# Clinical Policy: Thrombopoietics

Reference Number: PHW.PDL.731
Effective Date: 01/01/2020
Last Review Date: 11/2025

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health and Wellness® that Thrombopoietics are **medically necessary** when the following criteria are met:

## I. Requirements for Prior Authorization of Thrombopoietics

A. Prescriptions that Require Prior Authorization

All prescriptions for Thrombopoietics must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thrombopoietic, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the Thrombopietic forthe treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed the Thrombopoietic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **AND**

4. **One** of the following:

   a. For treatment of thrombocytopenia prior to a procedure, **both** of the following:

      i. Has a pretreatment platelet count < 50 x $10^9$/L
      ii. Will begin treatment with the requested Thrombopoietic prior to the scheduled procedure in accordance with FDA-approved package labeling

   b. For treatment of severe aplastic anemia, has **both** of the following:
      i. Marrow cellularity <25% (or 25%-50% with <30% residual hematopoietic cells)

ii. Two of the following:
1. Neutrophil count <0.5 x $10^9$/L,
2. Platelet count <20 x $10^9$/L,
3. Reticulocyte count <60 x $10^9$/L (using an automated reticulocyte count),

c. For a request for treatment of other indications, **one** of the following:
i. Has a pretreatment platelet count < 30 x $10^9$/L;
ii. Use is supported by the NCCN Drugs & Biologics Compendium, nationally recognized compendia, or peer-reviewed medical literature;

**AND**

5. Has documentation of baseline lab results and monitoring as recommended in the FDA-approved package labeling; **AND**

6. For a request for a non-preferred Thrombopoietic, has documented therapeutic failure, contraindication, or intolerance to the preferred Thrombopoietics approved or medically accepted for the member's indication.

7. If a prescription for a Thrombopoietic is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR THROMBOPOIETICS**:
The determination of medical necessity of a request for renewal of a prior authorization for a Thrombopoietic prescribed for an indication other than thrombocytopenia in a member scheduled to undergo a procedure that was previously approved will take into account whether the member:

1. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed the Thrombopoetic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **AND**

3. **One** of the following:

a. For treatment of severe aplastic anemia, has documentation of a positive clinical response;

b. For treatment of all other diagnoses, has an increased platelet count sufficient to avoid bleeding that requires medical attention

**AND**

4. Has documentation of repeat lab results and monitoring as recommended in the FDA-approved package labeling; **AND**

5. If a prescription for a Thrombopoietic is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thrombopoietic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. **Dose and Duration of Therapy**

1. **Initial and renewal** requests for prior authorization of Thrombopoietics will be approved for 6 months unless otherwise indicated below.

2. **Initial** requests for prior authorization of romiplostim for the treatment of ITP will be approved for 2 months of therapy.

3. **Initial** requests for prior authorization of eltrombopag for the treatment of ITP will be approved for 2 months of therapy.

4. **Initial** requests for prior authorization of eltrombopag for the treatment of refractory severe aplastic anemia will be approved for 5 months of therapy.

5. Requests for prior authorization of eltrombopag for the primary treatment of aplastic anemia will be limited to **one 6-month course** of treatment.

6. **Initial** requests for prior authorization of fostamatinib for the treatment of ITP will be approved for 4 months of therapy.

7. Requests for prior authorization of avatrombopag for the treatment of thrombocytopenia **prior to a procedure** will be approved for 5 days.

8. Requests for prior authorization of lusutrombopag for the treatment of thrombocytopenia **prior to a procedure** will be approved for 7 days.

   NOTE: Requests for additional courses of therapy of avatrombopag or lusutrombopag for the treatment of thrombocytopenia prior to a procedure will be considered to be an initial request.

E. References

1. Doptelet Prescribing Information. AkaRx, Inc. July 2024.
2. NDA Multi-disciplinary Review and Evaluation Doptelet (avatrombopag). February 1, 2016.
3. Mulpleta Prescribing Information. Shionogi Pharma. July 2018.
4. NDA Multi-disciplinary Review and Evaluation Mulpleta (lusutrombopag). February 1, 2016.
5. Tavalisse Prescribing Information. Patheon, Inc. April 2018.
6. NDA Multi-disciplinary Review and Evaluation Tavalisse (fostamatinib). February 1, 2016.
7. Nplate Prescribing Information. Amgen Inc. February 2022.
8. Promacta Prescribing Information. Novartis Pharmaceuticals Co. March 2023.
9. Alvaiz Prescribing Information. Teva Pharmaceuticals. November 2023.
10. Neunert C, Terrel D, Arnold D, et.al.. The American Society of Hematology 2019 evidence-based practice guideline for immune thrombocytopenia. Blood. 2019;3 (22):3829-3866.George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Up To Date; accessed February 1, 2019.
11. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Up To Date; accessed February 1, 2019 August 14, 2024
12. Kulasekararaj A, Cavenagh J, Dokal I, Foukaneli T, Gandhi S, Garg M, et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society for Haematology Guideline. British Journal of Haematology. 2024;204(3):784–804.
13. Schrier SL. Treatment of aplastic anemia in adults. Up To Date; accessed August 15, 2024.
14. Schrier SL. Treatment of aplastic anemia in children and adolescents. Up To Date; accessed August 15, 2024.
15. Terrault N, Chen Y, Izumi N, et.al. Avatrombopag before procedures reduces need for platelet transfusion in patients with chronic liver disease and thrombocytopenia. Gastroenterology. 2018;155:705-718.

16. DeAngelis GA, Khot R, Haskal ZJ, et al. Bleeding risk and management in interventional procedures in chronic liver disease. Journal of Vascular and Interventional Radiology. 2016;27:1665-1674.
17. Patel IJ, Davidson JC, Nikolic B, et al. Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. Journal of Vascular and Interventional Radiology. 2012; 23:727-736.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |
| Q1 2021 annual review: no changes. | 01/2021 |
| Q1 2022 annual review: no changes. | 11/2021 |
| Q1 2023 annual review: no changes. | 11/2022 |
| Q1 2024 annual review: no changes. | 11/2023 |
| Q1 2025: policy revised according to DHS revisions effective 01/06/2025. | 11/2024 |
| Q1 2026: policy revised according to DHS revisions effective 01/05/2026. | 11/2025 |