Soliris (eculizumab)

Line(s) of Business:  
HMO; PPO; QUEST Integration  
Akamai Advantage  

Original Effective Date:  
10/01/2015  

Current Effective Date:  
10/18/2016  

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

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:

- 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 continuation of therapy for 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.

D. CONTINUATION OF THERAPY
   1. Paroxysmal Nocturnal Hemoglobinuria (PNH)
      Reauthorization of 12 months may be granted to members requesting authorization for
      continuation of therapy that was previously authorized by HMSA/CVS when there is a
      documented clinical benefit from Soliris therapy.

   2. Atypical Hemolytic Uremic Syndrome (aHUS)
      Reauthorization of 6 months may be granted to members requesting authorization for
      continuation of therapy that was previously authorized by HMSA/CVS when there is a
      documented clinical benefit from Soliris therapy.

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’s determination as to medical necessity in a given case, the physician may request that
   CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light
   of any supporting documentation.
H. REFERENCES


Revised: May 2016.