Gateway Health℠ It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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. See the Preferred Drug List (PDL) for the list of preferred Colony Stimulating Factors at: https://papdl.com/preferred-drug-list

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.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

Gateway Health℠ It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

COLONY STIMULATING FACTORS PRIOR AUTHORIZATION FORM

☐ **FOR ONCOLOGY USE**

☐ New request ☐ Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	Office NPI:
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Drug requested*:		Strength:	Dosage form (e.g., vial, syringe, kit, etc.):
Dose/route/frequency:			Quantity: Refills:
Diagnosis *(submit documentation)*:			Dx code (*required*):
Beneficiary's height: ins / cms	Beneficiary's weight: lbs / kg		BSA (*Leukine only*): m^2

***For a non-preferred Colony Stimulating Factor:** *SUBMIT DOCUMENTATION* showing the reason a preferred CSF can't be used. *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred agents in this class.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐ Has recent results of a CBC with differential
☐ Is or will be receiving chemotherapy
☐ Is or will be receiving radiation therapy – dates: _____

☐ **Prophylaxis of chemotherapy-induced febrile neutropenia (FN):**
- ☐ Hast at least 1 of the following risk factors for the development of febrile neutropenia:
  - ☐ Age ≥ 65 years ☐ History of FN ☐ Current infection or open wound ☐ Cardiovascular disease
  - ☐ Recent surgery ☐ Poor liver/kidney function ☐ Previous chemo or radiation ☐ Poor nutritional or performance status
- ☐ Receiving or will receive a chemotherapy regimen with an expected incidence of neutropenia > 20%
- ☐ **For pegfilgrastim (Neulasta, Udenyca, etc.):**
  Last date of chemo: _____ Planned administration date: _____ Next expected chemo date: _____

☐ **Treatment of febrile neutropenia:**
- ☐ Received or is receiving myelosuppressive anticancer drugs associated with neutropenia
- ☐ Is at high risk for infection-related complications

☐ **Bone marrow or stem cell transplant –** transplant date: _____
- ☐ Non-myeloid malignancy and is undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT
- ☐ Mobilization of hematopoietic progenitor cells into the blood for collection – planned date of leukapheresis: _____
- ☐ Peripheral stem cell transplant and has received myeloablative chemotherapy
- ☐ Will be using the requested medication in combination with Mozobil (plerixafor) *(also complete Mozobil prior authorization form)*

☐ **Acute myeloid leukemia (AML):**
- ☐ CSF will be used following induction chemotherapy
- ☐ CSF will be used following consolidation chemotherapy

☐ **Hematopoietic syndrome of acute radiation syndrome (H-ARS):**
- ☐ Suspected or confirmed exposure to a radiation dose > 2 gray (Gy)

☐ **Severe chronic neutropenia – specify type:** ☐ congenital neutropenia ☐ cyclic neutropenia ☐ idiopathic neutropenia
- ☐ Experiencing symptoms of neutropenia

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	**Date**:

FORM: COLONY STIMULATING FACTORS