# Clinical Policy: Fostamatinib (Tavalisse)

Reference Number: ERX.SPA.244
Effective Date: 06.05.18
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

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. Member meets one of the following (a or b):
   a. Failure of a systemic corticosteroid;
   b. Member has intolerance or contraindication to systemic corticosteroids, and failure of an immune globulin, 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 (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 (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.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Corticosteroids*** | | |
| dexamethasone | Oral dosage:<br>Initially, 0.75 to 9 mg/day in 2 to 4 divided doses. Adjust according to patient response<br><br>Intramuscular or intravenous dosage:<br>Initially, 0.5 to 9 mg/day IV or IM in 2 to 4 divided doses. Adjust according to patient response | Highly variable depending on the nature and severity of the disease, route of treatment, and on patient response |
| methylprednisolone | Oral dosage:<br>4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response.<br><br>Intravenous dosage:<br>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** | | |
| immune globulins (e.g., Carimune® NF, Flebogamma® DIF 10%, Gammagard® S/D, Gammaked™, Gamunex®-C, Gammaplex®, Octagam® 10%, Privigen®, etc.) | Refer to prescribing information | Refer to prescribing information |

*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/immunosuppressives provided are not all inclusive*

*Appendix C: Contraindications/Boxed Warnings*
None reported

*Appendix D: General Information*

- Definitions of acute vs. 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 2019 ASH guidelines, a durable response to treatment was defined by the following:
  - A durable response would be defined as a platelet count ≥ 30,000/μL and a greater than 2-fold increase in platelet count from baseline at 6 months.
  - A failure would be defined as a platelet count < 30,000/μL or a less than 2-fold increase in platelet count from baseline.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| ITP | 100 mg PO BID; after 4 weeks, increase to 150 mg BID, if needed, to achieve platelet counts of at least 50,000/μL | 300 mg/day |

## VI. Product Availability

Tablets: 100 mg, 150 mg

## VII. References

1. Tavalisse Prescribing Information. San Francisco, CA: Rigel Pharmaceuticals Inc.; November 2020. Available at: www.Tavalisse.com. Accessed November 23, 2021.
2. 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. *American Journal of Hematology*. 2018;93(7):921-930. doi: 10.1002/ajh.25125.
3. Khan AM, Halina M, and Nevarez A. Clinical practice updates in the management of immune Thrombocytopenia. *P&T*. 2017;42(12):756-763.
4. Bussel J, Arnold DM, Cooper N, et al. Long-term maintenance of platelet responses in adults with persistent/chronic immune thrombocytopenia treated with fostamatinib: 1-year efficacy and safety results [abstract]. *Blood*. 2017;130:16.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/.
6. Portielje JEA, Westendorp RGJ, Kluin-Nelemans HC, Brand A. Morbidity and mortality in adults with idiopathic thrombocytopenic purpura. *Blood*. 2001;97(9):2549-2554.
7. Neunert C, Terrell D, Arnold D, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Advances*. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created. | 06.05.18 | 08.18 |
| Removed requirement related to splenectomy based on specialist feedback. | 08.20.18 | 11.18 |
| 1Q 2019 annual review: no significant changes; added requirement that initial platelet counts be current (within 30 days); references reviewed and updated. | 10.30.18 | 02.19 |
| 1Q 2020 annual review: revised systemic corticosteroid *and* immune globulin trial to tiered re-direction with immune globulin trial only if corticosteroid cannot be used to align with Nplate criteria, ASH 2011 guideline and specialist feedback; references reviewed and updated. | 01.14.20 | 02.20 |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 10.12.20 | 02.21 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q 2022 annual review: no significant changes; referenced reviewed and updated. | 11.23.21 | 02.22 |

**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.