crovalimab-akkz (PiaSky)

Commercial Medical Benefit Drug Policy

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Complement C5 inhibitor
HCPCS:
J1307:Injection, crovalimab-akkz, 10 mg
How Supplied:
340 mg/2 mL (170 mg/mL) in a single-dose vial (NDC 50242-115-01)

Condition(s) listed in policy *(see coverage criteria for details)*

- Paroxysmal Nocturnal Hemoglobinuria (PNH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy with Piasky [first intravenous dose and first 4 subcutaneous doses] or is being re-initiated on Piasky after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Piasky based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Piasky based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Meets medical necessity if all the following are met:

Initial

1. Age and weight consistent with the FDA-approved indication (at least 13 years of age and weighs at least 40 kg)
2. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or oncologist
3. ***Effective 2/1/2026 and after:*** Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

Reauthorization

1. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or oncologist
2. ***Effective 2/1/2026 and after:*** Clinical response from baseline (e.g. increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, etc)
3. ***Effective 2/1/2026 and after:*** Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

Covered Doses:

≥ 40 kg to < 100 kg

- 1,000 mg given intravenously (IV) on Day 1
- 340 mg given subcutaneously (SC) on Day 2, 8, 15, 22
- 680 mg given SC on Day 29 then every 4 weeks thereafter

≥ 100 kg

- 1,500 mg given intravenously (IV) on Day 1
- 340 mg given subcutaneously (SC) on Day 2, 8, 15, 22
- 1,020 mg given SC on Day 29 then every 4 weeks thereafter

Coverage Period:
Yearly

ICD-10:
D59.5

Additional Information

- PiaSky is available only through a restricted program called the PiaSky REMS

References

1. PiaSky (crovalimab-akkz) Prescribing Information. Genentech, Inc., South San Francisco, CA. 6/2024.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Replace initial coverage for Paroxysmal Nocturnal Hemoglobinuria (PNH) - add specialist requirement and clarify that PiaSky will not be used in combination with other complement inhibitors (rationale: ensure appropriate use).
- Add reauthorization coverage for Paroxysmal Nocturnal Hemoglobinuria (PNH) - requires documentation regarding clinical response from baseline (rationale: ensure appropriate use).
- Updated Denial Code: A
- Added Denial Codes: B, C, D, E, F, G

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee