

Prior Authorization DRUG Guidelines

NEUPOGEN® (Filgrastim)

Effective Date: 7/28/05

Date Developed: 7/12/05 by C. Wilhelmy MD

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Neupogen is a Colony Stimulating Factor. It stimulates the production, maturation, and activation of neutrophils, G-CSF activates neutrophils to increase both their migration and cytotoxicity.

Pre-Authorization Criteria:

Neupogen is used for the stimulation of granulocyte production in patients with malignancies, including myeloid malignancies; receiving myelosuppressive therapy associated with a significant risk of neutropenia; severe chronic neutropenia (SCN); receiving bone marrow transplantation (BMT); undergoing peripheral blood progenitor cell (PBPC) collection.

Coverage of filgrastim is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Cancer patients receiving myelosuppressive chemotherapy.** Approve if prescribed by, or in consultation with, an oncologist or hematologist. Filgrastim is FDA-approved for this condition to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia and fever.¹ Guidelines also support the use of filgrastim in this setting.^{15,25-26}
2. **Patients with AML receiving chemotherapy.** Approve if prescribed by, or in consultation with, an oncologist or hematologist. Filgrastim is indicated to reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.¹
3. **Cancer patients receiving bone marrow transplant (BMT).** Approve. Filgrastim is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by BMT.¹

4. **Patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy.** Approve if prescribed by, or in consultation with, an oncologist or hematologist. Filgrastim is indicated for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Mobilization allows for the collection of increased numbers of progenitor cells capable of engraftment compared with collection by leukapheresis without mobilization or bone marrow harvest. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to a more rapid engraftment, which may result in a decreased need for supportive care.¹
5. **Patients with severe chronic neutropenia (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia).** Approve if prescribed by, or in consultation with, a hematologist. Use of chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.^{1,26}

VCHCP requires that Neupogen be prescribed by a hematologist or an oncologist.

MONITORING PARAMETERS — CBC and platelet count should be obtained twice weekly. Leukocytosis (white blood cell counts 100,000/mm³) has been observed in ~2% of patients receiving G-CSF at doses >5 mcg/kg/day. Monitor platelets and hematocrit regularly.

DOSING: ADULTS — Refer to individual protocols. Consult [Lexi-Comp Online](#)TM Note:

Dosing should be based on actual body weight (even in morbidly obese patients). Rounding doses to the nearest vial size often enhances patient convenience and reduces costs without compromising clinical response.

DOSING: PEDIATRIC — Children: Refer to adult dosing.

DOSING: ELDERLY — Refer to adult dosing.

DOSAGE FORMS

Injection, solution [preservative free]: 300 mcg/mL (1 mL, 1.6 mL) [vial; contains sodium 0.035 mg/mL and sorbitol]

Injection, solution [preservative free]: 600 mcg/mL (0.5 mL, 0.8 mL) [prefilled Singleject® syringe; contains sodium 0.035 mg/mL and sorbitol]

ADMINISTRATION — May be administered undiluted by SubQ or by I.V. infusion over 15-60 minutes in D5W; incompatible with sodium chloride solutions

CONTRAINDICATIONS — Hypersensitivity to filgrastim, E. coli-derived proteins, or any component of the formulation; concurrent myelosuppressive chemotherapy or radiation therapy

WARNINGS / PRECAUTIONS — Complete blood count and platelet count should be

obtained prior to chemotherapy. Do not use G-CSF in the period 24-48 hours before to 24 hours after administration of cytotoxic chemotherapy because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy. Precaution should be exercised in the usage of G-CSF in any malignancy with myeloid characteristics. G-CSF can potentially act as a growth factor for any tumor type, particularly myeloid malignancies. Tumors of nonhematopoietic origin may have surface receptors for G-CSF.

Allergic-type reactions have occurred in patients receiving the parent compound, filgrastim (G-CSF) with first or later doses. Reactions tended to occur more frequently with intravenous administration and within 30 minutes of infusion. Rare cases of splenic rupture or adult respiratory distress syndrome have been reported in association with filgrastim; patients must be instructed to report left upper quadrant pain or shoulder tip pain or respiratory distress. Use caution in patients with sickle cell diseases; sickle cell crises have been reported following filgrastim therapy. Most patients experience a 30% to 50% decrease in circulating leukocytes within 1-2 days following discontinuation of filgrastim.

DRUG INTERACTIONS — Drugs which may potentiate the release of neutrophils (eg, lithium) should be used with caution

(PREGNANCY RISK FACTOR — C (show table))

LACTATION — Excretion in breast milk unknown/use caution

PATIENT EDUCATION — Follow directions for proper storage and administration of SubQ medication. Never reuse syringes or needles. You may experience bone pain (request analgesic); nausea or vomiting (small frequent meals may help); hair loss (reversible); or sore mouth (frequent mouth care with a soft toothbrush or cotton swab may help). Report unusual fever or chills; unhealed sores; severe bone pain; pain, redness, or swelling at injection site; unusual swelling of extremities or difficulty breathing; or chest pain and palpitations.

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