



PRIOR AUTHORIZATION POLICY

POLICY: Thrombocytopenia – Mulpleta Prior Authorization Policy

- Mulpleta® (lusutrombopag tablets – Shionogi/Quotient)

REVIEW DATE: 04/24/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Mulpleta, a thrombopoietin receptor agonist, is indicated for the treatment of **thrombocytopenia** in adults with **chronic liver disease** who are scheduled to undergo a procedure.¹

Begin Mulpleta treatment 8 to 14 days before the scheduled procedure. The recommended dose is 3 mg once daily with or without food for 7 days. In the pivotal clinical studies for the approved indication, patients had a platelet count < 50 x 10⁹/L.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Mulpleta. All approvals are provided for the duration noted below.

- **Mulpleta® (lusutrombopag tablets (Shionogi/Quotient) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

- 1. Thrombocytopenia in a Patient with Chronic Liver Disease.** Approve for 7 days if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has a current platelet count $< 50 \times 10^9/L$ ($< 50,000/mcL$); AND
 - C)** Patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy.

CONDITIONS NOT COVERED

- **Mulpleta[®] (lusutrombopag tablets (Shionogi/Quotient)) is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

- 1. Chronic Immune Thrombocytopenia.** Data are not available regarding use of Mulpleta in patients with persistent and chronic immune thrombocytopenia. Many other agents are FDA-approved for this condition and are recommended in standard guidelines and have established efficacy and safety.²

REFERENCES

1. Mulpleta[®] tablets [prescribing information]. Florham Park, NJ and Philadelphia, PA: Shionogi and Quotient; April 2020.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/12/2023
Annual Revision	No criteria changes.	04/24/2024

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