AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Piasky	Page:	1 of 2
Effective Date:	8/4/2025	Last Review Date:	5/2025

Applies to:	☒Illinois	☐New Jersey	☐Maryland	☐KY PRMD
	☐Florida Kids	☐Pennsylvania Kids	☐Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Piasky under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Piaksy is in 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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Piasky

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests: Flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency.
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval:

Paroxysmal nocturnal hemoglobinuria

Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when ALL the following criteria are met:

A. Member is 13 years of age or older.
B. Member has a body weight of at least 40 kg.
C. The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) (e.g., at least 5% PNH cells, at least 51% of GPI-AP deficient poly-morphonuclear cells).
D. Flow cytometry is used to demonstrate GPI-APs deficiency.
E. Member has and exhibits clinical manifestations of disease (e.g., LDH > 1.5 ULN, thrombosis, renal dysfunction, pulmonary hypertension, dysphagia).
F. The requested medication will not be used in combination with another complement inhibitor (e.g., Empaveli, Fabhalta, Soliris, Ultomiris) for the treatment of PNH.

Criteria for Continuation of Therapy

Paroxysmal nocturnal hemoglobinuria

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when ALL the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
2. The member demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).
3. The requested medication will not be used in combination with another complement inhibitor (e.g., Empaveli, Fabhalta Soliris, Ultomiris) for the treatment of PNH.

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months
Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit	FDA-Recommended Dosing
Piasky 340mg/2 mL (170mg/mL) single-dose vial	2 single-dose vials per 28 days	Loading Dose: • < 100 kg: 1,000 mg (IV) on Day 1 followed by 340 mg subcutaneous injection on Day 2, 8, 15, 22 • ≥ 100 kg: 1,500 mg (IV) on Day 1 followed by 340 mg subcutaneous injection on Day 2, 8, 15, 22 Maintenance Dose: • < 100 kg: 680 mg subcutaneous injection on Day 29 and every 4 weeks thereafter • ≥ 100 kg: 1,020 mg subcutaneous injection on Day 29 and every 4 weeks thereafter

References:

1. Piasky [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. Hematology. 2011; 21-29.
3. Borowitz MJ, Craig F, DiGiuseppe JA, et al. Guidelines for the Diagnosis and Monitoring of Paroxysmal Nocturnal Hemoglobinuria and Related Disorders by Flow Cytometry. Cytometry B Clin Cytom. 2010: 78: 211-230.
4. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.
6. Dezern AE, Borowitz MJ. ICCS/ESCCA consensus guidelines to detect GPI-deficient cells in paroxysmal nocturnal hemoglobinuria (PNH) and related disorders part 1 - clinical utility. Cytometry B Clin Cytom. 2018 Jan;94(1):16-22.