Reference number(s)
2560-A

Specialty Guideline Management
Tavalisse

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tavalisse	fostamatinib disodium hexahydrate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- For initial requests: pretreatment platelet count
- For continuation requests: current platelet count

Exclusions

Coverage will not be provided when Tavalisse will be used concomitantly with thrombopoietin receptor agonists (e.g., Promacta, Alvaiz, Nplate, Doptelet, Mulpleta).

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Prescriber Specialties

This medication must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Chronic Immune Thrombocytopenia (ITP)

Authorization of 12 weeks may be granted to members with chronic ITP who meet both of the following criteria:

- Member has had an inadequate response or intolerance to prior therapy (e.g., corticosteroids, immunoglobulins).
- Member has an untransfused platelet count at any point prior to the initiation of the requested medication of either of the following:
  - Less than $30x10^9$/L
  - $30x10^9$/L to $50x10^9$/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Appendix)

Continuation of Therapy

Chronic Immune Thrombocytopenia (ITP)

- Authorization of up to 12 weeks may be granted to members with current platelet count less than $50x10^9$/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received the requested drug for at least 12 weeks.
- Authorization of 12 months may be granted to members with current platelet count less than $50x10^9$/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
- Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.
- Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L for whom Tavalisse dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Appendix

Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidities for bleeding (e.g., peptic ulcer disease)

- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma

References

1. Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; November 2020.
2. Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019;3(23):3829–3866.
3. 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.
4. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. Blood. 2009;113(11):2386-2393.
5. Bussel J, Arnold DM, Grossbard E, et al. Fostamatinib for the treatment of adult chronic and persistent immune thrombocytopenia: Results of two, phase 3, randomized, placebo-controlled trials. Am J Hematol. 2018;93(7):921-930.