

Voydeya (danicipan)
Effective 03/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Voydeya (danicipan) is a complement factor D inhibitor. It is indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

Voydeya has not been shown to be effective as monotherapy and should only be prescribed as add-on to ravulizumab or eculizumab.

Coverage Guidelines

Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all of the following criteria are met:

1. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry
2. Voydeya will be prescribed in combination with either eculizumab OR ravulizumab

Continuation of Therapy

Reauthorization will be granted when all of the following criteria are met:

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, improvement in hemoglobin levels, decreased number of red blood cell transfusions)
2. Voydeya will continue to be used in combination with either eculizumab OR ravulizumab

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. Quantity limitations are as follows:

Drug Name and Dosage Form	Quantity Limit
Voydeya (danicipan) tablet	180 tablets per 30 days

References

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3. Kulasekararaj AG, Kuter DJ, Griffin M, Weitz IC, Röth A. Biomarkers and laboratory assessments for monitoring the treatment of patients with paroxysmal nocturnal hemoglobinuria: Differences between terminal and proximal complement inhibition. *Blood Rev*. 2023;59:101041.
4. Lee JW, Griffin M, Kim JS, et al. 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;10(12):e955-e965. doi:10.1016/S2352-3026(23)00315-0.
5. Loirat C, Fakhouri F, Ariceta G, et al; HUS International. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. *Pediatr Nephrol*. 2016;31(1):15-39.
6. Makam AN, Suh K, Fahim SM, et al. Iptacopan and danicopan for paroxysmal nocturnal hemoglobinuria: effectiveness and value. Institute for Clinical and Economic Review. February 1, 2024. Accessed February 2, 2024. https://icer.org/wp-content/uploads/2023/07/PNH_Evidence-Report_For-Publication_02012024.pdf
7. Michael M, Bagga A, Sartain SE, Smith RJH. Haemolytic uraemic syndrome. *Lancet*. 2022;400(10364):1722-1740. doi:10.1016/S0140-6736(22)01202-8.
8. Oliver M, Patriquin CJ. Paroxysmal nocturnal hemoglobinuria: Current management, unmet needs, and recommendations. *J Blood Med*. 2023;14:613-628. Published 2023. Doi:10.2147/JBM.S431493.
9. Pugh D, O'Sullivan ED, Duthie FAI, Masson P, Kavanagh D. Interventions for atypical haemolytic uraemic syndrome. *Cochrane Database of Systematic Reviews*. 2021;3:CD012862.
10. Raina R, Krishnappa V, Blaha T, et al. Atypical hemolytic-uremic syndrome: an update on pathophysiology, diagnosis, and treatment. *Ther Aph Dial*. 2019; 23(1): 4-21.
11. Risitano AM, Frieri C, Urciuoli E, Marano L. The complement alternative pathway in paroxysmal nocturnal hemoglobinuria: From a pathogenic mechanism to a therapeutic target. *Immunol Rev*. 2023;313(1):262-278.
12. Voydeya (danicopan) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.

Review History

08/14/2024 – Reviewed at August P&T. Effective 10/1/2024.

07/09/2025 – Reviewed at July P&T. No clinical changes. Effective 08/01/2025.

02/11/2026 – Reviewed at February P&T. No clinical changes. Effective 03/01/2026.

