Soliris® (eculizumab)

When requesting Soliris® (eculizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

Soliris is a complement inhibitor indicated for:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive.
- The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive.

Coverage Guidelines

Atypical Hemolytic Uremic Syndrome (aHUS)

The individual must meet **all** of the following criteria for authorization:

- The individual does not have Shiga toxin *Escherichia coli* related hemolytic uremic syndrome; AND
- Soliris is prescribed by or in consultation with a nephrologist.

Approval duration: 12 months

Paroxysmal Nocturnal Hemoglobinuria (PNH)

The individual must meet **all** of the following criteria for initial authorization:

- The diagnosis of PNH has been confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least 2 cell lineages;
- The individual is 18 years of age or older; AND
- Soliris is prescribed by or in consultation with a hematologist.

For re-authorization:

- The individual is continuing to receive benefits from Soliris therapy (e.g., stabilization of hemoglobin levels, decreased transfusion requirement/transfusion independence, reduction in hemolysis).

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

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Generalized Myasthenia Gravis (gMG)

The individual must meet **all** of the following criteria for initial authorization:

- Has a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive generalized myasthenia gravis;
- Is 18 years of age or older;
- Is currently receiving pyridostigmine unless failed, contraindicated or intolerant to pyridostigmine;
- Is currently receiving 2 different immunosuppressive therapies for over 1 year unless failed, contraindicated, or intolerant to 2 different immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, cyclophosphamide);
- Has evidence of unresolved symptoms of generalized myasthenia gravis resulting in the discontinuation of physical activity (e.g., difficulty swallowing, difficulty breathing, double vision, impairment of mobility); AND
- Soliris is prescribed by or in consultation with a neurologist.

For re-authorization:

- The individual is continuing to receive benefits from Soliris therapy (e.g., reductions in exacerbations of myasthenia gravis; improvement in speech, swallowing, mobility, and respiratory functions).

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

Neuromyelitis Optica Spectrum Disorder (NMOSD)

The individual must meet **all** of the following criteria for authorization:

- Diagnosis has been confirmed by blood serum test for anti-aquaporin-4 antibody positive NMOSD;
- Is 18 years of age or older;
- Has tried either Enspryng (satralizumab-mwge) or Uplinza (inebilizumab-cdon); OR
- Has previously tried or is currently taking two of the following therapies: azathioprine, corticosteroid, mycophenolate mofetil, or rituximab;
- The patient has a history of at least 1 relapse in the last 12 months or two relapses in the last 2 years; AND
- Soliris is prescribed by or in consultation with a neurologist.

For re-authorization:

- The individual is continuing to receive benefits from Soliris therapy (e.g., reduction in relapse rates, reduction in symptoms (pain, fatigue, motor function), and a slowing progression in symptoms.
- Diagnosis has been confirmed by blood serum test for anti-aquaporin-4 antibody positive NMOSD;
- Is 18 years of age or older;
- Soliris is prescribed by or in consultation with a neurologist

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Approval duration (initial and renewal): 12 months

Dosing Recommendations

Soliris is only administered as an intravenous infusion.

Paroxysmal nocturnal hemoglobinuria (PHN)
- 600 mg weekly for the first 4 weeks, followed by
- 900 mg for the fifth dose 1 week later, then
- 900 mg every 2 weeks thereafter.

Atypical hemolytic uremia syndrome (aHUS) *(for patients 18 years of age and older)*
- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

Atypical hemolytic uremia syndrome (aHUS) *(for patients less than 18 years of age)*

Body weight	Induction	Maintenance
40 kg and over	900 mg weekly x 4 doses	1200 mg at week 5; then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly x 2 doses	900 mg at week 3; then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly x 2 doses	600 mg at week 3; then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 3 weeks

Generalized myasthenia gravis (gMG)
- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

Neuromyelitis optica spectrum disorder (NMOSD)
- 900mg weekly for first 4 weeks, followed by
- 1200mg for the fifth dose 1 week later, then
- 1200mg every 2 weeks thereafter.

References

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