POLICY NUMBER UM ONC_1213	SUBJECT Neumega™ (oprelvekin)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/12/12, 02/12/14, 12/17/15, 12/20/16, 10/31/17, 11/08/17, 09/04/18, 08/14/19, 12/11/19	APPROVAL DATE December 11, 2019	EFFECTIVE DATE December 11, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 09/12/12, 02/12/14, 12/17/15, 12/20/16, 10/31/17, 11/08/17, 09/04/18, 08/14/19, 12/11/19	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Neumega (oprelvekin) usage in the treatment of cancer

II. DEFINITIONS

Neumega (oprelvekin): Oprelvekin functions similarly to endogenous interleukin (IL)-11 and stimulates platelet production. The primary hematopoietic activity of oprelvekin is stimulation of megakaryocytopoiesis and thrombopoiesis. At the molecular level, IL-11 binds to the IL-11 receptor (IL-11Ralpha) on megakaryocytes and megakaryocyte progenitor cells. The IL-11 receptor belongs to a family of cytokine receptors which includes the receptors for IL-6, ciliary neurotrophic factor (CNTF), leukemia inhibitory factor (LIF), and oncostatin M (OSM), which are all capable of interacting with the signal transducing receptor gp130 after ligand binding. Binding of IL-11 to IL-11Ralpha stimulates the proliferation of hematopoietic stem cells and megakaryocyte progenitor cells and induces megakaryocyte maturation resulting in increased platelet production. Platelets produced in response to oprelvekin are morphologically and functionally normal and possess a normal life-span. Oprelvekin has also been shown to have non-hematopoietic activities in animals including regulation of intestinal epithelium growth (enhanced healing of gastrointestinal lesions), inhibition of adipogenesis, induction of acute phase protein synthesis, inhibition of pro-inflammatory cytokine production by macrophages, and stimulation of osteoclastogenesis and neurogenesis.

Neumega (oprelvekin) is FDA approved for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adult patients with non-myeloid malignancies who are at high risk of severe thrombocytopenia.

Neumega (oprelvekin) is available as lyophilized powder for solution in 5 mg vial.

III. POLICY

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Neumega (oprelvekin) may be considered medically necessary when any of the following selection criteria is met:

1. **Chemotherapy-Induced Thrombocytopenia (CIT)**
    a. The member is receiving myelosuppressive chemotherapy for non-myeloid malignancy and is at high risk of developing thrombocytopenia **AND**
    b. Member has a history of severe thrombocytopenia defined as a platelet count ≤ 20,000 **AND**
    c. Neumega (oprelvekin) is being used as prophylaxis to prevent severe chemotherapy induced thrombocytopenia.

Exclusion Criteria: Neumega (oprelvekin) is not considered medically necessary when any of the following selection criteria is met:

1. Neumega (oprelvekin) is not indicated in **ANY** of the following:
    a. Treatment of thrombocytopenia OR chemotherapy induced thrombocytopenia (only approved as prophylaxis).
    b. Prevention of thrombocytopenia due to other medical conditions (i.e. idiopathic thrombocytopenia)
    c. Following myeloablative chemotherapy (i.e. intensification chemotherapy that will eliminate tumor load)
    d. Member with a myeloid malignancy (i.e. CML, AML, etc.)
    e. Platelet count is > 50,000.
2. Dosing exceeds single dose limit of Neumega (oprelvekin) 50 mcg/kg/day.
3. Treatment with Neumega (oprelvekin) exceeds the maximum duration limit of 21 days.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Neumega (oprelvekin) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration**
    a. 50 mcg/kg SUBQ once daily for 14 to 21 days or until post-nadir platelet count is greater than 50,000. Oprelvekin has not been evaluated in members receiving regimens longer than 5 days duration or with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C). Treatment should be discontinued at least 2 days before the start of the next planned cycle of chemotherapy.
2. **Dosage Adjustments**
    a. Renal impairment (CrCl less than 30 mL/min): 25 mcg/kg SUBQ once daily.
3. **Monitoring**

a. Neumega (oprelvekin) 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.

b. Baseline and periodic CBC.

c. Platelet counts at the time of expected nadir and until post-nadir counts are greater than or equal to 50,000.

d. Fluid and electrolyte status in members receiving chronic diuretic therapy.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Neumega prescribing information. Wyeth Pharmaceuticals, Inc. Philadelphia, PA. 2016.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.