

Mulpleta® (lusutrombopag) (Oral)

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I. Length of Authorization

Thrombocytopenia in patients with chronic liver disease

- Coverage is provided for 1 month and may not be renewed.

All other indications §

- Initial coverage will be provided for 6 months and may be renewed every 12 months thereafter

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) [HPCS Unit]:

- 3 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- ONE the following:
 - The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following:
 - The patient has a platelet count less than $50 \times 10^9/L$; AND
 - The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure); AND
 - The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent); OR
 - The patient has another FDA approved indication for the requested agent §; OR
 - The patient has another indication supported in compendia** for the requested agent §; AND

- If the patient has an FDA approved indication, ONE of the following:
 - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
 - The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication; **AND**
- The patient will NOT use the requested agent in combination with another agent included in this program (i.e., avatrombopag, romiplostim, eltrombopag, or fostamatinib disodium hexahydrate); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

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| <ul style="list-style-type: none"> • Patient has tried and failed to tolerate or respond to a trial of Doptelet therapy or a documented contraindication exists |
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****Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence NCCN 1 or 2a recommended use

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process; **AND**
- ONE of the following:
 - Treatment of thrombocytopenia with chronic liver disease should always be reviewed under initial criteria; **OR**
 - The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency); **AND**
- The patient will NOT use the requested agent in combination with another agent included in this program (i.e., avatrombopag, romiplostim, eltrombopag, or fostamatinib disodium hexahydrate); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Thrombocytopenia in patients with chronic liver disease	<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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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