MEDICAL MUTUAL®

Drug Policy

Policy:	Tavalisse (fostamatinib)	Annual Review Date:
SD		07/20/2023
		Last Revised Date:
		07/20/2023

OVERVIEW

Tavalisse, a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase, is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The major metabolite of Tavalisse, R406, inhibits signal transduction by Fc-activing receptors and B-cell receptor. The R406 metabolite reduces antibody-mediated destruction of platelets. 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. In subchronic, chronic, and carcinogenicity studies involving Tavalisse, chondrodystrophy of the femoral head was observed in rodents. In a study involving juvenile rabbits, growth plate dysplasia was noted in the proximal femur and femoro-tibial joint, and bone marrow cellularity was reduced in the femur and sternum.

POLICY STATEMENT

This policy involves the use of Tavalisse. Prior authorization is recommended for pharmacy benefit coverage of Tavalisse. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Tavalisse be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Chronic Immune Thrombocytopenia (ITP), Initial Therapy/New Starts</u>
Criteria. *Patient must meet the following criteria (A, B, C, D <u>and</u> E):*

- **A.** The patient is 18 years of age or older; AND
- **B.** The agent is prescribed by, or in consultation with a hematologist; AND
- **C.** The patient has tried corticosteroids or IVIG, unless contraindicated; AND
- **D.** The patient has tried Doptelet, or Doptelet is contraindicatedAND

E. The patient meets one of the following (i or ii):

i. The patient has a platelet count < 30 x 10^9/L (< 30,000/µL): OR
ii. The patient has a platelet count < 50 x 10^9/L (< 50,000/µL) and according to the prescriber the patient is at an increased risk of bleeding; (e.g. upcoming medical or dental procedure with expected blood loss; peptic ulcer disease; hypertension; anticoagulation therapy; or profession or lifestyle that predisposes patient to trauma, such as construction worker or plays contact sports).

2. Patient is Currently Receiving Tavalisse
Criteria. *Approve if the initial therapy criteria and the following criteria are met.*

A. According to the prescriber the patient demonstrates a beneficial clinical response (e.g., increased platelet counts); AND
B. The patient remains at risk for bleeding complications.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 90 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tavalisse has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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]). Many other therapies are available for this use.

2. **Rheumatoid Arthritis.** Tavalisse has been studied in patients with rheumatoid arthritis. Other well-established therapies are available.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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