**PRIOR AUTHORIZATION POLICY**

**POLICY:** Neulasta® (pegfilgrastim injection for subcutaneous use – Amgen)

**TAC APPROVAL DATE:** 07/30/2014

**LAY CRITERIA EFFECTIVE DATE:** Previously in Effect

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**OVERVIEW**

Neulasta is a leukocyte growth factor, sometimes referred to as a colony stimulating factor (CSF). Neulasta 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. Neulasta is indicated to be administered as a single subcutaneous (SC) injection (6 mg) once per chemotherapy cycle. Neulasta should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Common adverse events (AEs) noted in placebo-controlled trials with Neulasta include bone pain and extremity pain.1 Some data are available for Neulasta in pediatric patients. However, the Neulasta prescribing information notes that the safety and effectiveness of Neulasta in pediatric patients have not been established.

**POLICY STATEMENT**

Prior authorization is recommended for prescription benefit coverage of Neulasta. Because of the specialized skills required for evaluation and diagnosis of patients treated with Neulasta as well as the monitoring required for AEs and efficacy, initial approval requires Neulasta to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 12 months in duration unless otherwise noted below.

**Automation:** None.

**RECOMMENDED AUTHORIZATION CRITERIA**

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

**Food and Drug Administration (FDA)-Approved Indications**

1. **Patients with Cancer (Adults and Children) Receiving Myelosuppressive Chemotherapy.** Approve for 6 months if the patient meets the following criteria (a and b):
   a) The agent is prescribed by, or in consultation with, an oncologist or hematologist; AND
   b) The patient meets ONE of the following conditions (i, ii, or iii):
      i. The patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); OR
      ii. The patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to
the prescribing physician (e.g., older patient [aged ≥ 65 years]; history of previous chemotherapy or radiation therapy; pre-existing neutropenia; open wounds or active infection; poor performance status); OR

iii. The patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (Leukine® [sargramostim injection], Neulasta, Neupogen® [filgrastim injection]) and a reduced dose or frequency of chemotherapy may compromise treatment.

Neulasta 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.1-3 The National Comprehensive Cancer Network (NCCN) guidelines for myeloid growth factors (version 2.2014), recommends use of CSF in various scenarios in patients with cancer receiving myelosuppressive chemotherapy.2 Data are also available in children.1,4-7 In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.

Other Uses with Supportive Evidence

2. Patients with Cancer Following Peripheral Blood Progenitor Cell (PBPC) Transplantation. Approve one dose if prescribed by, or in consultation with, an oncologist, a hematologist, or a physician that specializes in transplantation.2,8-20

Neulasta has been studied in patients with cancer undergoing high dose chemotherapy, followed by infusion of stem cell transplantation, which was usually autologous.2,8-20 Results have been similar to that noted with use of daily Neupogen. Neulasta was usually administered on Day 1 and sometimes up to Day 5 after stem cell transplantation. In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.

3. Radiation Injury (Syndrome). Approve one dose if prescribed by, or in consultation with, a physician with expertise in treating acute radiation injury (syndrome).

The Strategic National Stockpile Radiation Working Group published recommendations for the medical management of acute radiation syndrome in 2004.21 In any adult with a whole body or significant partial body-exposure greater than 3 Grays, therapy with a CSF should be started as soon as biodosimetry results indicate that exposure has occurred or when clinical signs and symptoms indicate a level 3 or 4 degree of hematotoxicity. People at the extremes of age (children aged < 12 years and adults aged > 60 years) may be more susceptible to irradiation and therefore a lower threshold exposure dose (2 Grays) for initiation of CSF therapy is appropriate, as well as in patients who have major trauma injuries or burns.21 The Radiation Injury Treatment Network updated guidelines in September 2010 for the treatment of acute radiation syndrome (injury).22 CSF therapy is recommended in a variety of clinical scenarios in patients who have experienced radiation injury (syndrome) based on factors such as the radiation dose.22 In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Neulasta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-
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coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Myelodysplastic Syndrome (MDS).** Only limited data report use of Neulasta for patients with MDS.23 Guidelines from the NCCN for MDS (version 2.2014) do not mention use of Neulasta in this patient population.24

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES


**Other References Utilized**

**History**

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TAC – Therapeutic Assessment Committee; DEU – Drug Evaluation Unit; TAC – Therapeutic Assessment Committee; *For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.