



Reference number(s)
3280-D

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This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input type="checkbox"/>
Standard Control – Choice (SCCF)	<input type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA)	<input type="checkbox"/>
Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input type="checkbox"/>

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
Standard Formulary Chart (SFC)	<input type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSF)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input type="checkbox"/>
Medical Benefit	<input checked="" type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input checked="" type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

# Exceptions Criteria

## Colony Stimulating Factors – Long Acting

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Medical Benefit, and Managed Medicaid Medical Benefit (MMMB).

### Plan Design Summary

This program applies to the long-acting colony stimulating factor products specified in this document. 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

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

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	Products
Preferred	<ul style="list-style-type: none"> <li>• Fulphila (pegfilgrastim-jmdb)</li> <li>• Neulasta (including Onpro kit) (pegfilgrastim)</li> </ul>
Target	<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>

## 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

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
2. Fulphila [package insert]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
3. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
4. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
5. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; February 2024.
6. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
7. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.