

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
THROMBOPOIETICS

**Proposed Effective Date:** January 5, 2026

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

**I. Requirements for Prior Authorization of Thrombopoietics**

Proposed revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

**A. Prescriptions that Require Prior Authorization**

All prescriptions for Thrombopoietics must be prior authorized.

**B. Revisions to 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 for the 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 are 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  $<50 \times 10^9/L$
    - 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 haematopoietic cells)
    - ii. **Two** of the following:
      1. Neutrophil count  $<0.5 \times 10^9/L$ ,
      2. Platelet count  $<20 \times 10^9/L$ ,

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
THROMBOPOIETICS

3. Reticulocyte count  $<60 \times 10^9/L$  (using an automated reticulocyte count),
- c. For treatment of other indications, **one of the following**:
  - i. Has a pretreatment platelet count  $<30 \times 10^9/L$ ,
  - 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 non-preferred Thrombopoietic, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thrombopoietics approved or medically accepted for the beneficiary's indication. See the Preferred Drug List for the list of preferred Thrombopoietics at: <https://papdl.com/preferred-drug-list>; **AND**
7. If a prescription for a Thrombopoietic is for 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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
THROMBOPOIETICS

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**
6. If a prescription for a Thrombopoietic is for 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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:  
<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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 up to six months unless otherwise indicated below.
2. Initial requests for prior authorization of romiplostim for the treatment of immune thrombocytopenia (ITP) will be approved for up to two months of therapy.
3. Initial requests for prior authorization of eltrombopag for the treatment of ITP will be approved for up to two months of therapy.
4. Initial requests for prior authorization of eltrombopag for the treatment of refractory severe aplastic anemia will be approved for up to five months of therapy.

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
THROMBOPOIETICS

5. Requests for prior authorization of eltrombopag for the primary treatment of aplastic anemia will be limited to one six-month course of treatment.
6. Initial requests for prior authorization of fostamatinib for the treatment of ITP will be approved for up to four months of therapy.
7. Requests for prior authorization of avatrombopag for the treatment of thrombocytopenia prior to a procedure will be approved for five days.
8. Requests for prior authorization of lusutrombopag for the treatment of thrombocytopenia prior to a procedure will be approved for seven 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

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4. NDA Multi-disciplinary Review and Evaluation Mulpleta (lusutrombopag). February 1, 2016.
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