Voydeya™ (danicopan)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Voydeya is indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

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

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
    a. Flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-Aps) deficiency.
    b. Hemoglobin and absolute reticulocyte count demonstrating clinically significant extravascular hemolysis.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

The requested medication must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Authorization of 6 months may be granted for treatment of extravascular hemolysis (EVH) in patients with PNH when all the following criteria are met:

1. The patient is ≥ 18 years of age
2. The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) (e.g., at least 5% PNH cells, at least 51% of GPI-AP deficient poly-morphonuclear cells)
3. Flow cytometry is used to demonstrate GPI-APs deficiency
4. Patient has clinically significant extravascular hemolysis while on Ultomiris (ravulizumab) or eculizumab as evidenced by both of the following:
    A. Hemoglobin less than or equal to 9.5 g/dL
    B. Absolute reticulocyte count greater than or equal to 120 x 10^9/L
5. The patient has been receiving treatment with Ultomiris (ravulizumab) or eculizumab for at least 6 months
6. The requested medication will be used concomitantly with Ultomiris (ravulizumab) or eculizumab
7. The requested medication will not be used concomitantly with Empaveli (pegcetacoplan) or Fabhalta (Iptacopan)

Continuation of Therapy

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Authorization of 12 months may be granted for continued treatment in patients requesting reauthorization when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. The patient demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels)
3. The requested medication will be used concomitantly with Ultomiris (ravulizumab) or eculizumab
4. The requested medication will not be used concomitantly with Empaveli (pegcetacoplan) or Fabhalta (Iptacopan)

Other

Voydeya (danicopan) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Voydeya (danicopan) Four blister cards with 21 x 50 mg tablets and 21 x 100 mg tablets per blister card	4 blister cards per 28 days	Initial dose: 150 mg three times a day administered orally. Dose can be increased to 200 mg three times a day administered orally if the patient's hemoglobin level has not increased by >2 g/dL after 4 weeks of therapy, if the patient required a transfusion during the previous 4 weeks, or to achieve an
Voydeya (danicopan)	4 blister cards per 28 days	

Four blister cards with 42 x 100 mg tablets per blister card		appropriate Hgb response based on clinical judgement.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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Borowitz MJ, Craig F, DiGiuseppe JA, et al. Guidelines for the Diagnosis and Monitoring of Paroxysmal Nocturnal Hemoglobinuria and Related Disorders by Flow Cytometry. Cytometry B Clin Cytom. 2010: 78: 211-230.

Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.

Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.

Dezern AE, Borowitz MJ. ICCS/ESCCA consensus guidelines to detect GPI-deficient cells in paroxysmal nocturnal hemoglobinuria (PNH) and related disorders part 1 - clinical utility. Cytometry B Clin Cytom. 2018 Jan;94(1):16-22.

POLICY HISTORY

Policy #: 05.05.48

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