pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 21, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Thrombopoietics – Pharmacy Services

BY

Sally A. Kozak, Deputy Secretary
Office of Medical Assistance Programs

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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Thrombopoietics to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

*01-19-41	09-19-39	27-19-37	33-19-39
02-19-36	11-19-35	30-19-35	
03-19-35	14-19-35	31-19-41	
08-19-44	24-19-37	32-19-35	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

through the Department Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the March 21, 2019, DUR Board meeting, the DUR Board recommended that the Department require prior authorization of Thrombopoietics (thrombopoietin [TPO] receptor agonists Doptelet [avatrombopag], Mulpleta [lusutrombopag], Nplate [romiplostim], and Promacta [eltrombopag] and kinase inhibitor Tavalisse [fostamatinib]) to ensure appropriate patient selection and drug utilization of Thrombopoietics. At the May 15, 2019, meeting, the Department's Pharmacy and Therapeutics Committee recommended addition of Thrombopoietics as a new drug class to the Preferred Drug List.

The DUR Board recommended guidelines to determine medical necessity of Thrombopoietics that 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 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
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

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. See the Preferred Drug List (PDL) for the list of preferred Thrombopoietics at: https://papdl.com/preferred-drug-list; **AND**

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 the Quantity Limits Chapter. The list of drugs that are subject to

quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

   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 6 months unless otherwise indicated below.

2. Initial requests for prior authorization of Nplate (romiplostim) for the treatment of ITP will be approved for up to 2 months of therapy.

3. Initial requests for prior authorization of Promacta (eltrombopag) for the treatment of ITP will be approved for up to 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 up to 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 up to 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.