POLICY Document for SOLIRIS

The overall objective of this policy is to support the appropriate and cost effective use of the medication, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care

Section 2: Enhanced Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care Policy

Site of Care Criteria
Administration of Soliris

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Soliris in an outpatient hospital setting for up to 2 doses when a member is new to therapy.

This policy provides coverage for administration of Soliris in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced a moderate or severe adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications).
B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
C. The member has severe venous access issues that require the use of a special intervention.
D. The member has a physical or cognitive impairment that would present unnecessary health risk.
E. Alternative infusion sites are not available.

For situations where administration of Soliris does not meet the criteria for outpatient hospital infusion, coverage for Soliris is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced a moderate or severe adverse reaction and did not respond to conventional interventions.
B. Medical records supporting the member is medically unstable.
C. Medical records supporting the member has severe venous access issues.
D. Medical records supporting the member has a physical or cognitive impairment.
E. Records supporting alternative infusion sites are not available.

Section 2: Enhanced Clinical Criteria

SOLIRIS (eculizumab) ENHANCED SGM

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.

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) 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. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for new requests for treatment of:

A. Atypical hemolytic uremic syndrome: ADAMTS 13 level
B. Paroxysmal nocturnal hemoglobinuria: deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins, flow cytometry used to show results of GPI-APs deficiency
C. Generalized myasthenia gravis: anti-acetylcholine receptor (AchR) antibody positive, clinical classification of myasthenia gravis score, MG activities of daily living score, use of IVIG and rituximab, use of two immunosuppressive therapy

III. CRITERIA FOR INITIAL APPROVAL

A. Atypical hemolytic uremic syndrome

Authorization of 6 months may be granted for treatment of atypical hemolytic uremic syndrome not caused by Shiga toxin when all of the following criteria are met:

1. ADAMTS 13 activity level above 5%
2. Absence of Shiga toxin

B. Paroxysmal nocturnal hemoglobinuria

Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria when all of the following criteria are met:

1. Deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs)

2. Flow cytometry is used to demonstrate GPI-APs deficiency

C. Generalized myasthenia gravis (gMG)

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

1. Anti-acetylcholine receptor (AchR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
3. MG activities of daily living (MG-ADL) total score ≥6
4. Meets both of the following:
   a. Patent has had an inadequate response to at least two immunosuppressive therapy listed below:
      i. azathioprine
      ii. cyclosporine
      iii. mycophenolate mofetil
      iv. tacrolimus
      v. methotrexate
      vi. cyclophosphamide
   b. Patient has inadequate response to chronic IVIG AND rituximab

IV. CONTINUATION OF THERAPY

A. Atypical hemolytic uremic syndrome

Authorization of 12 months may be granted to all members (including new members) requesting continuation of therapy provided they meet all initial authorization criteria and demonstrate a positive response to therapy (e.g., normalization of LDH levels, platelet counts).

B. Paroxysmal nocturnal hemoglobinuria

Authorization of 12 months may be granted to all members (including new members) requesting continuation of therapy provided they meet all initial authorization criteria and demonstrate a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of LDH levels).

C. Generalized myasthenia gravis (gMG)

Authorization of 12 months may be granted to all members (including new members) requesting continuation of therapy provided they meet all initial authorization criteria and demonstrate a positive response to therapy (e.g., improvement in MG-ADL scores, changes in baseline in Quantitative Myasthenia Gravis (QMG) total score).

REFERENCES:

SECTION 1

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

SECTION 2

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.

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