Piasky™ (crovalimab-akkz)
(Intravenous/Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Loading Dose: 170 billable units IV on day 1; 34 billable units SQ on days 2, 8, 15, & 22; and 102 billable units SQ on day 29
- Maintenance Dose: 102 billable units SQ every 4 weeks

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
  - The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (lab tests required); **OR**
  - The patient has another FDA labeled indication for the requested agent and route of administration; **AND**
- Tried and had an inadequate response, intolerance, or contraindication to Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), or Ultomiris (ravulizumab-cwvz; **AND**
- If the patient has an FDA labeled indication, then ONE of the following:
  - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
  - There is support for using the requested agent for the patient's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), or Empaveli (pegcetacoplan); **AND**

- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient was previously approved for the requested agent through the plan's Medical Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review); **AND**
- The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase [LDH], stabilization/improvement of symptoms) (medical records required); **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), or Empaveli (pegcetacoplan); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

V. Dosage/Administration

Indication	Dose
Paroxysmal Nocturnal Hemoglobinuria (PNH)	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 (SQ) 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. Administer doses based on the patient's actual body weight. – **Weight ≥ 40 kg to <100 kg** • Loading Dose: 1,000 mg IV on day 1 followed by 340 mg SQ on days 2, 8, 15, 22. • Maintenance Dose: 680 mg SQ on day 29 and every 4 weeks thereafter – **Weight ≥ 100 kg** • Loading Dose: 1,500 mg IV on day 1 followed by 340 mg SQ on days 2, 8, 15, 22. • Maintenance Dose: 1,020 mg SQ on day 29 and every 4 weeks thereafter Switch Therapy from C5-inhibitors: – Healthcare providers should consider the benefits of the timing of switching C5 inhibitors vs. the risks of Type III hypersensitivity reactions. For patients switching from another C5 inhibitor (e.g., eculizumab or ravulizumab), the first intravenous loading dose of Piasky should be administered no sooner than the time of the next scheduled complement inhibitor administration. The administration of the additional subcutaneous loading doses and maintenance doses of Piasky should follow as per the schedule shown above.

– *Piasky is administered by healthcare providers ONLY.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1307 – Injection, crovalimab-akkz, 10 mg; 1 billable unit = 10 mg

NDC:

- Piasky 340 mg/2 mL solution in single-dose vials for infusion: 50242-0115-xx

VII. References

1. Piasky prescribing information. Genentech, Inc. June 2024.
2. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up and treatment guidelines. PubMed Central (PMC). Published 2016. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4981648/.
3. Cançado RD, Da Silva Araújo A, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. Hematology, Transfusion and Cell Therapy. 2021;43(3):341-348. doi:10.1016/j.htct.2020.06.006.
4. Shah N, Bhatt H. Paroxysmal nocturnal hemoglobinuria. StatPearls - NCBI Bookshelf. Published July 31, 2023. https://www.ncbi.nlm.nih.gov/books/NBK562292/.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC