

DRUG POLICY

PiaSky™ (crovalimab)

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 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

Piaskey is indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.

POLICY

Required Documentation

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

1. For initial requests:
 - A. Paroxysmal nocturnal hemoglobinuria: flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval

Paroxysmal nocturnal hemoglobinuria

Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:

1. The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
 - A. At least 5% PNH cells

- B. At least 51% of GPI-AP deficient poly-morphonuclear cells
2. Flow cytometry is used to demonstrate GPI-AP deficiency
3. The requested medication will not be used concomitantly with eculizumab or ravulizumab

Continuation of Therapy

Paroxysmal nocturnal hemoglobinuria

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and they demonstrate a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).

Other

PiaSky (crovalimab) 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.

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.

- J1307 – Injection, crovalimab-akkz, 10 mg (effective 1/1/25)
- J3490 – Unclassified drugs (when specified as [PiaSky] (crovalimab))
- J3590 – Unclassified biologics (when specified as [PiaSky] (crovalimab))
- J9999 – not otherwise classified, antineoplastic drugs (when specified as [PiaSky] (crovalimab))
- C9399 – Unclassified drugs or biologics (when specified as [PiaSky] (crovalimab))

REFERENCES

- PiaSky [package insert]. South San Francisco, CA: Genentech; June 2024.
- Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. *Hematology*. 2011; 21-29.
- Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. *Hematology Am Soc Hematol Educ Program*. 2016;2016(1):208-216.
- Röth A, He G, Brodsky A, et al. S181: The Phase III, Randomized Commodore 2 Trial: Results from a Multicenter study of Crovalimab vs. Eculizumab in Paroxysmal Nocturnal Hemoglobinuria (PNH) in Patients Naïve to Complement Inhibitors. *Hemasphere*. 2023 Aug 8;7(Suppl):e72750f1. doi: 10.1097/01.HS9.0000967636.72750.f1. PMID: PMC10428346.
- Scheinberg P, Clé DV, Kim JS, et al. Phase 3 randomized COMMODORE 1 trial: Crovalimab versus eculizumab in complement inhibitor-experienced patients with paroxysmal nocturnal hemoglobinuria. *Am J Hematol*. 2024; 99(9): 1757-1767. doi:[10.1002/ajh.27413](https://doi.org/10.1002/ajh.27413)

POLICY HISTORY

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Revised:

Current Effective Date: October 13, 2024