# Clinical Policy: Colony Stimulating Factors

Reference Number: PHW.PDL.148
Effective Date: 01/01/2020
Last Review Date: 11/2024

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health and Wellness® that Colony Stimulating Factors are **medically necessary** when the following criteria are met:

## I. Requirements for Prior Authorization of Colony Stimulating Factors

A. Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Colony Stimulating Factor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Colony Stimulating Factor for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Colony Stimulating Factor by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, transplant specialist); **AND**

5. Does not have a contraindication to the prescribed Colony Stimulating Factor; **AND**

6. For primary prophylaxis of chemotherapy-induced febrile neutropenia in patients with non-myeloid malignancies, **one** of the following:

    a. Will be receiving a chemotherapy regimen with an expected incidence of febrile neutropenia > 20% as defined by the National Comprehensive Cancer Network (NCCN)

b. Has one or more risk factors for developing febrile neutropenia as defined by the NCCN;

**AND**

7. For a prescription for a pegfilgrastim-containing product, will be receiving the medication according to a dosing schedule supported by NCCN, other nationally recognized compendia, or peer-reviewed medical literature; **AND**

8. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure, contraindication, or intolerance of the preferred Colony Stimulating Factors approved or medically accepted for the member's diagnosis or indication. **AND**

9. If a prescription for a Colony Stimulating Factor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Colony Stimulating Factor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Fulphila Package Insert. Cambridge, MA: Biocon Biologics Inc.; June 2023.
2. Fylnetra Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
3. Granix Package Insert. Vilnius, Lithuania: UAB Teva Baltics; November 2023.
4. Leukine Package Insert, Package Insert. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
5. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) – Hematopoietic Growth Factors, Version 3.2024.
6. Neupogen Package Insert, Thousand Oaks, California: Amgen Inc. April 2023.
7. Neulasta Package Insert, Thousand Oaks, California; Amgen Inc. February 2021.

8. Nivestym Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; February 2024.
9. Nyvepria Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; March 2023.
10. Releuko Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.
11. Rolvedon Package Insert. Lake Forest, IL: Spectrum Pharmaceuticals, Inc.; November 2023.
12. Stimufend Package Insert. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
13. Udenyca Package Insert. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
14. Zarxio Package Insert. Princeton, NJ: Sandoz Inc.; January 2024.
15. Ziextenzo Package Insert. Princeton, NJ: Sandoz Inc.; March 2021.

E. **Approval Duration:**
**Initial: 6 months**
**Reauthorization: 12 months**

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |
| Q1 2021 annual review: no changes. | 01/2021 |
| Q1 2022 annual review: no changes. | 11/2021 |
| Q1 2023 annual review: no changes. | 11/2022 |
| Q1 2024 annual review: no changes. | 11/2023 |
| Q1 2025: revised according to DHS revisions effective 01/06/2025. | 11/2024 |