MEDICAL MUTUAL®

Drug Policy

Policy:	Voydeya (Danicopan)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Voydeya, a complement Factor D inhibitor, is indicated as add-on therapy to Soliris® (eculizumab intravenous infusion) or Ultomiris® (ravulizumab-cwvz intravenous infusion or subcutaneous injection) for the treatment of extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria (PNH). Voydeya has a Boxed Warning about serious infections caused by encapsulated bacteria.[1] Voydeya is only available through a restricted access program, Voydeya Risk Evaluation and Mitigation Strategy (REMS).

POLICY STATEMENT

This policy involves the use of Voydeya. Prior authorization is recommended for pharmacy benefit coverage of Voydeya. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Voydeya as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Voydeya be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Voydeya is recommended in those who meet the following criteria:

1. **Paroxysmal Nocturnal Hemoglobinuria Criteria.** *Patient must meet the following criteria*
   - **A.** Initial therapy, Approve for 3 months if the patient meets ALL the following (i, ii, iii, iv, v, and vi):
     - 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 [Documentation Required]; AND
     - iii. The medication is prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection); AND
     - iv. According to prescriber patient has clinically significant extravascular hemolysis while taking Ultomiris or Soliris,

v. The patient has been established on Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection) for at least 6 months; AND
vi. 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, 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. The patient has had a response to Voydeya as evidenced by at least one of the following changes from baseline: Hemoglobin increase of at least 2 g/dL in the absence of transfusions, transfusion avoidance, significant improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores, or significant reduction in absolute reticulocyte count; AND
v. The medication is prescribed by or in consultation with a hematologist.

Initial Approval/ Extended Approval.
A) *Initial Approval: 3 months*
B) *Extended Approval: 1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Voydeya has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with Empaveli (pegcetacoplan subcutaneous injection) or Fabhalta (iptacopan capsules).** There is no evidence to support concomitant use of Voydeya with Empaveli or Fabhalta.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Voydeya tablets [prescribing information]. Boston, MA: Alexion; March 2024.
2. Cançado RD, da Silva Araújo A, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. *Hematol Transfus Cell Ther*. 2021;43:341-348.
3. Shah N, Bhatt H. Paroxysmal Nocturnal Hemoglobinuria. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562292/. Accessed on April 11, 2024.
4. Roth A, Maciejewski J, Nishinura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. *Eur J Haematol*. 2018;101(1):3-11.