

**VOYDEYA
(danicopan)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Voydeya (danicopan) binds reversibly to complement Factor D and selectively inhibits the alternative complement pathway. Voydeya prevents the cleavage of complement Factor B into the Ba and Bb fragments which are required for the formation of the alternative pathway (AP) complement component C3 convertase (C3bBb), the generation of downstream effectors including C3 fragment opsonization, and the amplification of the terminal pathway. In paroxysmal nocturnal hemoglobinuria (PNH), intravascular hemolysis (IVH) is mediated by the terminal membrane attack complex (MAC), while extravascular hemolysis (EVH) is facilitated by C3 fragment opsonization. Voydeya acts proximally in the alternative pathway of the complement cascade to control preferentially C3 fragment-mediated (EVH) while co-administered ravulizumab or eculizumab is anticipated to maintain control over MAC-mediated IVH (1).

Regulatory Status

FDA-approved indications: Voydeya is a complement factor D inhibitor indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH) (1).

Limitations of Use: Vodeya has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab (1).

Voydeya includes a boxed warning citing serious infections caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B. Complete or update vaccination for encapsulated bacteria at least 2 weeks prior to the first dose of Voydeya, unless the risks of delaying Voydeya outweigh the risk of developing a serious infection. Patients receiving Voydeya are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infection and evaluate immediately if infection is suspected (1).

Voydeya is available only through a restricted program called Voydeya Risk Evaluation and Mitigation Strategy (REMS) (1).



**BlueCross
BlueShield**

Federal Employee Program.

VOYDEYA (danicopan)

In addition, Voydeya has warnings regarding hepatic enzyme increases and hyperlipidemia. Assess liver enzymes before treatment initiation and periodically during treatment. Consider treatment interruption or discontinuation if elevations are clinically significant or if the patient becomes symptomatic. Monitor serum lipids periodically during treatment and initiate cholesterol-lowering medication if indicated (1).

The safety and effectiveness of Voydeya in pediatric patients less than 18 years of age have not been established (1).

Summary

Voydeya (danicopan) is a complement factor D inhibitor indicated for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). Voydeya includes a boxed warning citing serious infections caused by encapsulated bacteria. Voydeya is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). In addition, Voydeya has warnings regarding hepatic enzyme increases and hyperlipidemia. The safety and effectiveness of Voydeya in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Voydeya [package insert]. Boston MA: Alexion Pharmaceuticals, Inc.; March 2024.