

Tavalisse™ (fostamatinib disodium hexahydrate) (Oral)

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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) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 300 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Chronic immune (idiopathic) thrombocytopenia (ITP) †

- Patient aged 18 years or older; **AND**
- Patient has previously failed any of the following treatments for ITP:
 - Patient has failed previous therapy with corticosteroids; **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 (e.g., eltrombopag, romiplostim, etc.); **AND**
- The patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) of less than $30 \times 10^9/L$ (30,000/mm³); **AND**
- Tavalisse is not being used to attempt to normalize platelet count

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity (abnormal liver enzymes), hypertension, severe diarrhea and severe neutropenia, etc.; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count of at least $50 \times 10^9/L$ 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

Indication	Dose
Chronic ITP	<ul style="list-style-type: none">• Initiate at a dose of 100 mg, orally, twice daily.• After 4 weeks, if platelet count has not increased to at least $50 \times 10^9/L$, increase dose to 150 mg twice daily.

VI. Billing Code/Availability Information

HCPCS:

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

NDC:

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

VII. References

1. Tavalisse [package insert]. San Francisco, CA; Rigel Pharmaceuticals; April 2018. Accessed April 2018.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011 Apr 21; 117(16):4190-207. doi: 10.1182/blood-2010-08-302984. Epub 2011 Feb 16. Review.
3. Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood*. 2017. 129:2829-2835. doi:10.1182/blood-2017-03-754119

Appendix 1 – Covered Diagnosis Codes

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

Tavalisse™ (fostamatinib disodium hexahydrate) Prior Auth Criteria

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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) 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/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 Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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