

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B	Reference # 3661-D
	Standard Opt-out		ACSF		MMT	✓	Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on	

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: FULPHILA, NYVEPRIA, UDENYCA, ZIEXTENZO

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	<ul style="list-style-type: none"> • Fulphila (pegfilgrastim-jmdb) • Nyvepria (pegfilgrastim-apgf) • Udenyca (pegfilgrastim-cbqv) • Ziextenzo (pegfilgrastim-bmez)
Targeted	<ul style="list-style-type: none"> • Neulasta (including Onpro kit) (pegfilgrastim)

II. EXCEPTION CRITERIA

Coverage for the targeted products is provided when the 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 reference product and biosimilar products).

REFERENCES

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen; January 2020.
2. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; June 2020.
3. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; June 2020.
4. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2019.
5. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; November 2019.

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	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B	Reference #
	Standard Opt-out		ACSF		MMT	✓	Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	3661-D
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on	