Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 21, 2025

Voydeya™ (danicopan)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
- Patient has clinically evident extravascular hemolysis (EVH) defined by anemia (hemoglobin [Hb] ≤ 9.5 g/dL) with absolute reticulocyte count ≥ 120 x 10^9/L with or without transfusion support; **AND**
- Patient has received a stable dose of C5 inhibitor therapy (ravulizumab-cwvz [Ultomiris] or eculizumab [Soliris]) for ≥ 6 months prior to starting therapy; **AND**
- Danicopan will be used as add-on therapy to eculizumab (Soliris) or ravulizumab-xwvz (Ultomiris); **AND**
- Patient does NOT have any of the following:
  - Severe hepatic impairment (Child-Pugh Class C); **AND**
  - Unresolved serious infection caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, or *Haemophilus influenzae* type B; **AND**
- Patient has documented vaccinations for *N. meningitidis* and *S. pneumoniae* ≥ 2 weeks prior to initiating danicopan therapy; **AND**
- Medication must be prescribed by or in consultation with a specialist (e.g., hematologist).

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient has demonstrated improvement or stabilization of PNH from baseline (e.g., decreased requirement of red blood cell [RBC] transfusions, Hb stabilization or improvement, lactate dehydrogenase [LDH] reduction, symptom improvement or stabilization, reduction in thrombotic events); **AND**
- Patient does NOT have treatment restricting adverse effects (e.g., encapsulated bacterial infection, clinically significant or symptomatic hepatic enzyme elevations); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 50 mg and 100 mg tablet.
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/