

Mulpleta® (lusutrombopag) (Oral)

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I. Length of Authorization ¹

Coverage is provided for one 7-day course of therapy and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Mulpleta 3 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 3 mg daily

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, avatrombopag, etc.) or fostamatinib; **AND**
- Patient does NOT have Child-Pugh Class-C liver disease; **AND**
- Laboratory values for platelet count are current (i.e., drawn within the previous 28 days); **AND**
- Lusutrombopag is not being used to attempt to normalize platelet count (i.e., use is limited to decreasing the risk of bleeding from thrombocytopenia by increasing platelet levels and not normalizing them); **AND**

Thrombocytopenia due to Chronic Liver Disease (CLD) † ^{1,2}

- Patient is scheduled to undergo a procedure with a risk of bleeding which would necessitate a platelet transfusion; **AND**
- Patient will not be undergoing any of the following procedures:

- Craniotomy; **AND**
- Thoracotomy; **AND**
- Laparotomy; **AND**
- Open-heart surgery; **AND**
- Organ resection; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 50 x 10⁹/L

- Patient has tried and failed to tolerate or respond to a trial of Doptelet therapy or a documented contraindication exists

† FDA Approved Indication(s); ‡ Compendia recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
Thrombocytopenia secondary to CLD	<ul style="list-style-type: none"> • Begin Mulpleta 8-14 days prior to scheduled procedure. • Patients should undergo their procedure 2-8 days after the last dose. • The recommended dosage of Mulpleta is 3 mg taken orally once daily with or without food for 7 days.

VI. Billing Code/Availability Information

HCPCS code:

- J8499 – Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

NDC:

- Mulpleta 3 mg tablets (7-day Blister Pack): 59630-0551-xx

VII. References

1. Mulpleta [package insert]. Florham Park, NJ; Shionogi & Co.; April 2020. Accessed January 2023.
2. American Society of Anesthesiologists Task Force on Perioperative Blood Management. Practice guidelines for perioperative blood management: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Blood Management*. *Anesthesiology*. 2015 Feb;122(2):241-75.
3. Argo CK, Balogun RA. Blood products, volume control, and renal support in the coagulopathy of liver disease. *Clin Liver Dis*. 2009;13(1):73.

4. Izumi B, Osaki Y, Yamamoto K, Kurokawa M, et al. A Phase 3, Randomized, Double-blind, Placebo-controlled Study of Lusutrombopag for Thrombocytopenia in Patients with Chronic Liver Disease Undergoing Elective Invasive Procedures in Japan (L-PLUS 1). Abstract no. LB-30 in AASLD Liver Meeting, 2015.
5. Afdhal N, Duggal A, Ochiai T, et al. Platelet Response to Lusutrombopag, a Thrombopoietin Receptor Agonist, in Patients with Chronic Liver Disease and Thrombocytopenia Undergoing Non-Emergency Invasive Procedures: Results from a Phase 3 Randomized, Double-Blind, Placebo-Controlled Study. Blood 2017 130:291.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC