

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 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 are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Chronic or persistent immune thrombocytopenia (ITP)

Authorization of 12 weeks may be granted to members 18 years of age or older with chronic or persistent ITP who meet all of the following criteria:

- A. Inadequate response or intolerance to prior therapy such as corticosteroids, immunoglobulins, splenectomy, or thrombopoietin receptor agonists.
- B. Untransfused platelet count prior to the initiation of ITP therapy 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 IV).

III. CONTINUATION OF THERAPY

Chronic or persistent ITP

- A. Authorization of 12 months may be granted to members 18 years of age or older with current platelet count less than or equal to $200 \times 10^9/L$.
- B. Authorization of 12 months may be granted to members 18 years of age or older with current platelet count greater than $200 \times 10^9/L$ for whom Tavalisse dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

IV. 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

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V. REFERENCES

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3. Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. *Blood*. 2010;115(2):168-186.
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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>.