Soliris (eculizumab)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Medicare Advantage

**Original Effective Date:** 10/01/2015

**Current Effective Date:** 12/01/2018

**POLICY**

**A. 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**
- Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
- Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
- 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)

**Compendial Use**
- PNH for secondary prevention of venous thrombosis

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

- **Initial therapy**
  - For PNH, initial therapy: Laboratory report of flow cytometry testing (must include at least 2 different reagents tested on at least 2 cell lineages), Where applicable, documentation of previous venous thrombotic event(s) (e.g., clinical notes, medical record)
  - For aHUS, initial therapy: Documentation supporting a confirmed diagnosis of aHUS (e.g., genetic testing, clinical notes/laboratory reports with evidence of microangiopathic hemolytic anemia, acute kidney injury, and thrombocytopenia)
  - For gMA: Documentation supporting a confirmed diagnosis of gMA (e.g., genetic testing, clinical notes/laboratory reports with evidence of anti-acetylcholine receptor (AchR) antibody positive)

- **Continuation of therapy**
  - PNH and aHUS: Documentation supporting a clinical benefit from Soliris therapy (e.g., clinical notes, laboratory results)
C. CRITERIA FOR INITIAL APPROVAL

1. Paroxysmal Nocturnal Hemoglobinuria (PNH)
   Authorization for 12 months may be granted when the following criteria are met:
   a. Member has a diagnosis of PNH confirmed by flow cytometry testing; AND
   b. The purpose of prescribing Soliris is for reduction of hemolysis; OR
   c. The purpose of prescribing Soliris is for secondary prevention of venous thrombosis.

2. Atypical Hemolytic Uremic Syndrome (aHUS)
   Authorization for 6 months may be granted when the following criteria are met:
   a. Member has a confirmed diagnosis of aHUS.
   b. The disease is NOT caused by Shiga toxin.

3. Generalized myasthenia gravis (gMA)
   • Authorization for 6 months may be granted for gMA members who are anti-acetylcholine receptor (AchR) antibody positive

D. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.

2. Reauthorization:
   Authorization of an additional 12 months for PNH and 6 months for aHUS and gMA may be granted to members requesting authorization for continuation of therapy who are benefiting from Soliris therapy and were previously authorized by HMSA/CVS.

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.

F. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

   This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with
HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES

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