

Prior Authorization DRUG Guidelines

**NEUMEGA® (Oprelvekin)**

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

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**(Archived 1/22/19)**

Neumega is a Biological Response Modulator and Human Growth Factor. It stimulates multiple stages of megakaryocytopoiesis and thrombopoiesis, resulting in proliferation of megakaryocyte progenitors and megakaryocyte maturation.

**Pre-Authorization Criteria:**

Neumega is used for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy.

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

**FDA-Approved Indications**

**FDA Approved Indications:**

- The prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia. Efficacy was demonstrated in patients who had experienced severe thrombocytopenia following the previous chemotherapy cycle. Neumega is not indicated following myeloablative chemotherapy.

VCHCP requires that Neumega be prescribed by an oncologist.

**MONITORING PARAMETERS** — Monitor electrolytes and fluid balance during therapy; obtain a CBC at regular intervals during therapy; monitor platelet counts until adequate recovery has occurred

**GENERAL INFORMATION:**

- The safety and effectiveness of Neumega have not been established in pediatric patients.

- Neumega is not indicated following myeloablative chemotherapy.

Neumega has caused allergic or hypersensitivity reactions including anaphylaxis. Administration of Neumega should be permanently discontinued in any patient who develops an allergic or hypersensitivity reaction. The administration of Neumega should be attended by appropriate precautions in case allergic reactions occur. Adults:

Recommended Dosing Regimen and Authorization Limit:

| <b>Drug</b> | <b>Dosing Regimen</b>                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Authorization Limit</b> |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Neumega     | <p>50 mcg/kg SC once daily.<br/>Start 6 to 24 hours after the completion of chemotherapy.<br/>Monitor platelet counts periodically to assess the optimal duration of therapy.<br/>Continue dosing until the post-nadir platelet count is <math>\geq 50,000</math> cells/mcL.</p> <p>In controlled clinical studies, doses were administered in courses of 10 to 21 days; dosing beyond 21 days per treatment course is not recommended.</p> | 21 days                    |

Note: First dose should not be administered until 24-36 hours after the end of chemotherapy. Discontinue the drug at least 48 hours before beginning the next cycle of chemotherapy.

#### DOSING: PEDIATRIC

Prevention of thrombocytopenia: SubQ: Children: 75-100 mcg/kg once daily for 10-21 days (until postnadir platelet count 50,000 cells/ $\mu$ L)

Note: First dose should not be administered until 24-36 hours after the end of chemotherapy. Discontinue the drug at least 48 hours before beginning the next cycle of chemotherapy.

DOSING: ELDERLY — Refer to adult dosing.

DOSAGE FORMS — Injection, powder for reconstitution: 5 mg [packaged with diluent]

ADMINISTRATION — Subcutaneously in either the abdomen, thigh, or hip (or upper arm if not self-injected). Discontinue treatment with oprelvekin 2 days before starting the next planned cycle of chemotherapy.

**CONTRAINDICATIONS** — Hypersensitivity to oprelvekin or any component of the formulation

**WARNINGS / PRECAUTIONS** — Oprelvekin may cause serious fluid retention and should be used cautiously in patients with conditions where expansion of plasma volume should be avoided (eg, left ventricular dysfunction, CHF, hypertension). Use caution in patients with cardiac arrhythmias or conduction defects, respiratory disease; history of thromboembolic problems; hepatic or renal dysfunction. Not indicated following myeloablative chemotherapy. Severe hypokalemia and/or sudden death have been reported in patients receiving chronic diuretic therapy. Permanently discontinue oprelvekin in any patient developing an allergic reaction. Per the manufacturer, should not be used in children, particularly those <12 years of age, except as part of a controlled clinical trial.

**DRUG INTERACTIONS** — Diuretics: Oprelvekin may increase the risk of hypokalemia in patients receiving chronic diuretic therapy; monitor.

**PREGNANCY RISK FACTOR** — C

**LACTATION** — Excretion in breast milk unknown

**PATIENT EDUCATION** — Report any swelling in the arms or legs (peripheral edema), shortness of breath (congestive failure, anemia), irregular heartbeat, headaches

#### REFERENCES

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