CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	PiaSky (crovalimab-akkz)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

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.
PNH is a hematopoietic stem cell disorder in which activation of the complement system destroys red blood cells because of an acquired mutation in the *PIGA* gene. Common manifestations can include hemolytic anemia and fatigue. Thrombosis and bone marrow suppression may also occur. Standard of care has been the existing C5 inhibitors Soliris and Ultomiris.

PiaSky (crovalimab-akkz) will be considered for coverage when the following criteria are met:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

For **initial** authorization:

1. Member is at least 13 years of age and weighs at least 40 kg; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a diagnosis of PNH confirmed by high sensitivity flow cytometry; AND
4. Member has a lactate dehydrogenase (LDH) level >1.5x upper limit of normal (ULN); AND
5. Member has at least one PNH-related sign/symptom e.g., fatigue, hemoglobin <10 g/dL, thrombosis, pRBC transfusion, shortness of breath; AND
6. Member has tried and failed Ultomiris; AND
7. Member has been or will be vaccinated for meningococcal infection (serogroups A, C, W, Y and B).
8. **Dosage allowed/Quantity limit:** 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. Dose based on body weight.
   QL: 3 vials/28 days for maintenance.

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 Q4W[a] thereafter	680 mg (SUBQ)	1,020 mg (SUBQ)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Clinical evidence of positive response to therapy such as increased hemoglobin level, decreased need for transfusions, normalized LDH levels, improved fatigue.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers PiaSky (crovalimab-akkz) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/27/2024	New policy for PiaSky created.

References:

1. PiaSky [prescribing information]. Genentech, Inc.; 2024.
2. Röth A, He G, Tong H, et al. Phase 3 randomized COMMODORE 2 trial: Crovalimab versus eculizumab in patients with paroxysmal nocturnal hemoglobinuria naive to complement inhibition. *Am J Hematol*. Published online June 17, 2024. doi:10.1002/ajh.27412
3. Oliver M, Patriquin CJ. Paroxysmal Nocturnal Hemoglobinuria: Current Management, Unmet Needs, and Recommendations. *J Blood Med*. 2023;14:613-628. Published 2023 Dec 6. doi:10.2147/JBM.S431493
4. Patriquin CJ, Kiss T, Caplan S, et al. How we treat paroxysmal nocturnal hemoglobinuria: A consensus statement of the Canadian PNH Network and review of the national registry. *Eur J Haematol*. 2019;102(1):36-52. doi:10.1111/ejh.13176
5. Devos T, Meers S, Boeckx N, et al. Diagnosis and management of PNH: Review and recommendations from a Belgian expert panel. *Eur J Haematol*. 2018;101(6):737-749. doi:10.1111/ejh.13166
6. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. *Hematology Am Soc Hematol Educ Program*. 2016;2016(1):208-216. doi:10.1182/asheducation-2016.1.208

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