

**Title:** *oprelvekin (Neumega)*

<b>Origination:</b> 03/01/10	<b>Revised:</b>	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- Neumega is a recombinant form of interleukin eleven (IL-11) which is a thrombopoietic growth factor that directly stimulates the proliferation of hematopoietic stem cells and megakaryocyte progenitor cells and induces maturation resulting in increased platelet production.
- Neumega is indicated for the prevention of severe thrombocytopenia and to reduce the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with non-myeloid malignancies who are at risk of severe thrombocytopenia.
- Neumega 50mcg/kg once daily or 25mcg/kg if CrCL is less than 30mL/min should be initiated within 6-24 hours after the completion of chemotherapy, to continue until post-nadir platelet count returns to greater than 50,000 cells/ $\mu$ L for up to 21 days of therapy, then should be discontinued at least two (2) days prior to next planned cycle of chemotherapy.

***Reference Statement***

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

***Exclusion Criteria***

- Hypersensitivity to Neumega or any component of the product.
- For use following myeloablative chemotherapy (i.e., bone marrow transplant or stem cell support).

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**Background Information, continued:**

***Additional Information***

- Requests received for Neumega for **Medicare Members** will be reviewed using CMS “LCD for Oprelvekin (Neumega) (L29243)”; refer to Attachment A or view on-line at:  
[http://www.cms.hhs.gov/mcd/results\\_index.asp?from=%27lmpcontractor%27&contractor=197&name=First+Coast+Service+Options%2C+Inc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter\\_range=4&retired](http://www.cms.hhs.gov/mcd/results_index.asp?from=%27lmpcontractor%27&contractor=197&name=First+Coast+Service+Options%2C+Inc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter_range=4&retired)

**Procedure:**

- 1.0 Request for *initial therapy* with Neumega for **thrombocytopenia due to the effect of chemotherapy for non-myeloid malignancies** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
  - 1.1 Prescriber is an oncologist;
  - 1.2 Diagnosis for any cancer type **EXCEPT** Acute Myelogenous Leukemia (AML), Chronic Myelogenous Leukemia (CML), Myeloid leukemia or Monocytic leukemia;
  - 1.3 Member received myelosuppressive chemotherapy within the past 30 days;
  - 1.4 Current laboratory values indicating platelet count less than 20,000 cells/ $\mu$ L;
  - 1.5 If all criteria are met, may approve Neumega 50mcg/kg once daily for up to 21 days of therapy per chemotherapy cycle (#21 injections) for up to three (3) months (#63 injections total).
- 2.0 Request for *continuation of therapy* with Neumega for **thrombocytopenia due to the effect of chemotherapy for non-myeloid malignancies** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
  - 2.1 Member received myelosuppressive chemotherapy within the past 30 days;
  - 2.2 Current laboratory values indicating platelet count less than 50,000 cells/ $\mu$ L;
  - 2.3 Current progress notes indicating Member is responding to Neumega without the need for platelet transfusions;
  - 2.4 If all criteria are met, may approve Neumega 50mcg/kg once daily for up to 21 days of therapy per chemotherapy cycle (#21 injections) for up to three (3) months (#63 injections total).

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**References:**

1. Neumega (oprelvekin) prescribing information. Wyeth Pharmaceuticals. Philadelphia, PA. 2009.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2010. URL: <http://cp.gsm.com>. Updated January 2010.

**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.