CLINICAL MEDICATION POLICY	
Policy Name:	Soliris® (eculizumab)
Policy Number:	MP-017-MC-NC
Responsible Departments:	Medical Management, Clinical Pharmacy
Provider Notice Date:	06/19/2017
Original Effective Date:	07/19/2017
Annual Approval Date:	04/19/2018
Revision Date:	N/A
Products:	North Carolina Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 5

DISCLAIMER

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ provides coverage under the medical benefits of the Company's Medicare products for medically necessary intravenous infusions of Soliris® (eculizumab).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

PROCEDURES

Gateway Health℠ considers Soliris® (eculizumab) medically necessary when the following criteria are met for:

1. Paroxysmal Nocturnal Hemoglobinuria (PNH)
    A. The member is 18 years of age or older; AND
    B. Flow cytometric confirms:
        1) At least 10% PNH type III red cells; OR
        2) Greater than 50% of glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs); AND
    C. Individual has been immunized with a meningococcal vaccine at least two weeks prior to the administration of the first dose of Soliris, unless the clinical record demonstrates that the risks of delaying Soliris outweigh the risk of meningococcal infection; AND
    D. There is no evidence of an active meningococcal infection; AND
    E. The member's hemoglobin is less than or equal to 7 g/dL, OR the member has symptoms of anemia, and the hemoglobin is less than or equal to 9 g/dL; AND
    F. Lactate dehydrogenase (LDH) is greater than 1000 U/L; OR
    G. The member has documented end organ manifestations such as disabling fatigue, thrombosis, transfusion-dependence, smooth muscle dystonia, renal insufficiency; AND
    H. Dosing is within the following prescribing-supported parameters:
        1) Dose does not exceed 900 mg per individual dose
        2) Dose does not exceed a maximum of 3300 mg over the first 30 days of therapy
        3) Dose does not exceed a maximum of 2700 mg per 30 days of therapy for ongoing treatment

2. Atypical Hemolytic Uremic Syndrome (aHUS)
    A. The diagnosis of aHUS is supported by the absence of the Shiga toxin-producing E. coli infection; AND
    B. Thrombotic thrombocytopenic purpura (TTP) has been ruled out, or if TTP cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement; AND
    C. The member has been immunized with a meningococcal vaccine at least two weeks prior to the administration of the first dose of eculizumab, unless the clinical record demonstrates that the risks of delaying eculizumab outweigh the risk of meningococcal infection; AND
    D. There is no evidence of an active meningococcal infection; AND
    E. The member is aged two months or older and has a weight of at least five kilograms

F. Dosing is within the following prescribing–supported parameters:

Weight range	Max per dose	Max total first 30 days	Max total per 30 days, ongoing
≥ 40 kg	1200 mg	4800 mg	3600 mg
30-39 kg	900 mg	3000 mg	2700 mg
20-29 kg	600 mg	2400 mg	1800 mg
10-19 kg	600 mg	1200 mg	900 mg
≥ 2 mo. old & 5-9 kg	300 mg	900 mg	600 mg

3. Contraindications
   Use of Soliris in PNH: The safety and effectiveness have not been established in the pediatric population.

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

4. When services are not covered
   Services are not covered for conditions other than those listed above because the scientific evidence has not been established.

   Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and will be reviewed on a case-by-case basis to determine medical necessity.

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

6. Place of Service
   The place of service for the administration of Soliris is outpatient.

7. Coverage Determination
   Gateway Health℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

   There is no specific NCD or North Carolina LCD for Soliris. For additional information, please see:
   http://www.palmettogba.com/palmetto/providers.nsf/docscat/Providers~JM%20Part%20B~Medical%20Policies~LCDs%20Coverage%20Articles%20NCDs

GOVERNING BODIES APPROVAL

Soliris was approved by the FDA on March 16, 2007, for treatment of paroxysmal nocturnal hemoglobinuria (PNH) in order to reduce hemolysis. Soliris was approved by the FDA on September 23, 2011, for treatment of atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or on the OneSource™ Safety Support website found at http://www.solirisrems.com.

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
J1300	Injection, Eculizumab, 10 mg

Diagnosis Codes

ICD-10 Codes	Description
D59.3	Hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria (Marchiafava-Micheli)

POLICY SOURCE(S)

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Lapeyraque AL, Malina M, Fremeaux-Bacchi V, et al. Eculizumab in severe Shiga-toxin-associated HUS. N Engl J Med. 2011 Jun 30; 364(26):2561-3. Available at: http://www.nejm.org/doi/full/10.1056/NEJMc1100859.

Robert A. Brodsky, Neal S. Young, Elisabetta Antonioli, et al. Multicenter phase 3 study of the complement inhibitor eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria. Blood, 15 February 2008. Volume 111, Number 4. Available at: http://www.bloodjournal.org/content/bloodjournal/111/4/1840.full.pdf.

Legendre CM, Licht C, Muus P, et al. Terminal complement inhibitor eculizumab in atypical hemolytic–uremic syndrome. N Engl J Med 2013; 368:2169-81. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1208981.

Policy History:

Date	Activity
04/07/2017	Initial policy developed
04/19/2017	QI/UM Committee approval
07/19/2017	Provider effective date