Mass General Brigham
Health Plan

PiaSky (crovalimab-akkz)
Effective 08/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
PiaSky (crovalimab-akkz) is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years of age and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kilograms.

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:
1. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry
2. Member is 13 years of age or older
3. Member weighs at least 40 kilograms
4. Member has had a trial and failure, intolerance, or contraindication to ONE of the following:
    a. Soliris (eculizumab)
    b. Ultomiris (ravulizumab)

Continuation of Therapy
Requests for reauthorization will be approved when the following criteria are met:
1. Documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH], levels, hemoglobin stabilization, decreased number of red blood cell transfusions)

Limitations
1. Initial and reauthorization requests will be approved for 12 months.

References

1. Hill A, DeZern AE, Kinoshita T, Brodsky RA. Paroxysmal nocturnal haemoglobinuria. *Nat Rev Dis Primers*. 2017;3:17028. Published 2017 May 18.
2. Kulasekararaj AG, Kuter DJ, Griffin M, Weitz IC, Röth A. Biomarkers and laboratory assessments for monitoring the treatment of patients with paroxysmal nocturnal hemoglobinuria: Differences between terminal and proximal complement inhibition. *Blood Rev*. 2023;59:101041.
3. Liu H, Xia L, Weng J, et al. Efficacy and safety of the C5 inhibitor crovalimab in complement inhibitor-naive patients with PNH (COMMODORE 3): A multicenter, Phase 3, single-arm study. *Am J Hematol*. 2023;98(9):1407-1414. doi:10.1002/ajh.26998
4. Oliver M, Patriquin CJ. Paroxysmal nocturnal hemoglobinuria: Current management, unmet needs, and recommendations. *J Blood Med*. 2023;14:613-628. Published 2023. Doi:10.2147/JBM.S431493.
5. PiaSky (crovalimab-akkz) [prescribing information] South San Francisco, CA. Genentech, Inc.; June 2024.
6. 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
7. Scheinberg P, Clé DV, Kim JS, et al. Phase 3 randomized COMMODORE 1 trial: Crovalimab versus eculizumab in complement inhibitor-experienced patients with paroxysmal nocturnal hemoglobinuria. *Am J Hematol*. Published online June 25, 2024. doi:10.1002/ajh.27413

Review History

12/11/2024 – Created and reviewed at December P&T. Effective 3/1/2025.
07/09/2025 – Reviewed at June P&T. No clinical changes. Effective 08/01/2025.