Reference number
1632-A

STANDARD MEDICARE PART B MANAGEMENT

SOLIRIS (eculizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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) positive.

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Paroxysmal Nocturnal Hemoglobinuria (PNH)
Authorization of 12 months may be granted for the treatment of paroxysmal nocturnal hemoglobinuria (PNH).

B. Atypical Hemolytic Uremic Syndrome (aHUS)
Authorization of 12 months may be granted for the treatment of atypical hemolytic uremic syndrome (aHUS) that is not caused by Shiga toxin.

C. Generalized myasthenia gravis (gMG)
Authorization of 12 months may be granted for treatment of generalized myasthenia gravis (gMG) when the member is anti-acetylcholine receptor (AchR) antibody positive.

D. Neuromyelitis Optica Spectrum Disorder (NMOSD)
Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when the member is anti-aquaporin-4 (AQP4) antibody positive.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with Soliris.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Soliris.
2. Soliris is being used to treat an indication enumerated in Section II.
3. Soliris has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2019.
2. Parker CJ. Management of paroxysmal nocturnal hemoglobulinuria in the era of complement inhibitory therapy. *Hematology.* 2011; 21-20.
3. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. *Pediatr Nephrol*. Published online: January 1, 2016.