Clinical Policy: Danicopan (Voydeya)

Reference Number: PA.CP.PHAR.665
Effective Date: 08/2024
Last Review Date: 07/2024

Description
Danicopan (Voydeya™) is a complement inhibitor of factor D.

FDA Approved Indication(s)
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).

Limitation(s) of use: Voydeya has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Voydeya is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Paroxysmal Nocturnal Hemoglobinuria (must meet all)**:**

1. Diagnosis of PNH;
2. Prescribed by or in consultation with an hematologist;
3. Age ≥ 18 years;
4. Member has clinically significant extravascular hemolysis while on a C5 inhibitor (e.g., Soliris®, Ultomiris®, Bkemv™) as evidenced by both of the following (a and b):
   a. Documentation of hemoglobin ≤ 9.5 g/dL;
   b. Documentation of reticulocyte count ≥ 120 $\times 10^9$/L;
5. Member has been receiving Ultomiris, Soliris, or Bkemv for the last 6 months;
6. Voydeya is prescribed concurrently with Ultomiris, Soliris, or Bkemv;*
   **Prior authorization may be required for Ultomiris, Soliris, or Bkemv*
7. Dose does not exceed both of the following (a and b):
   a. 600 mg per day;
   b. 6 tablets per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Paroxysmal Nocturnal Hemoglobinuria (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters (a – f):
   a. Improved measures of intravascular or extravascular hemolysis (e.g., normalization of LDH, reduced absolute reticulocyte counts, reduced bilirubin);
   b. Reduced need for red blood cell transfusions;
   c. Increased or stabilization of hemoglobin levels;
   d. Less fatigue;
   e. Improved health-related quality of life;
   f. Fewer thrombotic events;
3. Voydeya is prescribed concurrently with Ultomiris, Soliris, or Bkemv;*
   **Prior authorization may be required for Ultomiris, Soliris, or Bkemv*
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 600 mg per day;
   b. 6 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EVH: extravascular hemolysis	LDH: lactate dehydrogenase
FDA: Food and Drug Administration	PNH: paroxysmal nocturnal hemoglobinuria

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

<table>
<tr><th>Drug Name</th><th>Dosing Regimen</th><th>Dose Limit/ Maximum Dose</th></tr>
<tr><td>Soliris (eculizumab), Bkemv (eculizumab-aeeb)</td><td>IV infusion: 600 mg weekly for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, then 900 mg every 2 weeks thereafter</td><td>See regimen</td></tr>
<tr><td>Ultomiris (ravulizumab-cwvz)</td><td>IV dosing:
Day 1: Loading dose IV
Day 15 and thereafter: Maintenance dose IV. If currently receiving SC Ultomiris, administer IV Ultomiris maintenance dose starting 1 week after last SC Ultomiris maintenance dose
<table>
<tr><th>Body Weight Range (kg)</th><th>Loading Dose (mg)</th><th>Maintenance Dose (mg)</th></tr>
<tr><td>≥ 5 to < 10</td><td>600</td><td>300 every 4 weeks</td></tr>
<tr><td>≥ 10 to < 20</td><td>600</td><td>600 every 4 weeks</td></tr>
<tr><td>≥ 20 to < 30</td><td>900</td><td>2,100 every 8 weeks</td></tr>
<tr><td>≥ 30 to < 40</td><td>1,200</td><td>2,700 every 8 weeks</td></tr>
<tr><td>≥ 40 to < 60</td><td>2,400</td><td>3,000 every 8 weeks</td></tr>
<tr><td>≥ 60 to < 100</td><td>2,700</td><td>3,300 every 8 weeks</td></tr>
<tr><td>≥ 100</td><td>3,000</td><td>3,600 every 8 weeks</td></tr>
</table>
SC dosing (maintenance only for weight ≥ 40 kg): 490 mg SC per week, starting 2 weeks after IV Ultomiris loading dose or 8 weeks after last IV Ultomiris maintenance dose</td><td>IV: 3,600 mg/8 weeks

SC: 490 mg/week</td></tr>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): initiation in patients with unresolved serious infection caused by encapsulated bacteria
- Boxed warning(s): serious infections caused by encapsulated bacteria

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PNH	150 mg PO TID Depending on clinical response, can increase to 200 mg PO TID	600 mg/day

VI. Product Availability

Tablets: 50 mg, 100 mg

VII. References

1. Voydeya Prescribing Information. Boston, MA: Alexion Pharmaceuticals, Inc; March 2024. Available at: https://alexion.com/Documents/VOYDEYA_USPI.pdf. Accessed May 15, 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 Dec;10(12):e955-e965. doi: 10.1016/S2352-3026(23)00315-0.
3. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. *Blood.* 2005; 106(12):3699-3709. doi:10.1182/blood-2005-04-1717.
4. Borowitz MJ, Craig FE, DiGiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry Part B (Clinical Cytometry). 2010; 78B: 211–23
5. Risitano AM, Marotta S, Ricci P, et al. Anti-complement treatment for paroxysmal nocturnal hemoglobinuria: time for proximal complement inhibition? a position paper from the SAAWP of the EBMT. *Front Immunol.* 2019 Jun 14;10:1157. doi: 10.3389/fimmu.2019.01157.
6. Cançado RD, Araújo ADS, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. *Hematol Transfus Cell Ther*. 2021 Jul-Sep;43(3):341-348. doi: 10.1016/j.htct.2020.06.006.

Reviews, Revisions, and Approvals	Date
Policy created	07/2024