Premier Health Insuring Corporation
POLICY AND PROCEDURE MANUAL

Policy Number: MP.094.PC
Last Review Date: 01/17/2017
Effective Date: 03/01/2017

MP.211.PC – Soliris, Place of Service

This policy applies to the following lines of business:
- ✓ Premier Health Insuring Corporation MA – DSNP

Premier Health Insuring Corporation considers **Eculizumab** (**Soliris)** medically necessary for the following indications:
- 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.

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 weeks prior to the administration of the first dose of eculizumab

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 weeks prior to the administration of the first dose of eculizumab

Limitations
- *If the above criteria are met, the medication is approved for THREE months. However, the reauthorization is limited to x 1 year for reauthorizations.*

- Eculizumab is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

- When Soliris is administered at any place of service other than 011 and 012 (or is at an out of network facility), the service will be reviewed for medical necessity.

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.

See Also:
RX.PA.069 Eculizumab (Soliris)

Background

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

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
HCPCS Code(s)	

J1300	Injection, ecluizumab, 10 mg
ICD-9 codes covered if selection criteria are met:	
283.11	Hemolytic-uremic syndrome
283.2	Hemoglobinuria due to hemolysis from external causes
ICD-10 codes covered if selection criteria are met:	
D59.3	Hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria

References

1. 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
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Articl: Eculizumab (Soliris) – Related to LCD L3394 (A54848). Effective Date 10/01/2015. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54548&ver=3&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=All&KeyWord=soliris&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAAA%3d%3d&
3. Hayes. News – Government. Soliris Approved to Treat Blood Disorder, March 23, 2007.
4. 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
5. Hillmen P, Young NS, Schubert J, et al. The complement inhibitor eculizumab in paroxysmal nocturnal hemoglobinuria. N Engl J Med 2006;355:1233-43
6. Kavanagh D, Goodship T. Atypical hemolytic uremic syndrome. Curr Opin Hematol 2010;17;432-438
7. 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
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9. Soliris [prescribing information]. Revised 12/2015. http://soliris.net/resources/pdf/soliris_pi.pdf
10. 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

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Disclaimer:
Premier Health Insuring Corporation medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Premier Health Insuring Corporation and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Premier Health Insuring Corporation reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.