Drug Coverage Policy

Effective Date.....8/1/2026
Coverage Policy Number.....IP0647
Policy Title.....Voydeya

Complement Inhibitors – Voydeya

- Voydeya™ (danicopan tablets – Alexion)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Voydeya, a complement Factor D inhibitor, is indicated as add-on therapy to eculizumab intravenous infusion (Soliris®, biosimilars) or Ultomiris® (ravulizumab-cwvz intravenous infusion) for the **treatment of extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria (PNH)**.

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

Disease Overview
Paroxysmal nocturnal hemoglobinuria (PNH) is a rare genetic disorder of hematopoietic stem cells.[2,3] Variants in the X-linked phosphatidylinositol glycan class A (PIGA) gene result in a deficiency in the glycosylphosphatidylinositol (GPI) protein, which is responsible for anchoring other protein moieties to the surface of the erythrocytes. Loss of anchoring of these proteins causes cells to hemolyze and leads to complications such as hemolytic anemia, thrombosis, and peripheral blood cytopenias. PNH is a clinical diagnosis that should be confirmed with peripheral blood flow cytometry to detect the absence or severe deficiency of GPI-anchored proteins on at least two lineages.[2,4]

Safety
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).

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Voydeya. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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, approval requires Voydeya to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Voydeya is considered medically necessary when the following are met:

FDA-Approved Indication

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, and iv):
   - **i.** Patient is ≥ 18 years of age; AND
   - **ii.** 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 eculizumab intravenous infusion (Soliris, biosimilars) or Ultomiris (ravulizumab-cwvz intravenous infusion); AND
   - **iv.** According to the prescriber, patient has clinically significant extravascular hemolysis (while receiving eculizumab or Ultomiris), as evidenced by objective laboratory findings.; AND

Note: Examples of objective laboratory findings include reduction in hemoglobin levels, elevated reticulocyte counts, increased transfusion requirements, transfusion-dependence.

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 eculizumab intravenous infusion (Soliris, biosimilars) or Ultomiris (ravulizumab-cwvz intravenous infusion); 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.

Conditions Not Covered

Voydeya for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

1. **Concomitant Use with Empaveli (pegcetacoplan subcutaneous injection) or Fabhalta (iptacopan capsules), or PiaSky (crovalimab-akkz intravenous infusion or subcutaneous injection).** There is no evidence to support concomitant use of Voydeya with Empaveli, Fabhalta, or PiaSky.

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 May 5, 2026.
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.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	8/9/2024	10/15/2024
Paroxysmal Nocturnal Hemoglobinuria: Biosimilars to Soliris were added to the criteria where only Soliris was previously noted; Ultomiris subcutaneous injection was removed from criteria since the manufacturer has decided not to market	7/2/2025	08/15/2025

the product. Added documentation requirements for confirmation of diagnosis. **Conditions Not Recommended for Approval:** PiaSky was added to the list of medications that should not be used concomitantly with Voydeya.		
Updated policy template.	10/2/2025	11/1/2025
No criteria changes	6/4/2026	8/1/2026

The policy effective date is in force until updated or retired.

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