## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: N/A** |
| **Policy Number: PHW.PDL.731** | **Effective Date: 01/01/2020**<br>**Revision Date: 10/2021** |
| **Policy Name: Thrombopoietics** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

Q1 2022 annual review: no changes.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Venkateswara R. Davuluri, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Thrombopoietics

Reference Number: PHW.PDL.731
Effective Date: 01/01/2020
Last Review Date: 10/2021

Revision Log

**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 health plans affiliated with 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 beneficiary:

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

2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

3. 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**

4. **One** of the following:

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

        i. Has a documented 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 a request for treatment of other indications, has a documented pretreatment platelet count < 30 x $10^9$/L;

**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 for the beneficiary'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 beneficiary 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 beneficiary, 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 beneficiary scheduled to undergo a procedure that was previously approved will take into account whether the beneficiary:

1. Is prescribed the Thrombopoetic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **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. **One** of the following:

   a. Has a documented increased platelet count sufficient to avoid bleeding that requires medical attention
   b. For treatment of severe aplastic anemia, has documentation of a positive clinical response;

   **AND**

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

5. For renewal requests for Tavalisse (fostamatinib), does not have ≥ grade 3 diarrhea or has a documented plan to manage the diarrhea that is consistent with FDA-approved package labeling; **AND**

6. 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 beneficiary 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 beneficiary, 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 beneficiary.

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 Nplate (romiplostim) for the treatment of ITP will be approved for 2 months of therapy.

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

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

5. Requests for prior authorization of Promacta (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 Tavalisse (fostamatinib) for the treatment of ITP will be approved for 4 months of therapy.

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

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

   NOTE: Requests for additional courses of therapy of Doptelet (avatrombopag) or Mulpleta (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. May 2018.
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. December 2018.
8. Promacta Prescribing Information. Novartis Pharmaceuticals Co. November 2018.
9. Neunert C, Lim W, Crowther M, Cohen A, Solberg L, Crowther MA. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011;117(16):4190-4207.
10. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Up To Date; accessed February 1, 2019.
11. Killick, S.B, Brown, N, Cavenagh J, et al. Guidelines for the diagnosis and management of adult aplastic anaemia. British Journal Haematology 2016;172: 187-207.
12. Schrier SL. Treatment of aplastic anemia in adults. Up To Date; accessed February 1, 2019.
13. Schrier SL. Treatment of aplastic anemia in children and adolescents. Up To Date; accessed February 1, 2019.
14. 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.
15. 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.
16. 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. | 10/2021 |