

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Colony Stimulating Factors – Filgrastim Products Preferred Specialty Management Policy for High Performance and National Preferred Formularies
- Granix® (tbo-filgrastim subcutaneous injection – Teva)
 - Neupogen® (filgrastim intravenous or subcutaneous injection – Amgen)
 - Nivestym™ (filgrastim-aafi intravenous or subcutaneous injection – Hospira/Pfizer)
 - Releuko® (filgrastim-ayow intravenous or subcutaneous injection – Amneal)
 - Zarxio® (filgrastim-sndz intravenous or subcutaneous injection – Sandoz)

REVIEW DATE: 02/07/2024

OVERVIEW

Neupogen, Nivestym, Releuko, and Zarxio are indicated for the treatment of a variety of **neutropenia-related conditions**.¹⁻⁴ Nivestym, 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, 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.⁵ Granix is not considered a biosimilar to Neupogen.

POLICY STATEMENT

This Preferred Specialty Management 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 Prior Authorization 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). Approval durations are as noted in the respective standard *Colony Stimulating Factors Prior Authorization Policy*. If the patient meets the respective standard *Colony Stimulating Factors Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Product(s) will be authorized.

Documentation: Documentation is required for the use of Non-Preferred Products as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

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

02/07/2024

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RECOMMENDED EXCEPTION CRITERIA

REFERENCES

1. Neupogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2021.
2. Zarxio® intravenous or subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
3. Nivestym™ intravenous or subcutaneous injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; August 2022.
4. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; April 2022.
5. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; April 2020.