Reference number(s)
5356-D

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5356-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☑
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☑
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Colony Stimulating Factors – Short Acting

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Managed Medicaid Template (MMT), Medical Benefit, and Managed Medicaid Medical Benefit (MMMB).

Plan Design Summary

This program applies to the short-acting colony stimulating factor products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Granix, Neupogen, Nivestym, or Releuko and for members who are new to treatment with Leukine for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Short Acting

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Zarxio (filgrastim-sndz)
Target	• Granix (TBO-filgrastim) • Leukine (sargramostim) • Neupogen (filgrastim) • Nivestym (filgrastim-aafi) • Releuko (filgrastim-ayow)

Exception Criteria

Coverage for the targeted products, Granix, Neupogen, Nivestym, or Releuko, is provided when one of the following criteria is met:

- Member has had a documented intolerable adverse event to the preferred product and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)
- Member has a documented latex allergy and the prescriber states that the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
- Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

Coverage for the targeted product, Leukine, is provided when one of the following criteria is met:

- Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
- Leukine is being requested for an indication that is not FDA-approved for the preferred product.
- Member is currently receiving treatment with Leukine, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.

References

1. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; August 2024.
2. Neupogen [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
4. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.

5. Nivestym [package insert]. Lake Forest, IL: Hospira Inc., a Pfizer company: February 2024.
6. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.

