.
4. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; August 2023.
5. Nypozi™ subcutaneous or intravenous injection [prescribing information]. San Diego, CA: Tanvex, June 2024.
6. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; November 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/04/2023
Annual Revision	No criteria changes.	10/09/2024
Selected Revision	Nypozi was added to the Policy as a Non-Preferred Product and exception criteria were added. For the Non-Preferred Products previously in the policy, the exception criterion for a patient currently receiving the requested product option was removed.	02/26/2025