Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 305.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Rystiggo (rozanolixizumab-noli)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Rystiggo (rozanolixizumab-noli)

II. Purpose/Objective:
To provide a policy of coverage regarding Rystiggo (rozanolixizumab-noli)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial
Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare
Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP
Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid
Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Rozanolixizumab-noli, a humanized IgG4 monoclonal antibody, binds to the neonatal Fc receptor (FcRn), reducing circulating IgG.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Rystiggo (rozanolixizumab-noli) will be considered medically necessary for commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Rystiggo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 (with at least 3 points being non-ocular) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG).

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Rystiggo (rozanolixizumab-noli) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Rystiggo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive AND/OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 (with at least 3 points being non-ocular).

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Rystiggo [Prescribing Information]. Smyrna, GA. UCB, Inc. June 2023.
2. IPD Analytics. Rystiggo for the Treatment of Generalized Myasthenia Gravis. August 8, 2023. Accessed October 5, 2023. http://www.ipdanalytics.com
3. Bril PV, Druzdz A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383-394.
4. Bird SJ. Diagnosis of myasthenia gravis. UpToDate. Updated Sep 2023. Accessed October 24, 2023. https://www.uptodate.com/contents/diagnosis-of-myasthenia-gravis?search=myasthenia%20gravis&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H19
5. Bird SJ. Overview of the treatment of myasthenia gravis. UpToDate. Updated Oct 2023. Accessed November 9, 2023. https://www.uptodate.com/contents/overview-of-the-treatment-of-myasthenia-gravis?search=ivig%20myasthenia%20gravis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
6. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis 2020 Update. Neurology. 2021;96:114-122.
7. Myasthenia Gravis Foundation of America. MGFA Clinical Classification. Accessed October 24, 2023. https://myasthenia.org/Portals/0/MGFA%20Classification.pdf
8. National Institute of Neurological Disorders and Stroke. Myasthenia Gravis. Accessed October 24, 2023. https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/21/23

Revised: 11/13/24 (LOB tables, taglines)

Reviewed:

MA UM Committee approval: 5/22/24

DHS PARP approval: 1/28/25