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

## Colony Stimulating Factors

**Preferred:** Leukine<sup>®</sup>, Neupogen<sup>®</sup>, and Nyvepria<sup>™</sup>

**Clinical PA required (Non-Preferred):** Fulphila<sup>™</sup>, Fylnetra<sup>®</sup>, Granix<sup>®</sup>, Neulasta<sup>®</sup>, Nivestym<sup>®</sup>, Releuko<sup>®</sup>, Rolvedon<sup>™</sup>, Stimufend<sup>®</sup>, Udenyca<sup>®</sup>, Zarxio<sup>®</sup>, and Ziextenzo<sup>™</sup>

**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 – Length 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  $\leq$  1500 cells/ $\mu$ L (official laboratory documentation required)

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

- Severe neutropenia in AIDS patients on antiretroviral therapy; **AND**
- ANC  $\leq$  1000 cells/ $\mu$ L for initial therapy or ANC  $\leq$  1600 cells/ $\mu$ L 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**



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- 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/>