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: Add-on		Medicare Part B: Advanced Biosimilars First
	Balanced (BF)		Aetna Health Exchange (AHE)			✓	Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
	Value (VF)		IVL						

Reference #
6026-D

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: FULPHILA, NEULASTA (INCLUDING ONPRO KIT)

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 long-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 products 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 a targeted product.

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

Table. Colony Stimulating Factors – Long Acting

	Product(s)
Preferred*	• **Fulphila** (pegfilgrastim-jmdb) • **Neulasta (including Onpro kit)** (pegfilgrastim)
Targeted	• **Nyvepria (**pegfilgrastim-apgf) • **Udenyca** (pegfilgrastim-cbqv) • **Ziextenzo** (pegfilgrastim-bmez)

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

II. EXCEPTION CRITERIA

Coverage for the targeted products is provided when the member has had a documented intolerable adverse event to both of the preferred products, 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 products and biosimilar products).

REFERENCES

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen; February 2021.

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: Add-on**		**Medicare Part B: Advanced Biosimilars First**
	Balanced (BF)		**Aetna Health Exchange (AHE)**			✓	**Medical Benefit: Managed Medicaid**		**Medicare Part B: Add-on**
	Value (VF)		**IVL**						

Reference #
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2. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; October 2021.
3. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; October 2021.
4. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2021.
5. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; March 2021.