

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 1444-1
Program	Prior Authorization/Notification
Medication	Voydeya TM (danicopan)
P&T Approval Date	5/2024
Effective Date	8/1/2024

1. Background:

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

2. Coverage Criteria^a:

A. Initial Authorization

- 1. **Voydeya** will be approved based on <u>all</u> of the following criteria:
 - a. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

-AND-

b. Patient is currently receiving complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

-AND-

c. Patient is experiencing extravascular hemolysis (EVH) while on complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

-AND-

d. Patient will continue to receive complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

-AND-

e. Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

Authorization will be issued for 12 months.

B. Reauthorization

1. Voydeya will be approved based on all of the following criteria:



a. Documentation of positive clinical response to Voydeya therapy [e.g., decrease in extravascular hemolysis (EVH), increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, etc.]

-AND-

b. Patient continues to receive Voydeya in combination with complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab) for PNH

-AND-

c. Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Vodeya [package insert]. Boston, Massachusetts: Alexion Pharmaceuticals, Inc.; March 2024.

Program	Prior Authorization/Notification - Voydeya™ (danicopan)
Change Control	
5/2024	New program