

Applicable Drugs: Voydeya (danicopan)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/25/2024

Date Last Reviewed / Revised: 2/7/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through X are met)

- I. Paroxysmal nocturnal hemoglobinuria (PNH) diagnosis with flow cytometry analysis confirming presence of PNH clones
- II. PNH symptoms including anemia-related symptoms, transfusion-dependence, thrombosis, pain, or organ dysfunction
- III. Enrolled in REMS program
- IV. Must be used in combination with C5 inhibitor
- V. Must meet all of the following:
 - A. Tried C5 inhibitor monotherapy (Ravulizumab or Eculizumab) for at least 6 months
 - B. Clinically significant extravascular hemolysis indicated by hemoglobin levels ≤ 9.5 g/dL AND absolute reticulocyte count of at least $120 \times 10^9/L$
- VI. Must have received meningococcal vaccine and pneumonia vaccine at least 2 weeks before starting treatment. If unable to obtain, administer as soon as possible and provide antibacterial prophylaxis
- VII. Minimum age requirement: >18 years of age
- VIII. Treatment must be prescribed by or in consultation with a hematologist or oncologist
- IX. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- X. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment naïve

- Hematopoietic stem cell transplant, or known or suspected hereditary complement deficiency
- Not used in combination with iptacopan, pegcetacoplan, crovalimab

OTHER CRITERIA

- NA

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Pack of 50 mg (90 tablets) + 100mg (90 tablets) for 30 days
- Pack of 100 mg (180 tablets) per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication (eg, stabilized or increased hemoglobin levels, reduced transfusion requirements, improvement of symptoms (fatigue), and continued use along C5 inhibitor).

APPENDIX

- N/A

REFERENCES

1. Voydeya. Prescribing information. Alexion Pharmaceuticals inc. 2024. Accessed February 7, 2026. https://alexion.us/-/media/alexion_global/documents/regulatory/north-america/usa/2024/english/voydeya_uspi.pdf.
2. Lee JW, et al. Addition of danicopan to ravulizumab or eculizumab in patients with paroxysmal nocturnal haemoglobinuria and clinically significant extravascular haemolysis (alpha): a double-blind, randomised, phase 3 trial. The Lancet haematology. 2023;10(12):e955-e965.
3. Parker C, Omine M, Richards S, et al. International PNH Interest Group. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005;106(12):3699-709.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.