# Commercial PA Criteria

***Effective: July 31, 2024***

***Prior Authorization:*** Voydeya (danicopan)

***Products Affected:*** Voydeya (danicopan) tablet

***Medication Description:*** Voydeya is indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

***Covered Uses:***

1. Add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

***Exclusion Criteria:***

1. Concomitant Use with Empaveli (pegcetacoplan subcutaneous injection) or Fabhalta (iptacopan capsules).
2. VOYDEYA is contraindicated for initiation in patients with unresolved serious infection caused by encapsulated bacteria, including Neisseria meningitidis, Streptococcus pneumoniae, or Haemophilus influenzae type B

***Required Medical Information:***

1. Diagnosis
2. Medication history

***Prescriber Restriction:*** The medication is prescribed by, or in consultation with, a hematologist

***Age Restriction***: Patient is ≥ 18 years of age

***Coverage Duration:***

Initial: 3 months

Continuation: 12 months

***Other Criteria:***

**Initial Approval Criteria**

1. **Paroxysmal Nocturnal Hemoglobinuria.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A. Initial therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv **AND** v):
      i. Patient is ≥ 18 years of age; **AND**
      ii. Paroxysmal nocturnal hemoglobinuria diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages; **AND**
      iii. The medication is prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection); **AND**

iv. Patient has evidence of clinically significant extravascular hemolysis (while receiving Soliris or Ultomiris) as defined by hemoglobin level ≤ 9.5 mg/dL and absolute reticulocyte count ≥ 120 x $10^9$/L; **AND**
v. The medication is prescribed by or in consultation with a hematologist.

B. Patient is Currently Receiving Voydeya. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
i. Patient is ≥ 18 years of age; **AND**
ii. The medication is prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion or subcutaneous injection); **AND**
iii. According to the prescriber, patient is continuing to derive benefit from Voydeya; **AND**
*Note: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score.*
iv. The medication is prescribed by or in consultation with a hematologist

***References:***

1. Voydeya™ tablets [prescribing information]. Boston, MA: Alexion; March 2024.

***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 07/31/2024 |