CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 6466-A |

# Specialty Guideline Management Voydeya

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Voydeya | danicopan |

## 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 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.

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

## Documentation

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

### For initial requests:

* Flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency.
* Hemoglobin and absolute reticulocyte count demonstrating clinically significant extravascular hemolysis.

### For continuation requests:

* Chart notes or medical record documentation supporting positive clinical response.

## Coverage Criteria

### 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:

* 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).
* Flow cytometry is used to demonstrate GPI-APs deficiency.
* Member has clinically significant extravascular hemolysis while on ravulizumab or eculizumab as evidenced by both of the following:
  + Hemoglobin less than or equal to 9.5 g/dL
  + Absolute reticulocyte count greater than or equal to 120 x 109/L
* The requested medication will be used concomitantly with ravulizumab or eculizumab.

## 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:

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

## 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.