BlueCross BlueShield
Federal Employee Program

TAVALISSE
(fostamatinib disodium hexahydrate)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 (50×10^9/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).

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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.