

Drug Policy:

Mulpleta™ (lusutrombopag)

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| POLICY NUMBER UM ONC_1343 | SUBJECT Mulpleta™ (lusutrombopag) | DEPT/PROGRAM UM Dept | PAGE 1 OF 2 |
| DATES COMMITTEE REVIEWED 09/21/18, 07/10/19, 12/11/19, 08/12/20 | APPROVAL DATE August 12, 2020 | EFFECTIVE DATE August 28, 2020 | COMMITTEE APPROVAL DATES (latest version listed last) 09/21/18, 07/10/19, 12/11/19, 08/12/20 |
| 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, including FDA approved indications, and off-label indications.

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

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines](#) shall follow [NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

B. Thrombocytopenia in Chronic Liver Disease

NOTE: Per NCH Policy, Doptelet (avatrombopag) is the preferred agent to increase platelet counts in members with thrombocytopenia associated with chronic liver disease. *Please refer to UM ONC_1334 for Doptelet (avatrombopag) policy.*

1. Mulpleta (lusutrombopag) may be used in this setting if the member has failed/has an intolerance or contraindication to Doptelet (avatrombopag) **AND** all the following criteria are met:
 - a. The member has chronic liver disease and is scheduled to undergo an elective invasive procedure **AND**
 - b. Has a platelet count < 50,000/mm³ prior to procedure.

III. EXCLUSION CRITERIA

- A. Use in chronic immune thrombocytopenia (Idiopathic Thrombocytopenia Purpura- ITP).
- B. Dosing exceeds single dose limit of Mulpleta (lusutrombopag) 3 mg.
- C. Treatment exceeds the maximum limit of 7 (3 mg) tablets/month.
- D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Mulpleta PI prescribing information. Shionogi Inc., Florham Park, NJ 2020.
- B. Clinical Pharmacology Elsevier Gold Standard. 2020.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.