RXADVANCE
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Clinical Policy Title:	fostamatinib
Policy Number:	RxA.527
Drug(s) Applied:	Tavalisse®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Fostamatinib (Tavalisse®) is an oral spleen tyrosine kinase inhibitor. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Fostamatinib (Tavalisse®)	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

Dosage Forms

- Tablets: 100 mg, 150 mg

Clinical Policy

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

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 or more;
4. Current (within 30 days) platelet count less than 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/day (2 tablets/day).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Chronic Immune Thrombocytopenia (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance, or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ITP: Immune thrombocytopenia
ASH: American Society of Hematology

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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	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	
Immune globulins		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 provided are not all inclusive

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Definitions of acute and 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 ≥ 30,000/µL 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/µL 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.

References

1. Tavalisse® Prescribing Information. San Francisco, CA: Rigel Pharmaceuticals Inc.; April 2018. Available at: www.Tavalisse.com. Accessed September 25, 2020.
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. Am J Hematol. 2018;93(7):921-930. Accessed September 25, 2020.
3. Khan AM, Halina M, and Nevarez A. Clinical practice updates in the management of immune thrombocytopenia. P&T 2017;42(12):756-763. Accessed September 25, 2020.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed September 25, 2020.
5. George JN, Woolf SH, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. Blood 1996;88(1):3-40. 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. Accessed September 25, 2020.
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. Accessed September 25, 2020.
7. Fostamatinib, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed September 25, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. Appendix A: ASH was added. 4. Appendix B was updated: Pre table phrase was updated to *"Below are suggested therapeutic alternatives.."*; 5. References were updated.	09/25/2020	12/07/2020