

## Clinical Policy: Fostamatinib (Tavalisse)

Reference Number: CP.PHAR.24

Effective Date: 06.05.18

Last Review Date: 02.20

Line of Business: Commercial, HIM, 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.*

It is the policy of health plans affiliated with Centene Corporation® 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  $\geq$  18 years;
4. Current (within 30 days) platelet count  $<$  30,000/ $\mu$ L or member has an active bleed;
5. Member meets one of the following (a or b):
  - a. Failure of 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*);
6. Dose does not exceed 300 mg/day (2 tablets/day).

*\*Prior authorization may be required for immune globulins*

**Approval duration: 6 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Chronic Immune Thrombocytopenia (must meet all):**

1. Currently receiving medication via Centene benefit 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/day (2 tablets/day).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid 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 for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Corticosteroids*</b>		
dexamethasone	<p><u>Oral dosage:</u> Initially, 0.75 to 9 mg/day PO in 2 to 4 divided doses. Adjust according to patient response</p> <p><u>Intramuscular or intravenous dosage:</u> Initially, 0.5 to 9 mg/day IV or IM in 2 to 4 divided doses. Adjust according to patient response</p>	Highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylprednisolone	<u>Oral dosage:</u> 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response.  <u>Intramuscular or intravenous dosage:</u> 10-40 mg IV every 4-6 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	
<b>Immune globulins</b>		
Immune globulins (e.g., Carimune <sup>®</sup> NF, Flebogamma <sup>®</sup> DIF 10%, Gammagard <sup>®</sup> S/D, Gammaked <sup>™</sup> , Gamunex <sup>®</sup> -C, Gammaplex <sup>®</sup> , Octagam <sup>®</sup> 10%, Privigen <sup>®</sup> , etc.)	Refer to prescribing information	Refer to prescribing information

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*\*Examples of corticosteroids/immunosuppressive agents provided are not all inclusive*

*Appendix C: Contraindications/Boxed Warnings*

None reported

*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  $\geq 30,000/\mu\text{L}$  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  $< 30,000/\mu\text{L}$  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**

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 $50 \times 10^9/L$	300 mg/day

**VI. Product Availability**

Tablet: 100 mg, 150 mg

**VII. References**

1. Tavalisse Prescribing Information. San Francisco, CA: Rigel Pharmaceuticals Inc.; April 2018. Available at: [www.Tavalisse.com](http://www.Tavalisse.com). Accessed October 31, 2019.
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. George JN, Woolf SH, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guidelines developed by explicit methods for the American Society of Hematology. *Blood* 1996;88(1):3-40.
7. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood* 2011;117(16):4190-4207.
8. Portielje JEA, Westendorp RGJ, Kluin-Nelemans HC, Brand A. Morbidity and mortality in adults with idiopathic thrombocytopenic purpura. *Blood* 2001;97(9):2549-2554.

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: added HIM line of business; for platelet count requirement, corrected $\leq$ to $<$ per guidelines; added requirement that initial platelet counts be current (within 30 days); no significant changes; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: revised systemic corticosteroid <i>and</i> 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.	01.17.20	02.20

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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