CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tavalisse (fostamatinib disodium hexahydrate)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Tavalisse, approved by the FDA in 2018, is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. It has demonstrated activity against spleen tyrosine kinase (SYK), and the active metabolite (R406) reduces antibody-mediated destruction of platelets. Approval was based on the FIT clinical trial program.
Immune thrombocytopenia (ITP) is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. ITP duration of less than 3 months is referred to as newly diagnosed, 3-12 months as persistent, and greater than 12 months is considered chronic.

Tavalisse (fostamatinib disodium hexahydrate) will be considered for coverage when the following criteria are met:

Chronic Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of chronic ITP of at least 6 months duration; AND
4. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with at least one of the following treatments:
   a) Corticosteroids (i.e., prednisone, prednisolone, methylprednisolone, dexamethasone)
   b) Immunoglobulins
   c) Splenectomy; AND
5. Member has tried and failed treatment with a thrombopoietin receptor agonist (TPO-RA) (i.e., Promacta, Nplate, or Doptelet); AND
6. Member meets one of the following:
   a) Current platelet count is < 30 $x10^9$/L
   b) 30 $x10^9$/L to < 50 $x10^9$/L with one of the following:
      i) Active symptomatic bleeding other than minor mucocutaneous bleeding
      ii) High risk factor for bleeding (i.e., on an anticoagulant, of older age (>60 years), other clearly identified comorbidity); AND
7. Member does NOT have any of the following:
   a) Secondary immune thrombocytopenia (i.e., non-idiopathic, due to another condition)
   b) Uncontrolled or poorly controlled hypertension
   c) History of coagulopathy including prothrombotic conditions.
8. **Dosage allowed/Quantity limit:** Initiate at 100 mg orally twice daily. After 4 weeks, increase to 150 mg twice daily, if needed, to achieve platelet counts of at least 50 x 10^9 /L as necessary to reduce the risk of bleeding.
   QL: 60 tablets/30 days

Note: Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member's platelet count of at least 50 x 10^9 /L was achieved and documented in chart notes.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tavalisse (fostamatinib disodium hexahydrate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/31/2018	New policy for Tavalisse created.
02/02/2023	Transferred policy to new template. Updated and added references. Changed disease duration of at least 3 months to at least 6 months to match definition of chronic disease more closely. Added Doptelet as a TPO-RA option with Promacta, Nplate. Changed platelet count of <35,000 to <30,000 or <50,000 to be consistent with other ITP policies. Replaced autoimmune hemolytic anemia with secondary ITP. Removed monitoring and symptom components from renewal criteria. Changed renewal duration from 6 months to 12 months.

References:

1. Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; 2020.
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3. Bussel JB, Arnold DM, Boxer MA, et al. Long-term fostamatinib treatment of adults with immune thrombocytopenia during the phase 3 clinical trial program. *Am J Hematol*. 2019;94(5):546-553. doi:10.1002/ajh.25444
4. Cooper N, Altomare I, Thomas MR, et al. Assessment of thrombotic risk during long-term treatment of immune thrombocytopenia with fostamatinib. *Ther Adv Hematol*. 2021;12:20406207211010875. Published 2021 Apr 30. doi:10.1177/20406207211010875
5. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. *Blood Adv*. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
6. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv*. 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812
7. Connell NT, Berliner N. Fostamatinib for the treatment of chronic immune thrombocytopenia. *Blood*. 2019;133(19):2027-2030. doi:10.1182/blood-2018-11-852491
8. Wojciechowski P, Wilson K, Nazir J, et al. Efficacy and Safety of Avatrombopag in Patients with Chronic Immune Thrombocytopenia: A Systematic Literature Review and Network Meta-Analysis. *Adv Ther*. 2021;38(6):3113-3128. doi:10.1007/s12325-021-01752-4

Effective date: 07/01/2023
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