Mass General Brigham
Health Plan

Soliris (eculizumab)
Effective 11/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Soliris (eculizumab) is a complement inhibitor indicated for:

1. Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
2. Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy*
3. Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive
4. Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

**Limitation of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).*

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following diagnosis-specific criteria are met and documentation is provided:

Atypical hemolytic uremic syndrome

1. The member has a diagnosis of atypical hemolytic uremic syndrome (aHUS)

Paroxysmal nocturnal hemoglobinuria

1. The member has a diagnosis of paroxysmal nocturnal hemoglobinuria confirmed by flow cytometry

Generalized myasthenia gravis (gMG)

1. The member has a diagnosis of generalized myasthenia gravis (gMG) with both of the following:
    a. Myasthenic Gravis Foundation of America (MGFA) clinical classification II to IV
    b. MG activities of daily living (MG-ADL) total score ≥ 6
2. Anti-acetylcholine receptor (AchR) antibody positive
3. The member meets ONE of the following:
    a. Member has had an inadequate response to at least two immunosuppressive therapies listed below:
        i. azathioprine
        ii. cyclosporine
        iii. mycophenolate mofetil
        iv. tacrolimus
        v. methotrexate
        vi. cyclophosphamide
        vii. rituximab
    b. Member has had an inadequate response to chronic IVIG

Neuromyelitis Optica Spectrum Disorder (NMOSD)

1. Member has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
2. Anti-aquaporin-4 (AQP4) antibody positive confirmed by use of immunoassay

<u>Continuation of Therapy</u>

Authorization may be granted for continued treatment when the following diagnosis-specific criteria are met:

Atypical hemolytic uremic syndrome

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, platelet counts)

Paroxysmal nocturnal hemoglobinuria

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, hemoglobin stabilization, decreased number of red blood cell transfusions)

Generalized myasthenia gravis (gMG)

1. Prescriber submits documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis [QMG] total score)

Neuromyelitis optica spectrum disorder (NMOSD)

1. Prescriber submits documentation of a positive response to therapy (e.g., reduction in number of relapses)

Limitations

1. Initial and reauthorization approvals will be granted for 12 months

References

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3. Brodsky RA, Young NS, Antonioli E, et al. Multicenter phase 3 study of the complement inhibitor eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria. *Blood*. 2008;111(4):1840-1847.
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5. Howard JF, Utsugisawa K, Benatar M. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalized myasthenia gravis (REGAIN); a phase 3, randomized, double-blind, placebo-controlled, multicenter study. *Lancet Neurol*. 2017 Oct 20. http://dx.doi.org/10.1016/S1474-4422(17)30369-1Ingenix HCPCS Level II, Expert 2011.
6. Jaretzki A, Barohn RJ, Ernstoff RM et al. Myasthenia Gravis: Recommendations for Clinical Research Standards. *Ann Thorac Surg*. 2000;70: 327-34.
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9. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. *Hematology.* 2011; 21-29.
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11. Pittock SJ, Berthele A, Kim HJ, et al. Eculizumab in Aquaporin-4-Positive Neuromyelitis Optica Spectrum Disorder. *N Engl J Med*. 2019 May 3. doi: 10.1056/NEJMoA1900866.
12. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.
13. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122 .
14. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2024.
15. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology.* 2015; 85:177-189.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024
08/14/2024: Reviewed and updated at August P&T. Updated approval length for initial and reauthorization requests to 12 months. Updated initial criteria for aHUS to require diagnosis. Updated initial criteria for PNH to require diagnosis of PNH as confirmed by flow cytometry. Updated criteria for gMG to require the member has tried and failed either two immunosuppressive agents or IVIG. Updated criteria for NMOSD to require a diagnosis and AQP4 antibody positive confirmed by immunoassay. Reauthorization for all diagnoses require documentation of positive response to therapy. All initial and reauthorization requests to be approved for 12 months. Effective 11/01/2024.