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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	August 18, 2023
Subject:	Rystiggo	**Page:**	1 of 4

Last Review Date: June 13, 2024

Rystiggo

Description

Rystiggo (rozanolixizumab-noli)

Background
Rystiggo (rozanolixizumab-noli) is a humanized IgG4 monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG. Myasthenia gravis is an autoimmune disease in which immunoglobulin G (IgG) autoantibodies are formed that target neuromuscular junction proteins. In patients treated with Rystiggo, there was a reduction in total IgG levels and decreases in AChR autoantibody and MuSK autoantibody levels (1-2).

Regulatory Status
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) or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive (1).

The International Consensus Guidance for Management of Myasthenia Gravis recommends the use of chronic IVIG and immunosuppressants (3).

Because Rystiggo causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with Rystiggo. Evaluate the need to administer age-appropriate immunizations according to immunization guidelines before initiation of a new treatment cycle with Rystiggo (1).

Rystiggo includes warnings regarding infections, aseptic meningitis, and hypersensitivity reactions. Patient should be advised to monitor for hypersensitivity reactions and new-onset headache type. Prescriber should be vigilant about evaluating new-onset headache type in this immunosuppressed population with a lumbar puncture for cerebral spinal fluid (CSF) analysis for infections or aseptic meningitis and hold the dose accordingly (1).

The safety and effectiveness of Rystiggo in pediatric patients less than 18 years of age have not been established (1).

Related policies
Soliris, Ultomiris

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rystiggo may be considered **medically necessary** if the conditions indicated below are met.

Rystiggo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

a. Presence of autoantibodies against AChR or MuSK
b. Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IVa
c. Documented baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 3 with at least 3 points from non-ocular symptoms (*http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf*)
d. Serum IgG level ≥ 5.5 g/L

e. Patient has had an inadequate treatment response, intolerance, or contraindication to an acetylcholinesterase inhibitor and at least **ONE** immunosuppressive therapy either in combination or as monotherapy, such as:
    i. azathioprine
    ii. cyclosporine
    iii. mycophenolate mofetil
    iv. tacrolimus
    v. methotrexate
    vi. cyclophosphamide
f. **NOT** given concurrently with live or live-attenuated vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

a. Decrease of MG-ADL total score from baseline of ≥ 2 points (*http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf*)
b. **NO** unacceptable toxicity from the drug
c. **NOT** given concurrently with live or live-attenuated vaccines

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary
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) or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive. Rystiggo includes warnings regarding infections, aseptic meningitis, and hypersensitivity reactions. The safety and effectiveness of Rystiggo pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rystiggo while maintaining optimal therapeutic outcomes.

References

1. Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; June 2023.
2. Lazaridis K and Tzartos SJ (2020) Autoantibody Specificities in Myasthenia Gravis; Implications for Improved Diagnostics and Therapeutics. Front. Immunol. 11:212.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016; 87(4):419. Epub 2016 Jun 29.

Policy History

Date	Action
August 2023	Addition to PA
December 2023	Annual review. Per SME, removed requirement for fewer relapses for continuation and changed approval duration to 6 months. Also added headaches warning to regulatory status
March 2024	Per BCBSA policy, changed renewal duration to 12 months
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.