

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B	Reference #
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)		Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First	3280-D
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)					

## 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*	<ul style="list-style-type: none"> <li>Fulphila (pegfilgrastim-jmdb)</li> <li>Neulasta (including Onpro kit) (pegfilgrastim)</li> </ul>
Targeted	<ul style="list-style-type: none"> <li>Fylnetra (pegfilgrastim-pbbk)</li> <li>Nyvepria (pegfilgrastim-apgf)</li> <li>Stimufend (pegfilgrastim-fpgk)</li> <li>Udenyca (pegfilgrastim-cbqv)</li> <li>Ziextenzo (pegfilgrastim-bmez)</li> </ul>

\*: 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 all 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

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

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	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on			
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)							

2. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; June 2023.
3. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
4. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; March 2023.
5. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; March 2021.
6. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
7. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2022.