This policy applies to the following:

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

Reference #
4282-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 who are new to treatment with a targeted product 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

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

*: 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 the member meets one of the following criteria:
   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.

This policy applies to the following:

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

Reference #
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4. Member has received treatment with the requested targeted product in the past 365 days.

B. Coverage for the targeted product, Leukine, is provided when the member meets one of the following criteria:
   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 has received treatment with the requested targeted product in the past 365 days.

REFERENCES

1. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
2. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2022.
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
4. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc., a Pfizer Company: March 2023.
5. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; April 2022.
6. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; September 2022.