

## Clinical Policy: Colony Stimulating Factors

Reference Number: PHW.PDL.148

Effective Date: 01/01/2020

Last Review Date: 11/2023

[Revision Log](#)

### 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. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

#### B. Revisions to 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 the Colony Stimulating Factor by or in consultation with a hematologist or oncologist; **AND**
4. Does not have a history of a contraindication to the prescribed Colony Stimulating Factor; **AND**
5. 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 risk factors for developing febrile neutropenia as defined by the NCCN;

**AND**

6. For a prescription for Neulasta (pegfilgrastim), will not be receiving the medication during the period beginning 14 days before and ending 24 hours after administration of cytotoxic chemotherapy; **AND**
7. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure, contraindication, or intolerance of the preferred Colony Stimulating Factors. **AND**
8. 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. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) – Hematopoietic Growth Factors, Version 2.2019.
2. Neupogen prescribing information, Thousand Oaks, California. Amgen Inc. June 2018.
3. Neulasta Prescribing Information, Thousand Oaks, California. Amgen Inc. April 2019.
4. Leukine prescribing information, Bridgewater, NJ. Sanofi-Aventis. March 2018.

E. **Approval Duration: 6 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

**CLINICAL POLICY**  
**Colony Stimulating Factors**



Reviews, Revisions, and Approvals	Date
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023