Clinical Policy Title:	lusutrombopag
Policy Number:	RxA.229
Drug(s) Applied:	Mulpleta®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Lusutrombopag (Mulpleta®) is a thrombopoietin (TPO) receptor agonist. It is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lusutrombopag (Mulpleta®)	Thrombocytopenia	3 mg PO once daily for a total of 7 days. Start dosing 8-14 days prior to a scheduled procedure. Patients should undergo their procedure 2-8 days after the last dose.	3 mg/day

Dosage Forms

- Tablet: 3 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Thrombocytopenia (must meet all)**:**

1. Diagnosis of chronic liver disease;
2. Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist;
3. Age ≥ 18 years;
4. Recent (within the past 14 days) platelet count is < 50 x 10^9/L;
5. Member is scheduled to undergo a medical or dental procedure within the next 30 days;
6. Dose does not exceed 3 mg per day (1 tablet per day) for 7 days.

Approval Duration
Commercial: 14 days (no more than 7 total days of treatment)
Medicaid: 14 days (no more than 7 total days of treatment)

II. Continued Therapy Approval

A. Thrombocytopenia:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval Duration
Commercial: Not applicable
Medicaid: Not applicable

B. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TPO: Thrombopoietin

APPENDIX B: Therapeutic Alternatives

- Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Examples of chronic liver disease include: alcoholic liver disease, chronic viral hepatitis (e.g., hepatitis B and C), and non-alcoholic steatohepatitis.

References

1. Mulpleta Prescribing Information. Florham Park, NJ: Shionogi, Inc.; April 2020. Available at: https://www.mulpleta.com. Accessed March 04, 2021.
2. Kumar A, Mhaskar R, Grossman BJ, et al on behalf of the AABB (American Association of Blood Banks) Platelet Transfusion Guidelines Panel. Platelet transfusion: a systematic review of the clinical evidence. Transfusion. 2015; 55: 1116-1127.
3. Hayashi H, Beppu T, Shirabe K, Maehara Y, and Baba H. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroenterol. 2014; 20(10): 2595-2605.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated.	07/27/2020	09/14/2020

3. Line of Business Policy Applies to was update to all lines of business. 4. Initial Approval criteria: Commercial, Medicaid and HIM approval duration were updated to 14 days. 5. Dosing information was updated to add Start dosing 8-14 days prior to a scheduled procedure and patients should undergo their procedure 2-8 days after the last dose. 6. References were updated. 7. Updated initial approval criteria: “Dose does not exceed 3 mg per day (1 tablet per day) for 7 days”		
Policy was reviewed: 1. Statement about provider sample, ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Appendix B: Statement under Therapeutic Alternatives was changed to “Below are suggested therapeutic alternatives based on...”. 3. HIM approval duration was removed from initial approval criteria and continued Therapy Approval criteria. 4. References were reviewed and updated.	03/04/2021	06/10/2021