HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Voydeya (danicopan)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Voydeya, approved by the FDA in 2024, is a small molecule complement factor D inhibitor indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).
PNH is a hematopoietic stem cell disorder in which activation of the complement system destroys red blood cells because of an acquired mutation in the *PIGA* gene. Common manifestations can include hemolytic anemia and fatigue. Thrombosis and bone marrow suppression may also occur.
C5 inhibitors greatly reduce intravascular hemolysis (IVH; occurring within blood vessels) and thrombosis, however, EVH can be a mechanistic consequence of therapy and may lead to remaining dependent on transfusions. Voydeya acts proximally in the alternative pathway of the complement cascade to control EVH while the co-administered C5 inhibitor maintains control over IVH.

Voydeya (danicopan) will be considered for coverage when the following criteria are met:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of PNH; AND
4. Member has been treated with a C5 inhibitor (e.g., ravulizumab or eculizumab) for at least 6 months and will continue; AND
5. Member has clinically evident EVH with both of the following:
   a) Hemoglobin 9.5 g/dL or less, and
   b) Absolute reticulocyte count (ARC) 120 x 10^9/L or greater; AND
6. Member has been or will be vaccinated against encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B).
7. **Dosage allowed/Quantity limit:**
   Start 150 mg 3 times a day orally. If hemoglobin has not increased by greater than 2 g/dL after 4 weeks or a transfusion was required, may increase to 200 mg 3 times a day.
   QL: 180 tablets per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show clinical evidence of positive response to therapy such as increased hemoglobin level, decreased need for transfusions, improved fatigue; AND
2. Member is continuing treatment with a C5 inhibitor and not using Voydeya as monotherapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Voydeya (danicopan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/03/2024	New policy for Voydeya created.

References:

1. Voydeya [prescribing information]. Alexion Pharmaceuticals, Inc.; 2024.
2. 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
3. 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;10:1157. Published 2019 Jun 14. doi:10.3389/fimmu.2019.01157
4. Oliver M, Patriquin CJ. Paroxysmal Nocturnal Hemoglobinuria: Current Management, Unmet Needs, and Recommendations. *J Blood Med*. 2023;14:613-628. Published 2023 Dec 6. doi:10.2147/JBM.S431493
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. *Hematology Am Soc Hematol Educ Program*. 2016;2016(1):208-216. doi:10.1182/asheducation-2016.1.208
6. Patriquin CJ, Kiss T, Caplan S, et al. How we treat paroxysmal nocturnal hemoglobinuria: A consensus statement of the Canadian PNH Network and review of the national registry. *Eur J Haematol*. 2019;102(1):36-52. doi:10.1111/ejh.13176
7. Devos T, Meers S, Boeckx N, et al. Diagnosis and management of PNH: Review and recommendations from a Belgian expert panel. *Eur J Haematol*. 2018;101(6):737-749. doi:10.1111/ejh.13166
8. Bodó I, Amine I, Boban A, et al. Complement Inhibition in Paroxysmal Nocturnal Hemoglobinuria (PNH): A Systematic Review and Expert Opinion from Central Europe on Special Patient Populations. *Adv Ther*. 2023;40(6):2752-2772. doi:10.1007/s12325-023-02510-4
9. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up and treatment guidelines. *Am J Blood Res*. 2016;6(2):19-27. Published 2016 Aug 5.
10. Cançado RD, Araújo ADS, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. *Hematol Transfus Cell Ther.* 2021;43(3):341-348. doi:10.1016/j.htct.2020.06.006

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