Clinical Policy: Fostamatinib (Tavalisse)
Reference Number: ERX.SPA.244
Effective Date: 06.05.18
Last Review Date: 02.19
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Fostamatinib (Tavalisse™) is an oral spleen tyrosine kinase inhibitor.

FDA Approved Indication(s)
Tavalisse 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tavalisse is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Chronic Immune Thrombocytopenia (must meet all):
      1. Diagnosis of chronic ITP;
      2. Prescribed by or in consultation with a hematologist;
      3. Age ≥ 18 years;
      4. Current (within 30 days) platelet count is < 30,000/µL, or member has an active bleed;
      5. Failure of systemic corticosteroids and immune globulins, unless contraindicated or clinically significant adverse effects are experienced (see Appendix B);
         *Prior authorization may be required for immune globulins
      6. Dose does not exceed 300 mg per day (2 tablets per day).
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Chronic Immune Thrombocytopenia (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      2. Member is responding positively to therapy (e.g. increase in platelet count from baseline, reduction in bleeding events);
      3. If request is for a dose increase, new dose does not exceed 300 mg per day (2 tablets per day).
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III
   (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient
documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or
evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration
   ITP: immune thrombocytopenia

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria.
The drugs listed here may not be a formulary agent and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dexamethasone</td>
<td>Oral dosage: Initially, 0.75 to 9 mg/day in 2 to 4 divided doses. Adjust</td>
<td>Highly variable depending on the nature and severity of the</td>
</tr>
</tbody>
</table>
<pre><code>                 | according to patient response                                                  | disease, route of treatment, and on patient response         |
</code></pre>
<p>|                    | Intramuscular or intravenous dosage: Initially, 0.5 to 9 mg/day IV or IM in  |                                                              |
|                    | 2 to 4 divided doses. Adjust according to patient response.                    |                                                              |
| methylprednisolone | Oral dosage: 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient|                                                              |
|                    | response.                                                                     |                                                              |
|                    | Intravenous dosage: 10 to 40 mg IV every 4 to 6 hours for up to 72 hours      |                                                              |
| prednisone         | Initially, 1 mg/kg PO once daily; however, lower doses of 5 mg/day to 10      |                                                              |
|                    | mg/day PO are preferable for long-term treatment                               |                                                              |
| Immune globulins   | Refer to prescribing information                                              | Refer to prescribing information                           |
| immune globulins (e.g., Carimune® NF, Flebogamma® DIF 10%, Gammagard® S/D, Gammaken™, Gamunex®-C, Gammaplex®, Octagam® 10%, Privigen®, etc.) |                                                              |</p>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic
(Brand name®) when the drug is available by both brand and generic.
*Examples of corticosteroids provided are not all inclusive

Appendix C: Contraindications/Boxed Warnings
Not applicable

Appendix D: General Information
• Definitions of acute v. chronic ITP:
Per an International Working Group consensus panel of ITP experts, ITP is defined as newly diagnosed (diagnosis to 3 months), persistent (3 to 12 months from diagnosis), or chronic (lasting for more than 12 months). Although not formally validated, these definitions are supported and used by the American Society of Hematology (ASH).

- Per the 2011 ASH guidelines, response to treatment was defined by the following:
  - A response would be defined as a platelet count $\geq 30,000/\mu L$ and a greater than 2-fold increase in platelet count from baseline measured on 2 occasions > 7 days apart and the absence of bleeding.
  - A failure would be defined as a platelet count < $30,000/\mu L$ or a less than 2-fold increase in platelet count from baseline or the presence of bleeding. Platelet count must be measured on 2 occasions more than a day apart.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITP</td>
<td>100 mg PO BID; after 4 weeks, increase to 150 mg BID, if needed, to achieve platelet counts of at least 50,000/µL</td>
<td>300 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Tablet: 100 mg, 150 mg

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Policy created</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>06.05.18</td>
<td>08.18</td>
</tr>
<tr>
<td>Removed requirement related to splenectomy based on specialist feedback</td>
<td>08.20.18</td>
<td>11.18</td>
</tr>
<tr>
<td>1Q 2019 annual review: no significant changes; added requirement that initial platelet counts be current (within 30 days); references reviewed and updated</td>
<td>10.30.18</td>
<td>02.19</td>
</tr>
</tbody>
</table>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of
physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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