AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Tavalisse	Page:	1 of 3
Effective Date:	5/25/2023	Last Review Date:	3/1/2023

Applies to:	☒Illinois ☒Maryland ☒Michigan	☐Florida ☒Florida Kids ☒ Virginia	☒New Jersey ☒Pennsylvania Kids

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tavalisse under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

Applicable Drug List:

Tavalisse

Policy/Guideline:

Criteria for Initial Approval:

I. **Authorization may be granted for Chronic immune thrombocytopenia when the following criteria are met:**
- The patient is unable to take the preferred formulary alternative Promacta for the given diagnosis due to a trial and inadequate treatment response, intolerance, or a contraindication
- There was inadequate response or intolerance to prior therapy (for example, corticosteroids or immunoglobulins)
- Documentation of untransfused platelet count at any point prior to the initiation of the requested medication is less than 30x109/L OR 30x109/L to 50x109/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding, or trauma) or risk factors for bleeding
    - Examples of risk factors for bleeding (not all inclusive): a) Undergoing a medical or dental procedure where blood loss is anticipated, b) Comorbidity (e.g., peptic ulcer disease, hypertension), c) Mandated anticoagulation therapy, d) Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma
- Medication is prescribed by or is in consultation with a hematologist

- Tavalisse is not used concomitantly with thrombopoietin receptor agonists (e.g., Promacta, Nplate, Doptelet, Mulpleta)

Criteria for Continuation of Therapy

II. Authorization may be granted for continuation of therapy for Chronic immune thrombocytopenia when the following criteria are met:

- Medication is prescribed by or is in consultation with a hematologist
- Tavalisse is not used concomitantly with thrombopoietin receptor agonists (e.g., Promacta, Nplate, Doptelet, Mulpleta)
- Documentation of current platelet count less than $50x10^9$/L, and the platelet count is not sufficient to prevent clinically important bleeding, and the patient has not received the maximal dose for at least 8 weeks
- Documentation of current platelet count less than $50x10^9$/L, and the current platelet count is sufficient to prevent clinically important bleeding
- Documentation of current platelet count of $50x10^9$/L to $200x10^9$/L
- Documentation of current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L, and the dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding

Approval Duration and Quantity Restrictions:

Initial Approval: 12 weeks

Renewal Approval:

- 3 months for current platelet count of <50x109/L, and the platelet count is not sufficient to prevent clinically important bleeding, with the maximal dose not received for at least 8 weeks
- 12 months for current platelet count <50x109/L, and the platelet count is sufficient to prevent clinically important bleeding
- 12 months for current platelet count of 50x109/L to 200x109/L
- 12 months for current platelet count >200x109/L to ≤400x109/L, and dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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 III, randomized placebo-controlled trials. *Am J Hematol.* 2018; published online: https://doi.org/10.1002/ajh.25125.