Drug Coverage Policy

Effective Date 7/15/2026
Coverage Policy Number.....IP0154
Policy Title.....Tavalisse

Thrombocytopenia – Tavalisse

- Tavalisse® (fostamatinib disodium hexahydrate tablets – Rigel/Patheon)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Tavalisse, a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase, is indicated for the treatment of thrombocytopenia in adults with **chronic immune thrombocytopenia** (ITP) who have had an insufficient response to a previous treatment.[1]

The safety and efficacy of Tavalisse have not been established in pediatric patients. Use of Tavalisse is not recommended for patients < 18 years of age because adverse events on actively growing bones were observed in nonclinical studies. Discontinue Tavalisse if after 12 weeks of treatment, the platelet count does not increase to a sufficient level to control bleeding.

Guidelines
In 2019, the American Society of Hematology updated guidelines for ITP.[2] Tavalisse is noted as an agent that has been studied in the third-line setting and its role is not specifically addressed. However, there are several other recommendations. For adults with ITP for at least 3 months who are corticosteroid-dependent or unresponsive to corticosteroid, a thrombopoietin receptor agonist (either Promacta® [eltrombopag tablets and oral suspension] or Nplate® [romiplostim subcutaneous injection]) or a splenectomy are recommended. Other treatment options in children and adults include intravenous immunoglobulin, anti-D immunoglobulin, and rituximab.

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Tavalisse. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tavalisse as well as the monitoring required for adverse events and long-term efficacy, approval requires Tavalisse to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Tavalisse is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Chronic Immune Thrombocytopenia.** Approve if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL) **[documentation required]**; OR
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL) **[documentation required]**; AND
         - **(2)** According to the prescriber, the patient is at an increased risk of bleeding; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried at least ONE other therapy **[documentation required]**; OR
         Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag olamine tablets and oral suspension, Alvaiz (eltrombopag choline tablets, Nplate (romiplostim subcutaneous

injection), Doptelet (avatrombopag tablets), Walrilz (rilzabrutinib tablets), and rituximab.

b) Patient has undergone splenectomy **[documentation required]**; AND

iv. The medication is prescribed by or in consultation with a hematologist; OR

B) Patient is Currently Receiving Tavalisse. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. According to the prescriber, the patient demonstrates a beneficial clinical response; AND

Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or a decreased frequency of bleeding episodes; AND

ii. Patient remains at risk for bleeding complications.

Conditions Not Covered

Tavalisse for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **B-Cell Lymphomas.** Tavalisse has been investigated in patients with various B-cell lymphomas (e.g., non-Hodgkin's lymphoma, diffuse large B-cell lymphoma [DLBCL]).[3,4] Many other therapies are available for this use.

2. **Rheumatoid Arthritis.** Although Tavalisse has been studied in patients with rheumatoid arthritis, other therapies are more well-established and are recommended in guidelines.[5-9.]

References

1. Tavalisse® tablets [prescribing information]. South San Francisco, CA and Whitby, Ontario: Rigel and Patheon; November 2020.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829-3866.
3. Flinn IW, Bartlett NL, Blum KA, et al. A phase II trial to evaluate the efficacy of fostamatinib in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). *Eur J Cancer*. 2016;54:11-17.
4. Friedberg JW, Sharman J, Sweetenham J, et al. Inhibition of Syk with fostamatinib disodium has significant clinical activity in non-Hodgkin lymphoma and chronic lymphocytic leukemia. *Blood*. 2010;115(13):2578-2585.
5. Genovese MC, van der Heijde DM, Keystone EC, et al. A phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study of 2 dosing regimens of fostamatinib in patients with rheumatoid arthritis with an inadequate response to a tumor necrosis factor-α antagonist. *J Rheumatol*. 2014;41(11):2120-2128.
6. Weinblatt ME, Genovese MC, Ho M, et al. Effects of fostamatinib, an oral spleen tyrosine kinase inhibitor, in rheumatoid arthritis patients with an inadequate response to methotrexate: result from a phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. *Arthritis Rheumatol*. 2014;66(12):3255-3264.
7. Weinblatt ME, Kavanaugh A, Genovese MC, et al. An oral spleen tyrosine kinase (SYK) inhibitor for rheumatoid arthritis. *N Engl J Med*. 2010;363(14):1303-1312.
8. Taylor PC, Genovese MC, Greenwood M, et al. OSKIRA-4: a Phase IIb randomized, placebo-controlled study of the efficacy and safety of fostamatinib monotherapy. *Ann Rheumat Dis*. 2015;74(12):2123-2129.
9. Kunwar S, Davkota AR, Ghimire DK. Fostamatinib, an oral spleen tyrosine kinase inhibitor, in the treatment of rheumatoid arthritis: a meta-analysis of randomized controlled trials. *Rheumatol Int*. 2016;36(8):1077-1087.

Revision Details

Summary of Changes	Review Date	Effective Date
Chronic Immune Thrombocytopenia. Updated inadequate response/contraindication/intolerance TO tried Title change from Fostamatinib.	5/23/2024	08/01/2024
No criteria changes.	5/15/2025	06/15/2025
Added documentation throughout the policy.	7/24/2025	09/01/2025
Removed documentation requirements for patients currently receiving Tavalisse.	9/25/2025	11/01/2025
Chronic Immune Thrombocytopenia: Regarding the Note that cited medications used for this condition, Walrilz (rilzabrutinib tablets) and Alvaiz (eltrombopag choline tablets) were added. The listing of Promacta (eltrombopag tablets and oral suspension) was changed to recognize generic availability and is cited as eltrombopag olamine tablets and oral suspension (Promacta, generic).	5/7/2026	7/15/2026

The policy effective date is in force until updated or retired.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2026 The Cigna Group.