BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.85.029

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	May 25, 2018
Subject:	Tavalisse	**Page:**	1 of 5

Last Review Date: March 8, 2024

Tavalisse

Description

Tavalisse (fostamatinib disodium hexahydrate)

Background
Tavalisse (fostamatinib) is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase for the treatment of patients with chronic immune thrombocytopenia (ITP). The fostamatinib metabolite R406 reduces antibody-mediated destruction of platelets. This is useful for patients with ITP to increase the lifespan of the platelets in their body, thus increasing platelet counts (1).

Regulatory Status
FDA-approved indication: Tavalisse is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment (1).

Previous treatments (as defined in the clinical trials) include corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonists. Use the lowest dose of Tavalisse to achieve and maintain a platelet count at least 50,000 platelets/mcL (50×10^9/L) as necessary to reduce the risk of bleeding. Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding (1).

The use of this medication has been associated with clinically significant hypertension (including hypertensive crises), hepatotoxicity, diarrhea and neutropenia. After obtaining baseline assessments, prescribers are to monitor: CBCs, including platelet counts, monthly until a stable

platelet count at least 50,000 platelets/mcL (50 x 10^9/L) is achieved, liver function tests (LFTs) (e.g., ALT, AST, and bilirubin) monthly, and blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter. Additionally, treatment should be interrupted, reduced, or discontinued, based upon clinically significant adverse effects. Based on animal studies, Tavalisse can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Tavalisse and for at least 1 month after the last dose (1).

The safety and effectiveness of Tavalisse in pediatric patients have not been established (1).

Related policies
Cablivi, IVIG, Nplate, Promacta, Rituxan

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tavalisse may be considered **medically necessary** if the conditions indicated below are met.

Tavalisse may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic immune thrombocytopenia (ITP)

AND ALL of the following:

1. Inadequate response to at least **ONE** of the following therapies:
    a. Corticosteroids
    b. Immunoglobulins
    c. Splenectomy
    d. Thrombopoietin receptor agonists

2. Baseline platelet count prior to initiation must be less than 50,000/mcL (50 x 10^9/L)
3. Prescriber agrees to monitor liver enzymes (including ALT, AST and bilirubin) and CBC monthly until a stable dose is achieved
4. **NO** dual therapy with thrombopoietin receptor agonists

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic immune thrombocytopenia (ITP)

AND ALL of the following:

1. Improvement in platelet count to 50,000/mcL (50 x 10^9/L) or greater
1. Prescriber agrees to routinely monitor CBC, and liver enzymes, and blood pressure throughout therapy
2. **NO** dual therapy with thrombopoietin receptor agonists

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Strength	Quantity
100 mg	240 tablets per 120 days
150 mg	

Duration 4 months

Prior–Approval *Renewal* Limits

Quantity

Strength	Quantity
100 mg	180 tablets per 90 days
150 mg	

Duration 12 months

Rationale

Summary

Tavalisse (fostamatinib) is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase for the treatment of patients with chronic immune thrombocytopenia (ITP). It is for patients who have had an inadequate treatment response to at least one prior therapy. Use the lowest dose of Tavalisse to achieve and maintain a platelet count at least 50 x 109/L as necessary to reduce the risk of bleeding. Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tavalisse while maintaining optimal therapeutic outcomes.

References

1. Tavalisse [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; November 2020.

Policy History

Date	Action
May 2018	Addition to PA
September 2018	Annual editorial review Changed requirement of inadequate response to at least two therapies to at least one therapy per SME
June 2019	Annual review
September 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.85.029
June 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.