

When requesting Soliris®(eculizumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines for the covered indications.

FDA-approved indication

- Paroxysmal nocturnal hemoglobinuria to reduce hemolysis.
- Atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy.
- Generalized myasthenia gravis who are anti-acetylcholine receptor antibody positive.

Coverage Guidelines

The individual must meet all of the following for criteria for approval:

- Complete resolution of any serious *Neisseria meningitidis* infection.
- Evidence of immunization with a meningococcal vaccine at least 2 weeks prior to starting Soliris®(eculizumab), unless risks of delaying therapy outweigh the risk of developing a meningococcal infection.

Paroxysmal Nocturnal Hemoglobinuria

- Confirmed by peripheral blood flow cytometry.

Atypical hemolytic uremic syndrome

- Does not have a diagnosis of Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome.

Myasthenia Gravis

- Anti-acetylcholine receptor antibody positive.
- MGFA (Myasthenia Gravis Foundation of America) stage II-IV.
- Failed at least 1 year of treatment with at least 2 immunosuppressive therapies OR failed 1 immunosuppressive therapy and plasmapheresis/plasma exchange or intravenous immunoglobulin.
- Reauthorization must show clinical benefit.

Approval duration: 12 months

Dosing Recommendation

Soliris intravenous administration in patients 18 years and older. Soliris should be administered at the recommended dosing regimen time points or within 2 days of those time points.

Paroxysmal Nocturnal Hemoglobinuria (PHN) - 600mg weekly x 4 weeks, followed by 900mg for the fifth dose one week later, then 900mg every 2 weeks thereafter.

Atypical Hemolytic Uremia Syndrome (aHUS) - 900mg weekly x 4 weeks, followed by 1200mg for the fifth dose one week later, then 1200mg every 2 weeks thereafter.

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

Soliris intravenous administration in patients less than 18 years of age (for Atypical Hemolytic Uremic Syndrome (aHUS) only). Soliris should be administered at the recommended dosing regimen time points or within 2 days of those time points.

40kg and over- 900mg weekly x 4 doses, followed by 1200mg for the fifth dose 1 week later, then, 1200mg every 2 weeks thereafter.

30-39kg- 600mg weekly x 4 doses, followed by 900mg for the fifth dose 1 week later, then, 900mg every 2 weeks thereafter.

20-29kg- 600mg weekly x 4 doses, followed by 600mg for the fifth dose 1 week later, then, 600mg every 2 weeks thereafter.

10-19kg- 600mg weekly x 4 doses, followed by 300mg for the fifth dose 1 week later, then, 300mg every 2 weeks thereafter.

5-9kg- 300mg weekly x 4 doses, followed by 300mg for the fifth dose 1 week later, then, 300mg every 2 weeks thereafter.

References

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5. 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;31:15-39
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