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| <b>Policy Name:</b> | <b>Voydeya (danicopan)</b> | <b>Policy#:</b> | <b>3369P</b> |
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Voydeya (danicopan)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Voydeya (danicopan) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria for Paroxysmal Nocturnal Hemoglobinuria (PNH)

- 1.1 Diagnosis of paroxysmal nocturnal hemoglobinuria with evidence of clinically significant extravascular hemolysis (EVH)
  - Clinically significant EVH defined as hemoglobin  $\leq 9.5$  g/dL or absolute reticulocyte count  $\geq 120 \times 10^9/L$
- 1.2 Prescribed by or in consultation with a hematologist (blood disorder doctor)
- 1.3 Age 18 years or older
- 1.4 Lab cultures rule out any unresolved serious *Nisseria meningitidis* infection, if patient was diagnosed with *N meningitidis* infection recently
- 1.5 Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- 1.6 Documentation to support patient is already established on ravulizumab or eculizumab for at least 6 months and Voydeya will be used as add-on therapy
- 1.7 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Voydeya will not be used in combination with another treatment for PNH other than ravulizumab or eculizumab

### 3. Managed Dose Limit

- 3.1 Limit of #180 tablets/30 days

### 4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documented clinical benefit from therapy such as hemoglobin stabilization, decrease in the number of red blood cell transfusions, etc

## CPT Codes

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## HCPCS Codes

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## References

1. Voydeya (danicopan) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc; March 2024.
2. Lee JW, Griffin M, Kim JS, et al; ALXN2040-PNH-301 Investigators. 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. *Lancet Haematol.* 2023;10(12):e955-e965.

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