

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.

Coverage Guidelines

Atypical hemolytic uremic syndrome (aHUS)

For an initial authorization:

- An individual does not have Shiga toxin *Escherichia coli* related hemolytic uremic syndrome.
- Soliris is prescribed by or in consultation with a hematologist and/or a nephrologist

For re-authorization:

- An individual is responding to Soliris therapy

Paroxysmal Nocturnal Hemoglobinuria (PNH)

For an initial authorization:

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

For re-authorization:

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

Generalized Myasthenia Gravis (gMG)

For an initial authorization:

An individual must meet all of the following criteria for approval

- Has confirmed 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
- Has an evidence of unresolved symptoms of generalized Myasthenia Gravis that results in the discontinuation of physical activity (e.g., difficulty swallowing, difficulty breathing, double vision, impairment of mobility)
- Soliris is prescribed by or in consultation with a neurologist

For re-authorization:

- An 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 for PNH, gMG; 12 months for aHUS

Approval duration (renewal): 12 months

Dosing Recommendations

Soliris is only administered as an intravenous infusion

Paroxysmal nocturnal hemoglobinuria (PNH)

- 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

References

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4. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17768. Publication last updated: May 9, 2017. Available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myasthenia-Gravis-Fact-Sheet>. Accessed on April 27, 2018.
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6. Brodsky RA. Paroxysmal nocturnal hemoglobinuria. *Blood*. 2014;124(18):2804–2811.
7. Taylor CM, Machin S, Wigmore SJ, et al. Clinical Practice Guidelines for the management of atypical Haemolytic Uraemic Syndrome in the United Kingdom. *Br J Haematol*. 2010;148(1):37-47.
8. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. *Pediatr Nephrol*. 2016;31(1):15-3