



## Commercial/Healthcare Exchange PA Criteria

Effective: July 25<sup>th</sup>, 2018

**Prior Authorization:** Tavalisse

**Products Affected:** Tavalisse (fostamatinib) tablet

**Medication Description:**

Fostamatinib is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Stable platelet response occurred in a significantly greater proportion of patients treated with fostamatinib compared with placebo in 1 randomized study, but in another study there was no significant difference in the response rate between fostamatinib and placebo.

Fostamatinib is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase (SYK). The major metabolite of fostamatinib, R406, inhibits signal transduction of Fc-activating receptors and B-cell receptor. The fostamatinib metabolite R406 reduces antibody-mediated destruction of platelets.

**Covered Uses:** Treatment of adults with chronic immune thrombocytopenia (ITP) who have thrombocytopenia which has been unresponsive to a prior treatment

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Diagnosis
2. Medication history
3. Chart notes (documentation required)

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a hematologist.

**Coverage Duration:** Initial: 12 weeks, Renewal: 12 months

**Other Criteria:**

**Initial:**

Approve if the patient meets the following criteria (A AND B):

- A. Inadequate response or intolerance to prior therapy such as corticosteroids, immunoglobulins, splenectomy, or thrombopoietin receptor agonists; AND
- B. Platelet count (untransfused) prior to the initiation of ITP therapy is:
  - a. Less than 30x10<sup>9</sup>/L; OR
  - b. Between 30x10<sup>9</sup>/L to 50x10<sup>9</sup>/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma); OR
  - c. Patient currently has risk factors for bleeding such as undergoing a medical or dental procedure where blood loss is anticipated, comorbidity (e.g., peptic ulcer disease, hypertension), or anticoagulation therapy.

Last Res. 7.25.18



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***Renewal:***

Approve if the patient’s platelet count has increased to a level sufficient to avoid clinically important bleeding after 12 weeks of therapy ( $\geq 50 \times 10^9/L$ ).

***References:***

1. Tavalisse [package insert]. South San Francisco, CA; Rigel Pharmaceuticals; April 2018.
2. Izak M, Bussel JB. Management of thrombocytopenia. F1000Prime Reports. 2014;6:45. DOI:10.12703/P6-45. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4047949/>. Accessed May 11, 2018.
3. Bussel J, Arnold DM, Grossbard E, et al. Fostamatinib for the treatment of adult persistent and chronic immune thrombocytopenia: results of two phase 3, randomized, placebo-controlled trials. Am J Hematol. 2018, Apr 26. DOI: 10.1002/ajh.25125.

***Policy Revision history***

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	07/17/2018