Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 3, 2025

Colony Stimulating Factors

Preferred: Leukine®, Neupogen®, and Nyvepria™
Clinical PA required (Non-Preferred): Fulphila™, Fylnetra®, Granix®, Neulasta®, Nivestym®, Releuko®, Rolvedon™, Stimufend®, Udenyca®, Zarxio®, and Ziextenzo™

LENGTH OF AUTHORIZATION: Refer to specific indications below

REVIEW CRITERIA:

- Medication requested must have the FDA approved indication and patient must be within the FDA approved age limits

Cancer patients – Lenth of Authorization: Up to 12 months

- Indications included:
  - Patient has not yet undergone chemotherapy, but it has been prescribed
  - Cancer patients receiving myelosuppressive chemotherapy
  - Cancer patients receiving bone marrow transplants
  - Patients receiving induction or consolidated chemotherapy for acute myeloid leukemia (AML)
  - Peripheral blood progenitor cell collection and therapy in cancer patients
- Patient does not have to meet Absolute Neutrophil Count (ANC) requirements

Severe chronic neutropenia – Length of Authorization: Up to 12 months

- Patient has congenital, cyclic, or idiopathic severe chronic neutropenia; **AND**
- ANC ≤ 1500 cells/µL (official laboratory documentation required)

Acquired Immunodeficiency Syndrome (AIDS) – Length of Authorization: 6 months

- Severe neutropenia in AIDS patients on antiretroviral therapy; **AND**
- ANC ≤ 1000 cells/µL for initial therapy or ANC ≤ 1600 cells/µL for continuation of therapy (official laboratory documentation required)

Chemotherapy or radiation induced neutropenia – Length of Authorization: Up to 12 months

- Cancer patient with non-myeloid malignancies receiving myelosuppressive chemotherapy; **OR**
- Patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)
- Patient does not have to meet ANC requirements

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**

- Documentation of positive clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/