ALASKA MEDICAID
Prior Authorization Criteria

Rystiggo®
(rozanolixizumab-noli)

FDA INDICATIONS AND USAGE[1]

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.

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of generalize myasthenia gravis (gMG) class II to class IV disease as per Myasthenia Gravis Foundation of America (MGFA) Clinical Classification **AND**;
4. Patient has tested positive for AChR antibodies or MuSK antibodies **AND**;
5. Patient has a baseline MG-Activities of Daily Living (MG-ADL) composite score ≥ 3 **AND**;
6. Patient does not have a deficiency of immunoglobulin G (IgG) requiring supplementation with IgG **AND**;
7. Rystiggo® will not be used in combination with any other immunomodulatory biologic agent(s) **AND;**
8. One of the following applies:
   - AChR+ gMG: Patient has tried and failed two or more immunosuppressive therapies (eg. corticosteroids, azathioprine, mycophenolate, etc.) for a minimum of one year; **OR**
   - MuSK+ gMG: Patient has tried and failed one or more immunosuppressive therapies (eg. corticosteroids, azathioprine, mycophenolate, etc.) and rituximab for a minimum of one year **OR**
   - Patient has required treatment with plasma exchange (PE), intravenous immunoglobulin (IVIG) or plasmapheresis in addition to their maintenance therapy.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is or will be taking Rystiggo® in combination with any other immunomodulatory biologic agent(s) **OR**;
3. Patient has an active, clinically significant infection.

CAUTIONS[1]

- Cases of aseptic meningitis have been reported; monitor patients for signs/symptoms during treatment.
- Due to transient reduction in IgG levels, live or live-attenuated vaccines are not recommended during treatment.
- The most common adverse reactions include headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

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DURATION OF APPROVAL

- Initial Approval: 6 weeks
- Reauthorization Approval: up to 6 months if:
- Patient has demonstrated a minimum of a 1 point or more improvement in MG-ADL total score **AND;**
- Patient requires ongoing treatment due to new or worsening disease activity despite initial positive response **AND;**
- Patient has not experienced any treatment limiting adverse events due to Rystiggo® **AND;**
- Minimum 63 days must have elapsed since completion of previous treatment cycle.

QUANTITY LIMIT

- 24ml (12 2ml vials) per 28 days; 36ml (18 2ml vials) per 63 days
    - Maximum recommended dosage 840mg (3 2mg vials) once weekly for six weeks; subsequent cycles not to be initiated sooner than 63 days from completion of previous cycle.
- HCPCS: J9333

REFERENCES / FOOTNOTES:

1. Rystiggo® (rozanolixizumab-noli) [prescribing information]. Smyrna, GA: UCB; June 2024
2. van Dyck C, Swanson C, et al.; Lecanemab in Early Alzheimer's Disease. N Engl J Med 2022 DOI: 10.1056/NEJMoa2212948. Available at: https://nejm.org/doi/full10.1056/NEJMoe2212948
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology. 2021:96:114-122. DOI: 10.1212/WNL.0000000000011124.
4. Chronic Immunotherapy for Myasthenia gravis updated Feb 27, 2024. Available at: https://www.uptodate.com/contents/chronic-immunotherapy-for-myasthenia-gravis?sectionName=MuSK-positive%20MG&topicRef=5157&anchor=H3294628719&source=see_link#H3294628719 Accessed July 25, 2024.
5. Bril V, 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. DOI: 10.1016/S1474-4422(23)00077-7.