PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/23/2022

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. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tavalisse is recommended in those who meet the following criteria:

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 (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 [(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. 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 RECOMMENDED FOR APPROVAL

Coverage of Tavalisse is not recommended in the following situations:

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

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.