

This policy applies to the following:

Standard Control (SF)	✓	Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B
Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First
Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)	✓	Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)		Value (VF)					

Reference #
5356-D

**EXCEPTIONS CRITERIA**  
**COLONY STIMULATING FACTORS – SHORT ACTING**  
**PREFERRED PRODUCT: ZARXIO**

**POLICY**

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

**I. PLAN DESIGN SUMMARY**

This program applies to the short-acting colony stimulating factor products specified in this policy. 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**

Preferred*	Product(s)
Preferred*	<ul style="list-style-type: none"> <li>• <b>Zarxio</b> (filgrastim-sndz)</li> </ul>
Targeted	<ul style="list-style-type: none"> <li>• <b>Granix</b> (TBO-filgrastim)</li> <li>• <b>Leukine</b> (sargamostim)</li> <li>• <b>Neupogen</b> (filgrastim)</li> <li>• <b>Nivestym</b> (filgrastim-aafi)</li> <li>• <b>Releuko</b> (filgrastim-ayow)</li> </ul>

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

**II. EXCEPTION CRITERIA**

- A. Coverage for the targeted products, Granix, Neupogen, Nivestym, or Releuko, is provided when one of the following criteria is met:
1. 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)
  2. 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.
  3. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

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	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)	✓	Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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- B. Coverage for the targeted product, Leukine, is provided when one of the following criteria is met:
1. Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
  2. Leukine is being requested for an indication that is not FDA-approved for the preferred product.
  3. 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.; September 2022.
2. Neupogen [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
4. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2022.
5. Nivestym [package insert]. Lake Forest, IL: Hospira Inc., a Pfizer company; August 2023.
6. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.