Mass General Brigham
Health Plan

Voydeya (danicopan)
Effective 10/1/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Voydeya (danicopan) 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 the following criteria are met, and documentation is provided:

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

Continuation of Therapy
Reauthorization will be granted when 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 and reauthorization approvals will be granted for 12 months.
2. Quantity limitations are as follows:

Drug Name	Quantity Limit
Voydeya (danicopan)	180 tablets per 30 days

References

1. Fakhouri F, Schwotzer N, Fremeaux-Bacchi V. How I diagnose and treat atypical hemolytic uremic syndrome. *Blood*. 2023;141(9):984-995.
2. Fakhouri F, Zuber J, Frémeaux-Bacchi V, Loirat C. Haemolytic uraemic syndrome [published correction appears in Lancet. 2017;390(10095):648]. *Lancet*. 2017;390(10095):681-696. doi:10.1016/S0140-6736(17)30062-4.
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.; May 2024.

Review History

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