

POLICY NAME	Voydeya (danicopan)	POLICY #	3369P
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Criteria

Coverage Criteria for Paroxysmal Nocturnal Hemoglobinuria (PNH)

- ☐ 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 $\geq 120 \times 10^9/L$
- ☐ Prescribed by or in consultation with a hematologist (blood disorder doctor)
- ☐ Age 18 years or older
- ☐ Lab cultures rule out any unresolved serious *Nisseria meningitidis* infection, if patient was diagnosed with *N meningitidis* infection recently
- ☐ Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ 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
- ☐ 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

Exclusion Criteria – Any of the following prevents coverage

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