Drug Coverage Policy

Effective Date 1/15/2026
Coverage Policy Number.....IP0528
Policy Title.....Filgrastim Products

Colony Stimulating Factors – Filgrastim Products

- Granix® (tbo-filgrastim subcutaneous injection – Teva)
- Neupogen® (filgrastim intravenous or subcutaneous injection – Amgen)
- Nypozi™ (filgrastim-txid intravenous or subcutaneous injection – Apotex)
- Releuko® (filgrastim-ayow intravenous or subcutaneous injection – Amneal)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Neupogen, Nivestym, Nypozi, Releuko, and Zarxio are indicated for the treatment 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.

Coverage Policy

POLICY STATEMENT

This policy requires the use of Preferred Products as listed in the below table. All approvals are provided for up to 6 months unless otherwise noted.

Employer Plans

Product	Criteria
Granix (tbo-filgrastim)	**Granix is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients requiring a dose < 180 mcg AND the patient meets BOTH of the following (A and B): A. The patient has tried Nivestym B. Patient cannot continue to use the formulary alternative 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 (filgrastim)	**Neupogen is considered medically necessary when ONE of the following is met (1, 2, or 3):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio

	B. Patient cannot continue to use the formulary alternative 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 3. Patients requiring a dose < 180 mcg AND the patient meets BOTH of the following (A and B): A. The patient has tried Nivestym B. Patient cannot continue to use the formulary alternative 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
Nypozi (filgrastim-txid)	**Nypozi is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio B. Patient cannot continue to use the formulary alternative 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
Releuko (filgrastim-ayow)	**Releuko is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio B. Patient cannot continue to use the formulary alternative 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

Individual and Family Plans

Product	Criteria

Granix (tbo-filgrastim)	**Granix is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients requiring a dose < 180 mcg AND the patient meets BOTH of the following (A and B): A. The patient has tried Nivestym B. Patient cannot continue to use the formulary alternative 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 (filgrastim)	**Neupogen is considered medically necessary when ONE of the following is met (1, 2, or 3):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio B. Patient cannot continue to use the formulary alternative 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 3. Patients requiring a dose < 180 mcg AND the patient meets BOTH of the following (A and B): A. The patient has tried Nivestym B. Patient cannot continue to use the formulary alternative 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
Nypozi (filgrastim-txid)	**Nypozi is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio B. Patient cannot continue to use the formulary alternative 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
Releuko (filgrastim-ayow)	**Releuko is considered medically necessary when ONE of the following is met (1 or 2):** 1. Patient meets BOTH of the following (A and B): A. The patient has tried BOTH Nivestym AND Zarxio B. Patient cannot continue to use each of the formulary alternatives 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 2. Patients who require administration by intravenous infusion AND the patient meets BOTH of the following (A and B): A. The patient has tried ONE of Nivestym or Zarxio B. Patient cannot continue to use the formulary alternative 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

Conditions Not Covered

Filgrastim non-preferred products are considered medically necessary when the non-preferred product exception criteria are met. Any other exception is considered not medically necessary.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9173	Injection, filgrastim-txid (Nypozi), biosimilar, 1 mcg (Code effective Until 6/30/2025)
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 mcg

HCPCS Codes	Description
J1447	Injection, tbo-filgrastim, 1 mcg
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Q5148	Injection, filgrastim-txid (Nypozi), biosimilar, 1 microgram (Code effective 4/1/2025)

References

1. Neupogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2024.
2. Zarxio® intravenous or subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024.
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; 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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	No criteria changes	12/15/2024
Selected Revision	**Nypozi** (filgrastim-txid) added to the policy. **Updated** criteria for Granix, Neupogen and Releuko.	06/01/2025
Selected Revision	**Coding Information** **Added HCPCS**: Q5148 (Code effective 4/1/2025) **Updated** the description for C9173 to include the note "Code effective until 6/30/2025"	08/01/2025
Annual Revision	**Policy Title.** **Updated from** "Filgrastim" **to "**Colony Stimulating Factors – Filgrastim Products" **Updated** policy template. **Coding Information:** **Removed** HCPCS Codes Q5101 & Q5110	1/15/2026

The policy effective date is in force until updated or retired.