ALASKA MEDICAID
Prior Authorization Criteria

Zilbrysq™ (zilucoplan)

FDA INDICATIONS AND USAGE[1]

Zilbrysq™ is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

APPROVAL CRITERIA[1,2,3]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has a diagnosis of generalized myasthenia gravis (gMG), Myasthenia Gravis Foundation of America (MGFA) clinical classification II, III, or IV **AND**;
4. Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies **AND**;
5. Patient has baseline Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score of ≥ 6 **AND**;
6. Documentation of inadequate response to or has a labeled contraindication to TWO or more immunosuppressive drug agents used alone or in combination for at least 12 months (I.E. azathioprine, mycophenolate mofetil, cyclosporine, cyclophosphamide, methotrexate, tacrolimus, rituximab) **OR** documentation of inadequate response to or has a labeled contraindication to ONE or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange, plasmapheresis or intravenous immunoglobulin therapy **AND**;
7. Patient has completed or is current on meningococcal vaccination for serogroups A,C, W, and Y and serogroup B at least two weeks prior to administration of first dose.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Prescriber is not enrolled in the REMS program **OR;**
3. Patient has evidence of an active meningococcal infection.

CAUTIONS[1]

- Life threatening and fatal meningococcal infections have occurred inpatients treated with complement inhibitors, which may become rapidly life-threatening or fatal if not recognized and treated early.
- Pancreatitis and pancreatic cysts have been reported in patients treated with Zylbrysq™.
- Based on animal data, Zylbrysq™ may cause fetal harm.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months with prescriber documentation of patient positive clinical response and tolerability

QUANTITY LIMIT

- 32.4mg per day; 30 prefilled syringes per 30 days

REFERENCES / FOOTNOTES:

1. Zylbrysq(lecanemab-irmb) [prescribing information]. Smyrna, GA: UCB; October 2023
2. Howard JF Jr, Bresch S, Genge A, et al; RAISE Study Team. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023 May;22(5):395-406. DOI: 10.1016/S1474-4422(23)00080-7.
3. Narayanaswami P, Sanders D, Wolfe G, Benatar M, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology® 2021;96:114-122. doi:10.1212/WNL.0000000000011124.