CVS Caremark®

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| 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).

## 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 30x109/L
  + 30x109/L to 50x109/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 50x109/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 50x109/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 50x109/L to 200x109/L.
* Authorization of 12 months may be granted to members with current platelet count greater than 200x109/L to less than or equal to 400x109/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.