Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Soliris (Eculizumab)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: **July 2007**

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Soliris (Eculizumab).

Soliris (Eculizumab) is indicated for the following:

- Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
- Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
    - Limitations of use: Eculizumab is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS)
- Treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive

DEFINITIONS

Atypical Hemolytic Uremic Syndrome (aHUS) – a rare autoimmune disorder that results in low red blood cell counts, low platelet counts, and acute renal failure

Lactate Dehydrogenase (LDH) – a catalytic enzyme that is highly concentrated in red blood cells. Increased serum levels of LDH correlate with increase hemolysis of red blood cells.

Paroxysmal Nocturnal Hemoglobinuria (PNH) – a rare disorder where the immune system attacks red blood cells, resulting in anemia and thrombosis

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, eculizumab (Soliris), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. For the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

- Must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist
- Must have a laboratory confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as evidenced by having detectable GPI-deficient hematopoetic clones (Type III PNH RBC) via Flow Cytometry. Documentation of Flow Cytometry pathology report support must indicate presence of PNH-type RBC (red blood cell) and must be submitted.
- Must have an LDH level of 1.5 times the upper limit of the normal range (laboratory results with reference range must be submitted)
- Must provide documentation that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab

2. For the diagnosis of atypical hemolytic uremic syndrome (aHUS)

- Must be prescribed by or in consultation with a nephrologist, hematologist, oncologist, immunologist or genetic specialist
- Must have a diagnosis of atypical hemolytic uremic syndrome
- Must provide documentation that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab

3. For the diagnosis of generalized myasthenia gravis (gMG)

- Must be prescribed by or in consultation with a neurologist
- Must have a diagnosis of Myasthenia Gravis
- Must be anti-acetylcholine receptor (AChR) antibody positive
- Must provide documentation that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of treatment. Authorization may be extended at one-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Place of Service	When Soliris is administered at any place of service other than 011 and 012, the service will be reviewed for medical necessity. The place of service codes are outlined below in alignment with Medical Pay Policy MP-211.

Place of Service Code(s)	Place of Service Name	Place of Service Description
011	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.

012	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Soliris [prescribing information]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; October 2017.
2. Parker C. Eculizumab for paroxysmal nocturnal haemoglobinuria. *Lancet* 2009;373:759-67
3. Hillmen P, Young NS, Schubert J, et al. The complement inhibitor eculizumab in paroxysmal nocturnal hemoglobinuria. *N Engl J Med* 2006;355:1233-43
4. Brodsky RA, Young NS, Antonioli E, et al. Multicenter phase 3 study of the complement inhibitor eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria. *Blood* 2008;111:1840-1847
5. Hill A, Richards J, Hillmen P, et al. Recent developments in the understanding and management of paroxysmal nocturnal haemoglobinuria. *British Journal of Haematology* 2007; 137:181-192
6. Kelly RJ, Hill A, Arnold, LM, et al. Long-term treatment with eculizumab in paroxysmal nocturnal hemoglobinuria: sustained efficacy and improved survival. *Blood* 2011;117:6786-6792
7. Taylor CM, Machin S, Wigmore SJ, et al. Clinical practice guidelines for the management of atypical haemolytic uraemic syndrome in the United Kingdom. *British Journal of Haematology* 2009;148;37-47
8. Kavanagh D, Goodship T. Atypical hemolytic uremic syndrome. *Curr Opin Hematol* 2010;17;432-438

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Clarified site of service restrictions	*01/17*
Criteria Update	*02/18*