Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 14, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Thrombopoietics – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Thrombopoietics submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Thrombopoietics will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Thrombopoietics to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-31	09-25-31	27-25-31	33-25-31
02-25-31	11-25-31	30-25-31	
03-25-31	14-25-31	31-25-31	
08-25-32	24-25-31	32-25-31	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Thrombopoietics:

- Addition of guidelines for the treatment of severe aplastic anemia consistent with consensus treatment guidelines.
- Removal of the guideline from the requests for renewal of the prior authorization section related to diarrhea associated with Tavalisse (fostamatinib).
- Removal of brand name references from the Dose and Duration of Therapy section.

The revisions to the guidelines to determine medical necessity of prescriptions for Thrombopoietics submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Thrombopoietics are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Thrombopoietics) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

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 Thrombopoeitic 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 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 haematopoietic cells)

      ii. **Two** of the following:

         1. Neutrophil count <0.5 × 10^9/L,
         2. Platelet count <20 × 10^9/L,
         3. Reticulocyte count <60 × 10^9/L (using an automated reticulocyte count),

   c. For treatment of other indications, has a 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 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 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**

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.

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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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.
11. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Up To Date; accessed 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.
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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.
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