Reference number
2373-A

Specialty Guideline Management

SOLIRIS (eculizumab)

POLICY

I. INDICATIONS

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

A. 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 (gMA) patients who are anti-acetylcholine receptor (AchR) antibody positive

Limitations 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 are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

A. Atypical hemolytic uremic syndrome
Authorization of 24 months may be granted to members prescribed Soliris for the treatment of atypical hemolytic uremic syndrome which is not caused by Shiga toxin.

B. Paroxysmal nocturnal hemoglobinuria
Authorization of 24 months may be granted to members prescribed Soliris for the treatment of paroxysmal nocturnal hemoglobinuria.

C. Generalized myasthenia gravis (gMA)
Authorization of 24 months may be granted to members for treatment of generalized myasthenia gravis (gMA) who are anti-acetylcholine receptor (AchR) antibody positive.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Soliris [package insert]. New Haven, CT: Alexion Pharmaceuticals, Inc.; October 2017.
2. 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: April 11, 2015.

3. Parker CJ. Management of paroxysmal nocturnal hemoglobulinuria in the era of complement inhibitory therapy. *Hematology.* 2011; 21-29.