PiaSky™ (crovalimab-akkz)

When requesting PiaSky™ (crovalimab-akkz), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

PiaSky 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.

Coverage Guidelines

Paroxysmal Nocturnal Hemoglobinuria (PNH)

The individual must meet all of the following criteria for initial authorization:

- Is 13 years of age or older;
- Weighs 40 kg or greater;
- The diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages;
- PiaSky is prescribed by or in consultation with a hematologist.

The individual must meet all of the following criteria for re-authorization *(Note: A patient who has not started maintenance therapy with PiaSky subcutaneous, is reviewed under initial authorization criteria.);*

- Is 13 years of age or older;
- Weighs 40 kg or greater;
- Is continuing to derive benefits from PiaSky (e.g., increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reduction in hemolysis, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score);
- PiaSky is prescribed by or in consultation with a hematologist.

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

Dosing Recommendations

The recommended dosage regimen consists of one loading dose administered by intravenous (IV) infusion (on Day 1), followed by four additional weekly loading doses administered by subcutaneous (SUBQ) injection (on Days 2, 8, 15, and 22). The

maintenance dose starts on Day 29 and is then administered every 4 weeks by subcutaneous injection. The doses are based on the patient's actual body weight.

Body Weight	**≥ 40 kg to <100 kg**	**≥ 100 kg**
Loading Dose		
Day 1	1,000 mg (IV)	1,500 mg (IV)
Day 2, 8, 15, 22	340 mg (SUBQ)	340 mg (SUBQ)
Maintenance Dose		
Day 29 and every 4 weeks thereafter	680 mg (SUBQ)	1,020 mg (SUBQ)

References

1. PiaSky® [prescribing information]. South San Francisco, CA: Genentech; June 2024.
2. Cançado RD, da Silva Araújo A, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. *Hematol Transfus Cell Ther*. 2021;43:341-348.
3. Shah N, Bhatt H. Paroxysmal Nocturnal Hemoglobinuria. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562292/. Accessed on August 8, 2025.
4. Roth A, Maciejewski J, Nishinura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. *Eur J Haematol*. 2018;101(1):3-11.
5. Cella D, Johansson P, Ueda Y, et al. Clinically important change for the FACIT-Fatigue scale in paroxysmal nocturnal hemoglobinuria: a derivation from international PNH registry patient data. *Journal of Patient-Reported Outcomes*. 2023;7(1). doi:https://doi.org/10.1186/s41687-023-00609-4