This policy applies to the following:

	Standard Opt-in		**PDPD**		**VF**		**Medical Benefit**	✓	**Medical Benefit: Biosimilars First**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**
			Balanced		**Marketplace**		**Medicare Part B**		**Medicare Part B: Biosimilars First**

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EXCEPTIONS CRITERIA

Colony Stimulating Factors – Short Acting

PREFERRED PRODUCT: ZARXIO and NIVESTYM

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) • **Nivestym** (filgrastim-aafi)
Targeted	• **Granix** (TBO-filgrastim) • **Leukine** (sargramostim) • **Neupogen** (filgrastim)

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

A. Coverage for the targeted products, Neupogen or Granix, is provided when the member meets one of the following criteria:
   1. Member has failed treatment with all of the preferred products due to a documented intolerable adverse event (e.g., rash, nausea, vomiting) 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 brand and biosimilar medication)
   2. Member has a documented latex allergy and the prescriber states that the member must use latex-free vials and the member had an inadequate response or an intolerable adverse effect to Nivestym.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**VF**		**Medical Benefit**	✓	**Medical Benefit: Biosimilars First**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**
			Balanced		**Marketplace**		**Medicare Part B**		**Medicare Part B: Biosimilars First**

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3. Neupogen or Granix are requested for doses less than 180 mcg and the member had an inadequate response or an intolerable adverse effect to Nivestym.
4. Member has received treatment with the 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 effect to any of the preferred products.
2. Member has received treatment with the targeted product in the past 365 days.

REFERENCES

1. Zarxio [package insert]. Princeton, NJ: Sandoz; August 2019.
2. Neupogen [package insert]. Thousand Oaks, CA: Amgen; June 2018.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA; November 2019.
4. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2018.
5. Nivestym [package insert]. Lake Forest, IL: Hospira Inc, a Pfizer company: July 2018