

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Zilbrysq is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor antibody positive (AChR-Ab+).						
<b>Exclusion Criteria</b>	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Rystiggo. (Zilbrysq has not been studied and there is no data to support use in combination with other medications used to treat MG).						
<b>Required Medical Information</b>	<p><b>For initial requests, must have:</b></p> <ol style="list-style-type: none"> <li>1. Medical records supporting the request must be provided.</li> <li>2. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive.</li> <li>3. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of six or more.</li> </ol> <p>For reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.</p>						
<b>Age Restriction</b>	Must be at least 18 years old.						
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist.						
<b>Coverage Duration</b>	Twelve weeks (initial); one year (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J3490*, C9399*</td> <td>Zilbrysq (ziluoplan)</td> <td> <p>Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.</p> <p>16.6 mg/0.416 mL, 23 mg/0.574 mL, and 32.4 mg/0.81 mL prefilled syringes</p> </td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J3490*, C9399*	Zilbrysq (ziluoplan)	<p>Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.</p> <p>16.6 mg/0.416 mL, 23 mg/0.574 mL, and 32.4 mg/0.81 mL prefilled syringes</p>
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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	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025