

Reference number(s)
2560-A

## SPECIALTY GUIDELINE MANAGEMENT

### TAVALISSE (fostamatinib disodium hexahydrate)

#### POLICY

##### I. 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 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.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: pretreatment and current platelet counts

##### III. EXCLUSIONS

Coverage will not be provided for members with the following exclusion: concomitant use of Tavalisse with thrombopoietin receptor agonists (e.g., Promacta, Nplate, Doptelet, Mulpleta)

##### IV. CRITERIA FOR INITIAL APPROVAL

###### **Chronic immune thrombocytopenia (ITP)**

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

- A. Inadequate response or intolerance to prior therapy (for example, corticosteroids or immunoglobulins).
- B. Untransfused platelet count at any point prior to the initiation of the requested medication is less than  $30 \times 10^9/L$  OR  $30 \times 10^9/L$  to  $50 \times 10^9/L$  with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Section VI).

##### V. CONTINUATION OF THERAPY

###### **Chronic immune thrombocytopenia (ITP)**

- A. Authorization of 3 months may be granted to members with current platelet count less than  $50 \times 10^9/L$  for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal Tavalisse dose for at least 8 weeks.
- B. Authorization of 12 months may be granted to members with current platelet count less than  $50 \times 10^9/L$  for whom the current platelet count is sufficient to prevent clinically important bleeding.

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- C. Authorization of 12 months may be granted to members with current platelet count of  $50 \times 10^9/L$  to  $200 \times 10^9/L$ .
- D. Authorization of 12 months may be granted to members with current platelet count greater than  $200 \times 10^9/L$  to less than or equal to  $400 \times 10^9/L$  for whom Tavalisse dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

## VI. APPENDIX

### **Examples of risk factors for bleeding (not all inclusive)**

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma

## VII. 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, Gensheimer 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. CVS Caremark Clinical Programs Review: Focus on Primary Immune Thrombocytopenia Programs; December 2011.
6. CVS Caremark Clinical Programs Review: Focus on Primary Immune Thrombocytopenia Programs; May 2018.
7. 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>.
8. CVS Caremark Clinical Programs Review. Focus on Immune Thrombocytopenia (ITP) Programs; August 2020.
9. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology – Immune Thrombocytopenic Purpura (ITP) Clinical Programs. August 2021.