RX.PA.114.MPC Rystiggo (rozanolixizumab-noli)

The purpose of this policy is to define the prior authorization process for Rystiggo® (rozanolixizumab-noli)

Rystiggo® (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

PROCEDURE

A. Initial Authorization Criteria

Must meet all of the criteria listed under the respective product:

1. **Generalized Myasthenia Gravis (gMG)**
   - Must have a documented diagnosis of Myasthenia Gravis
   - Must have documentation of anti-acetylcholine receptor (AChR) antibody positive or muscle-specific tyrosine kinase (MuSKAb) antibody positive
   - Member must be 18 years of age or older
   - Documentation of Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
   - Documentation of Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 at baseline for non-ocular symptoms
   - Must be prescribed by or in consultation with a neurologist
   - Must have a trial and failure (at least 3 months), intolerance to, or contraindication to pyridostigmine
   - Documented failed treatment to azathioprine (at last 3 months) and at least one other immunosuppressive therapy or contraindication/intolerance to ALL listed below:
     - Cyclosporine
     - Mycophenolate mofetil
     - Tacrolimus
     - Methotrexate
     - Cyclophosphamide
     - Note: If members are contraindicated/intolerant to azathioprine, must have documentation of a trial and failure (at least 3 months) of 2 immunosuppressive therapies listed.
   - Must monitor for signs and symptoms of infections during treatment

- Must have a trial and failure (at least 3 months), intolerance to, or contraindication to a Soliris product or biosimilar
- Must not be prescribed concurrently with Ultomiris, Eculizumab (Soliris), Vyvgart/Vyvgart Hytrulo, Zilbrysq, or rituximab
- Treatment cycles are no more frequent than 63 days from the start of the previous treatment cycle

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Treatments will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

- All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Must be prescribed by or in consultation with a neurologist
- Treatment cycles are no more frequent than 63 days from the start of the previous treatment cycle

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has a documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

Applicable Codes:

CODE	DESCRIPTION
J9333	Injection, rozanolixizumab-noli, 1 mg

REFERENCES

1. Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; Mar 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
New Policy	*10/2025*