PRIOR AUTHORIZATION POLICY

POLICY: Thrombocytopenia – Tavalisse Prior Authorization Policy
- Tavalisse® (fostamatinib disodium hexahydrate tablets – Rigel/Patheon Whitby)

REVIEW DATE: 04/12/2023

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription 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.

Tavalisse® (fostamatinib disodium hexahydrate tablets (Rigel/Patheon Whitby)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Chronic Immune Thrombocytopenia.** Approve if the patient meets one of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets all of the following criteria (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets one of the following criteria (a or b):
       - **a)** Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL): OR
       - **b)** Patient meets both of the following criteria [(1) and (2)]:
         - **(1)** The patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); AND
         - **(2)** According to the prescriber, the patient is at an increased risk of bleeding; AND
     - **iii.** Patient meets one of the following criteria (a or b):
       - **a)** Patient has tried at least one other therapy; OR
         Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta (eltrombopag tablets and oral suspension), Nplate (romiplostim subcutaneous injection), Doptelet (avatrombopag tablets), or rituximab.
       - **b)** Patient has undergone splenectomy; 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 criteria (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® (fostamatinib disodium hexahydrate tablets (Rigel/Patheon Whitby) is(are) considered experimental, investigational, or unproven for ANY other use(s) 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]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	**Chronic Immune Thrombocytopenia:** The wording of "Continuation of Therapy" was changed to "Patient is Currently Receiving Tavalisse."	03/23/2022
Annual Revision	No criteria changes.	04/12/2023