PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Colony Stimulating Factors – Filgrastim Products Preferred Specialty Management Policy
- Granix® (tbo-filgrastim injection – Teva)
- Neupogen® (filgrastim injection – Amgen)
- Nivestym™ (filgrastim-aafi injection – Hospira/Pfizer)
- Zarxio™ (filgrastim-sndz injection – Sandoz)

REVIEW DATE: 09/23/2020

OVERVIEW

All filgrastim products bind to granulocyte colony-stimulating factor receptors and stimulates proliferation of neutrophils. Neupogen, Nivestym, and Zarxio are indicated for the treatment of a variety of neutropenia-related conditions.[1-3] Nivestym and Zarxio were approved as a biosimilar 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 and Zarxio have only demonstrated biosimilarity, not interchangeability. Granix is not considered a biosimilar to Neupogen. 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.[4] All medications are available as prefilled syringes.[1-4] Neupogen, Nivestym, and Granix are also available as vials.[1,3,4] The Zarxio prescribing information states that if intravenous administration is required, Zarxio may be diluted in a 5% dextrose injection.[2] However, the Zarxio and Nivestym prefilled syringes may not accurately measures volumes less than 0.3 mL due to the needle spring mechanism design. Therefore, the direct administration of a volume less than 0.3 mL of Zarxio is not recommended due to the potential for dosing errors, which may impact administration in young patients.[2] However, with Nivestym, for direct administration of doses less than 0.3 mL (180 mcg) the Nivestym single-dose vial can be used.

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, Zarxio
Non-Preferred Products: Granix, Neupogen

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, ii, or iii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Nivestym or Zarxio **[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 requires a dose < 180 mcg; OR **iii.** 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 Products.
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, ii, or iii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Nivestym or Zarxio **[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 requires a dose < 180 mcg; OR **iii.** 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 Products.

REFERENCES

1. Neupogen® injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2018.
2. Zarxio™ injection [prescribing information]. Princeton, NJ: Sandoz; August 2019.
3. Nivestym™ injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; July 2018.
4. Granix® injection [prescribing information]. North Wales, PA: Teva Pharmaceuticals; March 2019.