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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	May 3, 2024
Subject:	Voydeya	**Page:**	1 of 4

Last Review Date: December 13, 2024

Voydeya

Description

Voydeya (danicopan)

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).

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).

Related policies
Soliris, Ultomiris

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Extravascular hemolysis associated with paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Documented baseline value for hemoglobin (Hgb)
b. Used in combination with Soliris (eculizumab) or Ultomiris (ravulizumab)
c. Vaccination against encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae* type B at least 2 weeks prior to initiation [unless Voydeya (danicopan) treatment cannot be delayed]
d. Prescriber is enrolled in Voydeya REMS program

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Extravascular hemolysis (EVH) associated with paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Increase in hemoglobin (Hgb) from pretreatment baseline
b. Used in combination with Soliris (eculizumab) or Ultomiris (ravulizumab)
c. Absence of unacceptable toxicity from the drug
d. Prescriber is enrolled in Voydeya REMS program

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 600 mg per day

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 600 mg per day

Duration 12 months

Rationale

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.

Policy History

Date	Action
May 2024	Addition to PA
September 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.