PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Filgrastim Products Preferred Specialty Management Policy for High Performance Formulary

- 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: 09/21/2022

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 medications (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 corresponding *Colony Stimulating Factors Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Products 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

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Granix	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Granix Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried Nivestym **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Granix and requires further medication to complete the current cycle of chemotherapy. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Granix Prior Authorization Policy* criteria), but criterion 1B is not met and the requested agent is not approved: approve the Preferred Product.
Neupogen	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Filgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried Nivestym **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Neupogen and requires further medication to complete the current cycle of chemotherapy. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Filgrastim Prior Authorization Policy* criteria), but criterion 1B is not met and the requested agent is not approved: approve the Preferred Product.
Releuko	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Filgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried Nivestym **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Releuko and requires further medication to complete the current cycle of chemotherapy.

	2. If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Filgrastim Prior Authorization Policy* criteria), but criterion 1B is not met and the requested agent is not approved: approve the Preferred Product.
Zarxio	**1.** Patient must meet the following criteria (A and B): **A)** Patient meets the standard *Colony Stimulating Factors – Filgrastim Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried Nivestym **[documentation required]**; AND **b)** 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; OR **ii.** Patient has initiated therapy with Zarxio and requires further medication to complete the current cycle of chemotherapy. **2.** If the patient has met criterion 1A (the standard *Colony Stimulating Factors – Filgrastim Prior Authorization Policy* criteria), but criterion 1B is not met and the requested agent is not approved: approve the Preferred Product.

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.