Medical Policy:

PiaSky (crovalimab-akkz) intravenous infusion or subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.423	February 28, 2025	September 9, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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.

Length of Authorization

Initial: Coverage will be provided for 6 months

Continuation: Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

Approve ONE of the following weight-based regimens (A or B):

A. Patient weighs ≥ 40 kg to < 100 kg: Approve if the patient meets ALL of the following (i, ii, and iii):

i. Loading dose on Day 1: 1,000 mg via intravenous infusion; **AND**

ii. Loading doses on Days 2, 8, 15, and 22: 340 mg via subcutaneous injection; **AND**

iii. Maintenance doses, starting on Day 29 and every 4 weeks thereafter: 680 mg via subcutaneous injection;

OR

B. Patient weighs ≥ 100 kg: Approve if the patient meets ALL of the following (i, ii, and iii):

i. Loading dose on Day 1: 1,500 mg via intravenous infusion; **AND**
ii. Loading doses on Days 2, 8, 15, and 22: 340 mg via subcutaneous injection; **AND**
iii. Maintenance doses, starting on Day 29 and every 4 weeks thereafter: 1,020 mg via subcutaneous injection.

Guideline

1. **Paroxysmal Nocturnal Hemoglobinuria.** Approve for the duration noted if the patient meets ONE of the following (A or B):

A. Initial therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
i. Patient is ≥ 13 years of age; **AND**
ii. Patient weighs ≥ 40 kg; **AND**
iii. 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; **AND**
iv. The medication is prescribed by or in consultation with a hematologist.

B. Patient is Currently Receiving PiaSky subcutaneous. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
Note: A patient who has not started maintenance therapy with PiaSky subcutaneous should be considered under criterion A (Initial Therapy).
i. Patient is ≥ 13 years of age; **AND**
ii. Patient weighs ≥ 40 kg; **AND**
iii. According to the prescriber, patient is continuing to derive benefit from PiaSky; **AND**
Note: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.
iv. The medication is prescribed by or in consultation with a hematologist

Applicable Procedure Codes

Code	Description
J1307	Injection, crovalimab-akkz, 10 mg

Applicable NDCs

Code	Description
50242-0115-01	Piasky 340mg/2mL

ICD-10 Diagnoses

Code	Description
D59.5	Paroxysmal Nocturnal Hemoglobinuria [Marchiafava-Micheli]

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/28/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	9/9/2024	New Policy

References

1. PiaSky™ intravenous infusion or subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech and Roche; June 2024.