BlueCross BlueShield Federal Employee Program

HYMPAVZI
(marstacimab-hncq)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Hympavzi (marstacimab-hncq) is a human monoclonal IgG1 antibody directed against the Kunitz domain 2 (K2) of tissue factor pathway inhibitor (TFPI) to neutralize TFPI activity and enhance coagulation. TFPI is the primary inhibitor of the extrinsic coagulation cascade and negatively regulates thrombin generation within the extrinsic pathway of coagulation by inactivating the protease functions of FXa/FVIIa/TF complex. TFPI binds to and inhibits the factor Xa active site via its second Kunitz inhibitor domain (K2) (1).

Regulatory Status

FDA-approved indications: Hympavzi is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: (1)

- hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or
- hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

Hympavzi has been associated with thromboembolic events, hypersensitivity reactions, and embryofetal toxicity. Hympavzi treatment may increase the risk of thromboembolic complications. Treatment should be interrupted if diagnostic findings consistent with thromboembolism occur and managed as clinically indicated. Hympavzi may cause hypersensitivity reactions (including, but not limited to urticaria and pruritus). If a severe hypersensitivity reaction occurs, advise patients to discontinue Hympavzi and seek immediate emergency treatment. Hympavzi may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Hympavzi and for 2 months after the last dose (1).

The safety and effectiveness of Hympavzi in pediatric patients less than 12 years of age have not been established (1).

Summary

Hympavzi is a TFPI antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

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

References

1. Hympavzi [package insert]. New York, NY: Pfizer Inc.; October 2024.