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 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 (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 50x10⁹/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 50x10⁹/L for whom the current platelet count is sufficient to prevent clinically important bleeding.

Tavalisse 2560-A SGM P2021.docx

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Reference number(s) 2560-A

- C. Authorization of 12 months may be granted to members with current platelet count of 50x10⁹/L to 200x10⁹/L.
- D. 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.

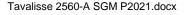
VI. APPENDIX

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, 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. 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.



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