Tavalisse

Description
Tavalisse (fostamatinib disodium hexahydrate)

Background
Tavalisse (fostamatinib) is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase for the treatment of patients with chronic immune thrombocytopenia (ITP). The fostamatinib metabolite R406 reduces antibody-mediated destruction of platelets. This is useful for patients with ITP to increase the lifespan of the platelets in their body, thus increasing platelet counts (1).

Regulatory Status
FDA approved indication: Tavalisse is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment (1).

Previous treatments (as defined in the clinical trials) include corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonists. Use the lowest dose of Tavalisse to achieve and maintain a platelet count at least 50,000 platelets/mcL (50 x 10^9/L) as necessary to reduce the risk of bleeding. Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding (1).

The use of this medication has been associated with clinically significant hypertension (including hypertensive crises), hepatotoxicity, diarrhea and neutropenia. After obtaining baseline assessments, prescribers are to monitor: CBCs, including platelet counts, monthly until a stable
platelet count (at least 50,000 platelets/mcL or 50 x 10⁹/L) is achieved, liver function tests (LFTs) (e.g., ALT, AST, and bilirubin) monthly, and blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter. Additionally, treatment should be interrupted, reduced, or discontinued, based upon clinically significant adverse effects. Based on animal studies, Tavalisse can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Tavalisse and for at least 1 month after the last dose (1).

The safety and effectiveness of Tavalisse in pediatric patients have not been established (1).

**Related policies**
Cablivi, IVIG, Nplate, Promacta, Rituxan

---

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tavalisse may be considered medically necessary in patients that are 18 years of age and older for the treatment of chronic immune thrombocytopenia (ITP) and if the conditions indicated below are met.

Tavalisse may be considered investigational in patients under 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

Chronic immune thrombocytopenia (ITP)

AND ALL of the following:
1. Inadequate response to at least ONE of the following therapies:
   a. Corticosteroids
b. Immunoglobulins

c. Splenectomy

d. Thrombopoietin receptor agonists

2. Baseline platelet count prior to initiation must be less than 50,000/ mcL

3. Prescriber agrees to monitor liver enzymes (including ALT, AST and bilirubin) and CBC monthly until a stable dose is achieved

4. NO dual therapy with thrombopoietin receptor agonists

Prior–Approval Renewal Requirements

Age

18 years of age and older

Diagnosis

Patient must have the following:

Chronic immune thrombocytopenia (ITP)

AND ALL of the following:

1. Improvement in platelet count to 50,000/ mcL or greater

2. Prescriber agrees to routinely monitor CBC, and liver enzymes, and blood pressure throughout therapy

3. NO dual therapy with thrombopoietin receptor agonists

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td>240 tablets per 120 days</td>
</tr>
<tr>
<td>150 mg</td>
<td></td>
</tr>
</tbody>
</table>
Duration 4 months

Prior–Approval *Renewal Limits*

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td></td>
</tr>
<tr>
<td>150 mg</td>
<td>180 tablets per 90 days</td>
</tr>
</tbody>
</table>

Duration 12 months

**Rationale**

**Summary**
Tavalisse (fostamatinib) is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase for the treatment of patients with chronic immune thrombocytopenia (ITP). It is for patients who have had an inadequate treatment response to at least one prior therapy. Use the lowest dose of Tavalisse to achieve and maintain a platelet count at least 50 x 10^9/L as necessary to reduce the risk of bleeding. Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Tavalisse while maintaining optimal therapeutic outcomes.

**References**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Changed requirement of inadequate response to at least two therapies to at least one therapy per SME</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2020</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2021</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>
Section: Prescription Drugs  Effective Date: January 1, 2022
Subsection: Hematological Agents  Original Policy Date: May 25, 2018
Subject: Tavalisse  Page: 5 of 5

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2021 and is effective on January 1, 2022.