POLICY NUMBER UM ONC_1343	SUBJECT Mulpleta™ (lusutrombopag)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/21/18, 07/10/19, 12/11/19	APPROVAL DATE July 10, 2019	EFFECTIVE DATE July 10, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 09/21/18, 07/10/19, 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 Mulpleta (lusutrombopag) usage in the treatment of cancer.

II. DEFINITIONS

Mulpleta (lusutrombopag): is a small molecule thrombopoietin (TPO) receptor agonist that interacts with the transmembrane domain of the TPO receptor expressed on megakaryocytes to cause proliferation and differentiation of megakaryocytic progenitor cells from hematopoietic stem cells and megakaryocyte maturation. Lusutrombopag upregulates the production of platelets through its agonistic effect on human TPO receptors.

Mulpleta (lusutrombopag) is FDA approved for the treatment of thrombocytopenia in patients with chronic hepatic disease who are scheduled to undergo a procedure. There is one approved treatment of thrombocytopenia inpatients with CLD who are scheduled to undergo a procedure, Doptelet (avatrombopag).

Mulpleta (lusutrombopag) is available in 3 mg tablets.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health 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: Mulpleta (lusutrombopag) may be considered medically necessary when any of the following selection criteria are met:

1. **Thrombocytopenia**
    a. Mulpleta (lusutrombopag) is being used for **ALL** of the following conditions:
        i. The member has chronic liver disease and is undergoing an elective invasive procedure
        ii. Has a platelet count < 50×10^9/L prior to procedure
        iii. Required no platelet transfusions and/or no rescue therapy for bleeding prior to the procedure.

Exclusion Criteria: Mulpleta (lusutrombopag) is not considered medically necessary when any of the following selection criteria are met:

1. Mulpleta (lusutrombopag) is being used after failure with Doptelet (avatrombopag).
2. Mulpleta (lusutrombopag) is being used for any of the following conditions:
    a. immune thrombocytopenia
    b. aplastic anemia
    c. hematopoietic tumor
    d. myelodysplastic syndrome
    e. myelofibrosis
    f. history of splenectomy/liver transplant
    g. thrombotic disease
3. Dosing exceeds single dose limit of Mulpleta (lusutrombopag) 3 mg.
4. Treatment exceeds the maximum limit of 7 (3 mg) tablets/month.
5. 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 Mulpleta (lusutrombopag) 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:** 3 mg orally once daily with or without food for 7 days. Begin dosing 8-14 days prior to a scheduled procedure. Patients should undergo their procedure 2-8 days after the last dose.
2. **Dosage Adjustments:** Dosage adjustments are not required for renal or hepatic impairment.
3. **Monitoring**
    a. No need for a platelet transfusion during the procedure and no rescue therapy for bleeding indicates efficacy.
    b. Platelet count: Prior to initiation of therapy and not more than 2 days before the procedure and during therapy.
    c. Thromboembolic events.

V. APPROVAL AUTHORITY

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

VI. ATTACHMENTS

None

VII. REFERENCES

1. Mulpleta PI prescribing information. Shionogi Inc., Florham Park, NJ 2019.
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.

VIII. ADDENDUM

1. **Preferred product(s) for Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid agency: Nplate/oral Promacta.**

   For AHCCCS members: when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy for a list of NON-preferred products.