Tavalisse (fostamatinib)
Effective 08/01/20

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated a specialty medication and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Fostamatinib is a small molecule prodrug of a tyrosine kinase inhibitor that inhibits the spleen tyrosine kinase (Syk). The major active metabolite of fostamatinib, R406, inhibits signal transduction of Fc-activating receptors and B-cell receptor and reduces antibody-mediated destruction of platelets.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Tavalisse, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
Or
Authorization may be granted when the following criteria are met:

1. Member is diagnosed with chronic immune thrombocytopenia (ITP)
2. Member is at least 18 years of age
3. Member meets one of the following:
    - platelet count < 30,000 cells/mcL
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding) **and**
4. Member has had an inadequate response or intolerance with corticosteroids or immunoglobulins or has not responded to a splenectomy **and**
5. Member has had an inadequate response to maximally dosed Promacta (eltrombopag)

Continuation of Therapy
Reauthorizations may be granted when clinical documentation is submitted showing improvement in the platelet count.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

Tavalisse 100mg and 150mg	60 tablets per 30 days

References

1. Tavalisse (fostamatinib) [prescribing information]. South San Francisco, CA: Rigel Pharmaceuticals, Inc; April 2018.
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 [published online April 26, 2018]. Am J Hematol.[PubMed 29696684]10.1002/ajh.25125
3. Nugent D, McMillan R, Nichol JL, Slichter SJ. Pathogenesis of chronic immune thrombocytopenia: increased platelet destruction and/or decreased platelet production. Br J Haematol 2009; 146:585
4. Rodeghiero F. A critical appraisal of the evidence for the role of splenectomy in adults and children with ITP. Br J Haematol 2018; 181:183
5. Promacta (eltrombopag) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019
6. Balitsky AK, Kelton JG, Arnold DM. Managing antithrombotic therapy in immune thrombocytopenia: development of the TH2 risk assessment score. Blood 2018; 132:2684
7. Wong RSM, Saleh MN, Khelif A, et al. Safety and efficacy of long-term treatment of chronic/persistent ITP with eltrombopag: final results of the EXTEND study. Blood 2017; 130:2527
8. Newland A, Lee EJ, McDonald V, Bussel JB. Fostamatinib for persistent/chronic adult immune thrombocytopenia. Immunotherapy 2018; 10:9.
9. Guidry JA, George JN, Vesely SK, et al. Corticosteroid side-effects and risk for bleeding in immune thrombocytopenic purpura: patient and hematologist perspectives. Eur J Haematol 2009; 83:175

Review History

04/17/2019 – Reviewed
05/20/2020 – Reviewed and Updated May P&T; references and overview updated; QL added to criteria; added started and stabilized statement. Effective 8/1/20.
09/21/2022 – Reviewed and updated; no clinical updates Effective 1/1/2023

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