

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Blood Modifiers-Excluding RBC Agents Policy

**Drug(s):** NEULASTA (pegfilgrastim)

**Covered Uses:** 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. All criteria in "other criteria" section must be met for coverage.

**Required Medical Information:** Current chemotherapy regimen, anticipated duration of chemotherapy regimen, laboratory data including complete blood count (CBC) with neutrophil count and platelet counts, previous treatments for chemotherapy associated neutropenia, medication administration records. Twice a week CBC with differential must be provided during previous neutropenia treatment to document failure of previous neutropenia therapy. Twice a week CBC with differential must be provided during Neulasta therapy. Clinical documentation of response including emergency room visits and hospitalizations must be provided. Medical history.

**Age Restrictions:** Restricted to 18 years of age or older

**Prescriber Restrictions:** Prescribed by an oncologist or a hematologist

**Other Criteria:** Coverage will only be provided if all of the following criteria are met:

- Members experiencing moderate to severe neutropenias\* associated with chemotherapy administration that has been documented by twice weekly complete blood counts (to include neutrophils), and has required administration of filgrastim for at least 10 days to recover their neutrophil counts; **AND**
- Reduced dose of the chemotherapy regimen may compromise disease-free or overall survival or treatment outcome, (Dose reduction or delay may be a reasonable alternative); **AND**
- Pegfilgrastim 6 mg should be given once, 24 hours after completion of chemotherapy.
- Initial approval for Neulasta will be for up to 2 courses of chemotherapy within a 3-month period. Continued authorization will be subject to clinical response to therapy and anticipated duration of chemotherapy regimen.
- All requests must be accompanied by laboratory data to include CBC results including neutrophil and platelet counts that have been monitored twice weekly during therapy (to avoid leukocytosis), and clinical documentation of response including emergency room visits and hospitalizations.
- Initial use in dose-dense chemotherapy (e.g. chemotherapy given with less time between treatments than in a standard chemotherapy treatment), high neutropenic risk individuals (e.g. ANC less than 100/uL, sepsis syndrome, invasive fungal infection), and high risk neutropenic chemotherapy regimens (e.g. greater than 85% of the standard dose and more than two of the following: topotecan, mitomycin, docetaxel, etoposide, gemcitabine, cisplatin/carboplatin,

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cyclophosphamide, ifosfamide, vinorelbine, daunorubicin, doxorubicin, epirubicin, and idarubicin) will be reviewed on a case-by-case basis.

- Any subsequent changes to the chemotherapy regimen (e.g. decreased dose, medication changes, less dense frequency, etc.) will require a new prior authorization.

\*Definition of neutropenia: Mild: ANC less than 1500/mm<sup>3</sup> but greater than 1000/mm<sup>3</sup>  
Moderate: ANC between 500/mm<sup>3</sup> and 1000/mm<sup>3</sup> Severe: ANC less than 500/mm<sup>3</sup>

**Exclusion Criteria:** Coverage will be excluded for the following:

- Neutropenia not associated with a concomitant chemotherapy regimen
- Previous febrile neutropenia requiring less than 10 days of filgrastim therapy to recover ANC to greater than 10,000/mm<sup>3</sup>
- Pegfilgrastim should not be administered within 14 days prior to and within 24 hours after administration of chemotherapy
- Prior use resulted in ANC greater than 10,000/mm<sup>3</sup> within 7 days following chemo administration
- Members receiving palliative chemo should receive lower doses of chemo in subsequent cycles
- Members receiving radiation treatment
- In myeloid malignancies or myelodysplastic/myeloproliferative disorders
- Mobilization of peripheral blood progenitor cells for transplantation
- Routine use in chemotherapy regimens that are not expected to produce significant rates (less than 20%) of febrile neutropenia or in members not at increased risk of developing chemotherapy induced infectious complications because of bone marrow compromise or other co-morbidities (e.g. previous radiation therapy to pelvis, previous history of febrile neutropenia while receiving a similar course of chemo)
- Treatment of aplastic anemia
- To increase dose intensity or schedule chemotherapy beyond established doses or frequency ranges
- Members weighing less than 45 kg
- Routine use in members who are afebrile and neutropenic
- For use as adjunctive therapy with or without antibiotics in members with uncomplicated febrile neutropenia (UFN) and not on chemotherapy\*\*
- Primary prophylaxis
- Combo therapy with Leukine, Neumega, Neupogen
- > 1 dose of pegfilgrastim per chemo cycle
- Use with FOLFOX or gemcitabine chemo regimens

\*\* UFN defined by ASCO: Fever < 10 days duration; no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies

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**Coverage Duration:** Initial approval: up to 3 months. Subsequent approvals up to a max of 6 months per each approval