UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2340-2
Program	Prior Authorization/Medical Necessity
Medication	Voydeya™ (danicopan)
P&T Approval Date	5/2024, 5/2025
Effective Date	8/1/2025

1. Background

Voydeya (danicopan) is a complement factor D inhibitor indicated as add-on therapy to Ultomiris (ravulizumab) or 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 **all** of the following criteria:

   a. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by **both** of the following[2,3,4,5]:

      (1) Flow cytometry analysis confirming presence of PNH clones

      -AND-

      (2) Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

      -AND-

   b. **All** of the following:

      (1) Patient is currently receiving complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)

      -AND-

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

      -AND-

      (3) Patient will continue to receive complement protein C5 inhibitor eculizumab or Ultomiris (ravulizumab)

-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

-AND-

d. Prescribed by, or in consultation with **one** of the following:

(1) Hematologist
(2) Oncologist

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 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

-AND-

d. Prescribed by, or in consultation with **one** of the following:

(1) Hematologist
(2) Oncologist

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 be in place

4. References:

1. Vodeya [package insert]. Boston, Massachusetts: Alexion Pharmaceuticals, Inc.; March 2024.
2. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005 Dec 1; 106(12): 3699–3709.
3. Devalet B, Mullier F, Chatelain B, et al. Pathophysiology, diagnosis, and treatment of paroxysmal nocturnal hemoglobinuria: a review. Eur J Haematol. 2015 Sep;95(3):190-8.
4. Sutherland DR, Keeney M, Illingworth A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. Cytometry B Clin Cytom. 2012 Jul;82(4):195-208.
5. Röth A, Maciejewski J, Nishimura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. Eur J Haematol. 2018 Jul;101(1):3-11.

Program	Prior Authorization/Medical Necessity - Voydeya™ (danicopan)
Change Control	
5/2024	New program.
5/2025	Annual review. Updated list of C5 inhibitors by removing trade name of Soliris from eculizumab.