UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2340-3
Program	Prior Authorization/Medical Necessity
Medication	Voydeya™ (danicopan)
P&T Approval Date	5/2024, 5/2025, 5/2026
Effective Date	8/1/2026

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:

      (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)

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-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.

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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.
5/2026	Annual review. No changes to coverage criteria.

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