Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 a beneficiary with non-myeloid malignancy, **one** of the following:

   a. Will be receiving a chemotherapy regimen with an expected incidence of febrile neutropenia >20% as defined by National Comprehensive Cancer Network (NCCN)
   b. Has one or more risk factors for developing febrile neutropenia as defined by NCCN;

   AND

7. For a prescription for a pegfilgrastim-containing product, will be receiving the drug 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 of or a contraindication or an intolerance to the preferred Colony Stimulating Factors approved or medically accepted for the beneficiary's diagnosis or indication. 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.

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.

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

COLONY STIMULATING FACTORS PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

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

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 or planned dates of radiation: _____

☐**For a NON-PREFERRED Colony Stimulating Factor (CSF):**

☐Has a history of trial and failure of or a contraindication or an intolerance to the preferred Colony Stimulating Factors that are approved or medically accepted for treatment of the beneficiary's diagnosis (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

☐**Prophylaxis of chemotherapy-induced febrile neutropenia:**

☐Has at least 1 of the following risk factors for the development of febrile neutropenia:

- ☐Age >65 years
- ☐Recent surgery
- ☐History of febrile neutropenia
- ☐Poor liver or kidney function
- ☐Current infection or open wound
- ☐Previous chemotherapy or radiation
- ☐Cardiovascular disease
- ☐Poor nutritional or performance status
- ☐other: _____

☐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: _____

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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

☐ **Bone marrow transplant:**
- ☐ Has a non-myeloid malignancy and is undergoing myeloablative chemotherapy to be followed by bone marrow transplant

  Planned transplant date: _____
- ☐ Has non-Hodgkin's lymphoma, acute lymphoblastic leukemia, or Hodgkin's lymphoma and had an autologous bone marrow transplant

  Transplant date: _____

☐ **Stem cell transplant:**
- ☐ Is planned for autologous peripheral stem cell transplant
- ☐ Is planned for allogeneic peripheral stem cell transplant
- ☐ Will be using the requested medication in combination with plerixafor *(also complete Mozobil prior authorization form)* or another stem cell mobilizer

  Planned leukapheresis date: _____

  Planned transplant date: _____
- ☐ Had an autologous or allogeneic peripheral stem cell transplant

  Transplant date: _____

☐ **Acute myeloid leukemia:**
- ☐ CSF will be used following induction chemotherapy
- ☐ CSF will be used following consolidation chemotherapy
- ☐ other: _____

☐ **Hematopoietic syndrome of acute radiation syndrome:**
- ☐ 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 WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: