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Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	July 26, 2024
Subject:	Piasky	**Page:**	1 of 5

Last Review Date: June 12, 2025

Piasky

Description

Piasky (crovalimab-akkz)

Background
Piasky (crovalimab-akkz) is a monoclonal antibody that specifically binds with high affinity to the complement protein C5, inhibiting its cleavage into C5a and C5b, preventing the formation of the membrane attack complex (MAC). Piasky inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH) (1).

Regulatory Status
FDA-approved indications: Piasky is a complement C5 inhibitor 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 (1).

Piasky includes a boxed warning citing the increased risk of serious infections caused by Neisseria meningitidis. Vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) should be completed or updated at least 2 weeks prior to the first dose of Piasky, unless the risks of delaying therapy with Piasky outweigh the risk of developing a serious infection (1).

Piasky is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Piasky REMS, prescribers must enroll in the program (1).

In addition, Piasky has warnings regarding Type III hypersensitivity reactions, other infections, and infusion- and injection-related reactions (1).

Piasky is contraindicated in patients with unresolved serious Neisseria meningitidis infection (1).

The safety and effectiveness of Piasky in pediatric patients less than 13 years of age and in those with body weight < 40 kg have not been established (1).

Related policies
Empaveli, Fabhalta, Soliris, Ultomiris

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Piasky may be considered **medically necessary** if the conditions indicated below are met.

Piasky may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 13 years of age or older

Diagnosis

Patient must have the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Weight ≥ 40 kg
b. Documented baseline value for serum lactate dehydrogenase (LDH)
c. Vaccination against Neisseria meningitidis at least 2 weeks prior to initiation [unless Piasky (crovalimab-akkz) treatment cannot be delayed]
d. Prescriber is enrolled in Piasky REMS program
e. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 13 years of age or older

Diagnosis

Patient must have the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Weight ≥ 40 kg
b. Decrease in serum LDH from pretreatment baseline
c. Absence of unacceptable toxicity from the drug
d. Prescriber is enrolled in Piasky REMS program
e. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 9 vials (for loading doses) +
9 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 9 vials per 84 days

Duration 12 months

Rationale

Summary

Piasky is a complement C5 inhibitor indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Piasky includes a boxed warning citing the risk of serious and life-threatening infections caused by Neisseria meningitidis. Piasky is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). The safety and effectiveness of Piasky in pediatric patients less than 13 years of age and in those with body weight < 40 kg have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Piasky while maintaining optimal therapeutic outcomes.

References

1. Piasky [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.

Policy History

Date	Action
July 2024	Addition to PA
December 2024	Annual review
June 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.

Appendix 1 - List of PA Medications for PNH

Generic Name	Brand Name
crovalimab-akkz	Piasky
eculizumab	Soliris
iptacopan	Fabhalta
pegcetacoplan	Empaveli
ravulizumab-cwvz	Ultomiris