Tavalisse™ (fostamatinib)
(Oral)

Document Number: IC-0361

Last Review Date: 02/02/2021
Date of Origin: 06/01/2018
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I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 100 mg tablets – 2 tablets per day
- 150 mg tablets – 2 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 300 mg daily

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient is not receiving a thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag, avatrombopag, etc.); **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Fostamatinib is not being used to attempt to normalize platelet count; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**

Chronic Immune Thrombocytopenia (ITP) † [1-5]

- Patient has had persistent/chronic ITP for at least 3 months; **AND**

- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had a splenectomy; **OR**
  - Patient has failed previous therapy with a thrombopoietin receptor agonist; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30 × 10^9/L (30,000/mm^3)

† FDA Approved Indication(s)

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (abnormal liver enzymes), hypertension, severe diarrhea, severe neutropenia, etc.; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk of bleeding and/or the patient has demonstrated a documented decrease in requiring rescue treatment with platelet transfusions

V. Dosage/Administration [1]

Indication	Dose
Chronic ITP	• Initiate at a dose of 100 mg, orally, twice daily. • After 4 weeks, if platelet count has not increased to at least 50 x 10^9/L, increase dose to 150 mg twice daily.

VI. Billing Code/Availability Information

HCPCS code:

J8499 – Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

NDC:

- Tavalisse 100 mg tablets: 71332-0001-xx
- Tavalisse 150 mg tablets: 71332-0002-xx

VII. References

1. Tavalisse [package insert]. San Francisco, CA; Rigel Pharmaceuticals; April 2018. Accessed January 2021.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019 Dec 10;3(23):3829-3866.
3. Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. Blood. 2017. 129:2829-2835. doi:10.1182/blood-2017-03-754119.
4. 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. doi: 10.1002/ajh.25125.
5. Bussel JB, Arnold DM, Boxer MA, et al. Long-term fostamatinib treatment of adults with immune thrombocytopenia during the phase 3 clinical trial program. Am J Hematol. 2019 May;94(5):546-553.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D69.3	Immune thrombocytopenic purpura

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC