Specialty Guideline Management

SOLIRIS (eculizumab)

POLICY

A. 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.

FDA-Approved Indications
- Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
- Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy

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.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- For paroxysmal nocturnal hemoglobinuria: flow cytometry results

C. CRITERIA FOR APPROVAL

1. 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.

2. Paroxysmal nocturnal hemoglobinuria
   Authorization of 24 months may be granted to members prescribed Soliris for the treatment of paroxysmal nocturnal hemoglobinuria who meet ALL of the following criteria:
   a. The diagnosis was confirmed by deficiency of glycosyl phosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by flow cytometry results.
   b. Soliris will be used to reduce hemolysis and/or prevent thrombosis.

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

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES