

Clinical Oversight Review Board (CORB) Criteria for Prescribing Eculizumab-aagh (Epysqli)

Notes:

- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ** Transfusion dependent = hemoglobin 7 g/dL or less OR hemoglobin less than or equal to 9 g/dL and patient is experiencing symptomatic anemia requiring transfusion

Non-Formulary **eculizumab-aagh (Epysqli)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **Eculizumab-aagh (Epysqli)** will be covered under the medical benefit when the following criteria are met:

1. Diagnoses of Myasthenia Gravis

- Prescribed by neurologist with specialty in neuromuscular disorders
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
- Prior inadequate response to at least two of the following:
 - Corticosteroid (at least 50 mg prednisone equivalent daily) for at least 3 months or
 - Azathioprine (at least 2 mg/kg daily) for at least 9-12 months or
 - Rituximab for at least 12 months or
 - Other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 6-9 months
- Patient is dependent on intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX)

2. Diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescribed by hematologist with specialty in benign hematology
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of PNH on problem list
- Patient meets one of the following:
 - Transfusion dependent** **OR**
 - Documented history of major adverse vascular events from thromboembolism

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3. Diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS)

- Prescribed by nephrologist
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of aHUS on problem list
- Negative test result for shiga toxin
- Negative test result for ADAMTS13 deficiency

4. **Diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD/NMO)**

- Prescribed by neurologist with specialty in Multiple Sclerosis or Neuroimmunology
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Confirmed diagnosis of NMOSD
- Anti-aquaporin-4 (AQP4) antibody positive
- Patient has tried and failed rituximab, as demonstrated with either of the following:
 - Severe breakthrough relapse[^] while on rituximab for at least 6 months not attributed to rapid steroid discontinuation **OR**
 - Recurrent moderate breakthrough relapses after 6-month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

1. Diagnoses of Myasthenia Gravis

- Prescribed by neurologist with specialty in neuromuscular disorders
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
- Prior inadequate response to at least two of the following:
 - Corticosteroid (at least 50 mg prednisone equivalent daily) for at least 3 months or
 - Azathioprine (at least 2 mg/kg daily) for at least 9-12 months or
 - Rituximab for at least 12 months or

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Revised: 06/12/25
Effective: 08/21/25

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- Other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 6-9 months
- Patient is dependent on intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX)

2. Diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescribed by hematologist with specialty in benign hematology
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of PNH on problem list
- Patient meets one of the following:
 - Transfusion dependent** **OR**
 - Documented history of major adverse vascular events from thromboembolism

3. Diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS)

- Prescribed by nephrologist
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of aHUS on problem list
- Negative test result for shiga toxin
- Negative test result for ADAMTS13 deficiency

5. **Diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD/NMO)**

- Prescribed by neurologist with specialty in Multiple Sclerosis or Neuroimmunology
- Prescriber enrolled in Epysqli Risk Evaluation and Mitigation Strategy (REMS) program
- Confirmed diagnosis of NMOSD
- Anti-aquaporin-4 (AQP4) antibody positive
- Patient has tried and failed rituximab, as demonstrated with either of the following:
 - Severe breakthrough relapse[^] while on rituximab for at least 6 months not attributed to rapid steroid discontinuation **OR**
 - Recurrent moderate breakthrough relapses after 6-month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine

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