

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	PiaSky is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) with a body weight of at least 40 kg.						
<b>Exclusion Criteria</b>	Patient is not receiving PiaSky in combination with another complement inhibitor for the treatment of PNH (Empaveli, Soliris, Ultomiris, Fabhalta, Voydeya).						
<b>Required Medical Information</b>	For initial coverage, medical records supporting the request must be provided and include the following: <ol style="list-style-type: none"> <li>1. Diagnosis confirmed by flow cytometry</li> <li>2. Hemolysis-associated symptoms (thrombosis, organ dysfunction, pain, dyspnea, hemoglobin &lt;10 g/dL etc.)</li> <li>3. Patient's body weight is at least 40 kg.</li> </ol>						
<b>Age Restriction</b>	Must be at least 13 years of age.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	<p><b>Initial:</b> One year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.</p> <p><b>For reauthorization:</b> Must have documentation confirming a positive clinical response to PiaSky including a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.</p>						
<b>Other Criteria/Information</b>	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 1171 1511 1314"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J1307</td> <td>PiaSky (crovalimab-akkz)</td> <td><b>Billing unit: 10 mg</b> 340mg/2mL SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J1307	PiaSky (crovalimab-akkz)	<b>Billing unit: 10 mg</b> 340mg/2mL SDV
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025