Clinical Policy: Fostamatinib (Tavalisse)

Reference Number: CP.PHAR.24
Effective Date: 06.05.18
Last Review Date: 02.25
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® 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. One of the following (a or b):
   a. Current (within the last 30 days) platelet count < 30,000/µL;
   b. 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. Tavalisse is not prescribed concurrently with thrombopoietin receptor agonists (e.g., Doptelet®, Nplate®, Promacta®, Mulpleta®);
7. Dose does not exceed both of the following (a and b):
   a. 300 mg per day;
   b. 2 tablets per day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Immune Thrombocytopenia (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy (e.g., increase in platelet count from baseline, reduction in bleeding events);
3. Tavalisse is not prescribed concurrently with thrombopoietin receptor agonists (e.g., Doptelet®, Nplate®, Promacta®, Mulpleta®);
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 300 mg per day;
   b. 2 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 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, HIM.PA.154 for health insurance marketplace, 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
Corticosteroids*		
dexamethasone	Oral dosage: Initially, 0.75 to 9 mg/day PO in 2 to 4 divided doses. Adjust according to patient response 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	Highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
methylprednisolone	Oral dosage: 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response. Intramuscular or intravenous dosage: 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	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Immune globulins		
Immune globulins (e.g., 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/immunosuppressive agents 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 x 10^9/L	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 October 17, 2024.

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.clinicalkey.com/pharmacology/.
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.
8. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Advances.* 2019;3(22):3780-3817.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.12.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.16.22	02.23
1Q 2024 annual review: added Tavalisse is not prescribed concurrently with thrombopoietin receptor agonists; references reviewed and updated.	10.19.23	02.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	10.17.24	02.25

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.