Generic Name: Danicopan

Therapeutic Class or Brand Name: N/A

Applicable Drugs: Voydeya

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/25/2024

Date Last Reviewed / Revised: N/A

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. Age >18 years of age
V. Must be used in combination with C5 inhibitor
VI. Must meet all three of the following:
    A. Trialed C5 inhibitor (Ravulizumab or Eculizumab) for at least 6 months
    B. Clinically significant extravascular hemolysis indicated by hemoglobin levels $\leq$ 9.5 g/dL AND absolute reticulocyte count of at least 120 × 10^9/L
VII. 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
VIII. Medication has been 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 or pegcetacoplan

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

APPENDIX

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REFERENCES

1. Voydeya (danicopan)[package insert]. Alexion pharmaceuticals inc. Boston, MA. Mar 2024.
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.