

Clinical Oversight Review Board (CORB) Criteria for Prescribing Eculizumab (Soliris)

Notes:

- ** 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 (Soliris)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **Eculizumab (Soliris)** will be covered on the prescription drug benefit when the following criteria are met:

1. Diagnoses of Myasthenia Gravis

- Prescribed by neurologist with specialty in neuromuscular disorders
- Prescriber enrolled in Soliris 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 Soliris 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 Soliris 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