Pharmacy Drug Policy & Procedure

Policy Name:	Voydeya (danicopan)	Policy#:	3369P

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 ≤9.5 g/dL or absolute reticulocyte count ≥120 x 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 *Nesseria 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	

HCPCS Codes	

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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