Reference number(s)
6466-A

SPECIALTY GUIDELINE MANAGEMENT

VOYDEYA (danicopan)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests:
   1. Flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency.
   2. Hemoglobin and absolute reticulocyte count demonstrating clinically significant extravascular hemolysis.
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. CRITERIA FOR INITIAL APPROVAL

Paroxysmal nocturnal hemoglobinuria
Authorization of 6 months may be granted for treatment of extravascular hemolysis (EVH) in members with paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:
A. The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
   1. At least 5% PNH cells
   2. At least 51% of GPI-AP deficient poly-morphonuclear cells
B. Flow cytometry is used to demonstrate GPI-APs deficiency.
C. Member has clinically significant extravascular hemolysis while on ravulizumab or eculizumab as evidenced by both of the following:
   1. Hemoglobin less than or equal to 9.5 g/dL
   2. Absolute reticulocyte count greater than or equal to 120 x 10^9/L
D. The requested medication will be used concomitantly with ravulizumab or eculizumab.

IV. CONTINUATION OF THERAPY

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

A. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
B. The member demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).
C. The requested medication will be used concomitantly with ravulizumab or eculizumab.

V. REFERENCES

1. Voydeya [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; April 2024
2. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. Hematology. 2011; 21-29.
3. 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.
4. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.
6. 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.