VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

NEULASTA™ (Pegfilgrastim)

Effective Date: 7/28/05
Date Developed: 7/12/05 by C. Wilhelmy MD
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Neulasta is a Colony Stimulating Factor. It stimulates the production, maturation, and activation of neutrophils, pegfilgrastim activates neutrophils to increase both their migration and cytotoxicity. Pegfilgrastim has a prolonged duration of effect relative to filgrastim and a reduced renal clearance.

Pre-Authorization Criteria:

Neulasta decreases the incidence of infection, by stimulation of granulocyte production, in patients with nonmyeloid malignancies receiving myelosuppressive therapy associated with a significant risk of febrile neutropenia.

Coverage of pegfilgrastim 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. Pegfilgrastim is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.[1]

Other Uses with Supportive Evidence

2. **Radiation Injury.** Approve under the following circumstances:
   a. It is prescribed by, or in consultation with, a physician with experience in treating acute radiation syndrome, AND
   b. The estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged < 60 years; OR at least 2 Grays in children (aged < 12 years) and in adults aged ≥ 60 years OR in those who have major trauma injuries or burns.

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

MONITORING PARAMETERS — Complete blood count and platelet count should be obtained prior to chemotherapy. Leukocytosis (white blood cell counts 100,000/mm3) has been observed in <1% of patients receiving pegfilgrastim. Monitor platelets and hematocrit regularly.

DOSING: ADULTS — Myelosuppressive therapy: SubQ: 6 mg once per chemotherapy cycle; do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy

DOSING: PEDIATRIC — Adolescents >45 kg: Refer to adult dosing.

DOSING: ELDERLY — Refer to adult dosing.

DOSAGE FORMS — Injection, solution [preservative free]: 10 mg/mL (0.6 mL) [prefilled syringe]

ADMINISTRATION — Do not use 6 mg fixed dose in infants, children, or adolescents <45 kg. Engage/activate needle guard following use to prevent accidental needlesticks.

CONTRAINDICATIONS — Hypersensitivity to pegfilgrastim, 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 pegfilgrastim in the period 14 days before to 24 hours after administration of cytotoxic chemotherapy because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy. Pegfilgrastim can potentially act as a growth factor for any tumor type, particularly myeloid malignancies. Precaution should be exercised in the usage of pegfilgrastim in any malignancy with myeloid characteristics. Tumors of nonhematopoietic origin may have surface receptors for pegfilgrastim.

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. Safety and efficacy in pediatric patients have not been established. The 6 mg fixed dose should not be used in adolescents weighing <45 kg.

DRUG INTERACTIONS — Lithium: May potentiate release of neutrophils from bone marrow.

PREGNANCY RISK FACTOR — C

PREGNANCY IMPLICATIONS — There are no adequate and well-controlled studies in pregnant women; use only if potential benefit to mother justifies risk to the fetus.

LACTATION — Excretion in breast milk unknown/use caution
MONITORING PARAMETERS — Complete blood count and platelet count should be obtained prior to chemotherapy. Leukocytosis (white blood cell counts 100,000/mm3) has been observed in <1% of patients receiving pegfilgrastim. Monitor platelets and hematocrit regularly.

PATIENT EDUCATION — Follow directions for proper storage and administration of SubQ medication. Never reuse syringes or needles. You may experience bone pain (request analgesic). Report unusual fever or chills; unhealed sores; severe bone pain; pain, redness, or swelling at injection site; pain in the upper abdomen or shoulder tip; unusual swelling of extremities or difficulty breathing; or chest pain and palpitations.

EXCLUSIONS

Coverage of pegfilgrastim is *not* recommended in the following circumstances:

1. **Patients undergoing peripheral blood progenitor cell (PBPC) mobilization or use after PBPC transplantation.** Studies have investigated use of pegfilgrastim in this patient population. However, the dosing, safety and efficacy are not clearly established and it is not a standard of care for transplant patients.[9-12,15-18,20-23,27-30]

2. **Myelodysplastic syndrome (MDS).** Only limited data report use of pegfilgrastim for patients with MDS and guidelines from the NCCN for MDS do not discuss use of pegfilgrastim.

REFERENCES

1. Neulasta® [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2011

2. ©2013 UpToDate® • www.uptodate.com
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Copyright (1978 to present) Lexi-Comp, Inc.

3. Epocrates 2013 – www.epocrates.com

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