

| Reference number(s) |  |
|---------------------|--|
| 4261-D              |  |
|                     |  |

#### This document applies to the following:

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

| Formulary   | Applies  |
|---|----------|
| New to Market (NTM)                                       |          |
| Standard Formulary Chart (SFC)                            | <b>V</b> |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) |          |
| Advanced Control Specialty Formulary Chart (ACSFC)        | <b>V</b> |
| Value Formulary Chart (VFC)                               |          |
| Medical Benefit   |          |
| Medical Benefit: Advanced Biosimilars First               |          |
| Medical Benefit: Managed Medicaid (MMMB)                  |          |
| Medicare Part B   |          |
| Medicare Part B: Advanced Biosimilars First               |          |

# 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: Advanced Control Specialty Formulary Chart (ACSFC), and Standard Control Formulary Chart (SFC).

## **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 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 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.

|           | Products  |
|-----------|---|
| Preferred | Fylnetra (pegfilgrastim-pbbk)     Nyvopria (pegfilgrastim-angf) |
|           | Nyvepria (pegfilgrastim-apgf)                                   |

Specialty Exceptions CSF-Long Acting SFC-ACSFC 4261-D P2025\_R.docx

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|        | Products  |
|--------|---|
| Target | <ul> <li>Fulphila (pegfilgrastim-jmdb)</li> <li>Neulasta (including Onpro kit) (pegfilgrastim)</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 product 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.