

| PA Criteria | Criteria Details | | | | | | |
|---|--|---|-------------|----------------------------|-------|---------------------------------|---|
| Covered Uses (FDA approved indication) | Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR-Ab+) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. | | | | | | |
| Exclusion Criteria | Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Zilbrysq. (Rystiggo has not been studied and there is no data to support use in combination with other medications used to treat MG). | | | | | | |
| Required Medical Information | <p>For initial coverage, must have:</p> <ol style="list-style-type: none"> Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least three. Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive or anti-muscle-specific tyrosine kinase [MuSK] anti-body positive. <p>For initial and reauthorization: Medical records supporting the request must be provided.</p> | | | | | | |
| Age Restriction | None. | | | | | | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a neurologist. | | | | | | |
| Coverage Duration | <p>One year initial; two years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.</p> <p>For Reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.</p> | | | | | | |
| Other Criteria/Information | <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>J9333</td> <td>Rystiggo (rozanolixizumab-noli)</td> <td>Billing unit: 1 mg 280mg/2ml (140mg/ml) SDV</td> </tr> </tbody> </table> | HCPCS | Description | Billing Units/How Supplied | J9333 | Rystiggo (rozanolixizumab-noli) | Billing unit: 1 mg 280mg/2ml (140mg/ml) 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 | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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