Tavalisse® (fostamatinib)
(Oral)

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I. Length of Authorization

Chronic immune (idiopathic) thrombocytopenia (ITP)

- Initial coverage will be provided for 6 months and may be renewed every 12 months thereafter.

All other indications §

- Initial coverage will be provided for 6 months and may be renewed every 12 months thereafter.

II. Dosing Limits

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

- Tavalisse 100 mg tablets: 2 tablets per day
- Tavalisse 150 mg tablets: 2 tablets per day

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

- 300 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- ONE of the following:
  - The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:
    - ONE of the following:
      - The patient has a platelet count less than or equal to 30 X 10^9/L; **OR**
      - The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding; **AND**
    - ONE of the following:

        - The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP; **OR**
        - The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP; **OR**
        - The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP; **OR**
        - The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta); **OR**
        - The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D); **OR**
        - The patient has had an inadequate response to a splenectomy; **OR**
        - The patient has tried and had an inadequate response to rituximab; **OR**
    - The patient has another FDA approved indication for the requested agent **§**; **OR**
    - The patient has another indication supported in compendia** for the requested agent **§**; **AND**
- If the patient has an FDA approved indication, ONE of the following:
    - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
    - The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication; **AND**
- The patient will NOT use the requested agent in combination with another agent included in this program (i.e., avatrombopag, lusutrombopag, romiplostim, or eltrombopag); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

***Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence NCCN 1 or 2a recommended use*

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process; **AND**
- ONE of the following:
    - The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
        - The patient's platelet count is greater than or equal to 50 x 10^9/L; **OR**
        - The patient's platelet count has increased sufficiently to avoid clinically significant bleeding; **OR**
    - The patient has another indication for the requested agent AND has shown clinical improvement (i.e., decreased symptom severity and/or frequency); **AND**

- The patient will NOT use the requested agent in combination with another agent included in this program (i.e., avatrombopag, lusutrombopag, romiplostim, or eltrombopag); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

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; November 2020. Accessed January 2023.
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
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