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CLINICAL MEDICAL POLICY

Policy Name:	Soliris® (Eculizumab)
Policy Number:	MP-019-MD-PA
Approved By:	Medical Management
Provider Notice Date:	06/01/16
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Annual Approval Date:	05/01/16
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Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	5

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization 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 provides coverage for Soliris® under the medical benefit and is administered under Gateway Health Plan® specialty pharmacy program for medically necessary therapy utilizing the criteria developed by the Gateway Pharmacy and Therapeutics Subcommittee and approved by the Quality Improvement/Utilization Management committee. Covered indications for Soliris® are: Paroxysmal Nocturnal Hemoglobinuria (PNH) and Atypical Uremic Syndrome (aHUS).

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Commonwealth of Pennsylvania (PA) Department of Human Services (DHS) and all applicable state and federal regulations.

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

(Current applicable PA HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS:

Prior Authorization Review Panel (PARP) — A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

PROCEDURES

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

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

2. Atypical Hemolytic Uremic Syndrome (aHUS)
   - The diagnosis of aHUS is supported by the absence of the Shiga toxin-producing *E. coli* infection; AND
   - 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
   - The patient has been immunized with a meningococcal vaccine at least two weeks prior to the administration of the first does of eculizumab, unless the clinical record demonstrates that the risks of delaying eculizumab outweigh the risk of meningococcal infection; AND
   - There is no evidence of an active meningococcal infection; AND
   - The patient is age two months or older and has a weight of at least five kilograms
   - Dosing is within the following prescribing –supported parameters:

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

Governing Bodies Approval

FDA

Eculizumab (Soliris®) was approved by the FDA on March 16, 2007, for treatment of paroxysmal nocturnal hemoglobinuria (PNH) in order to reduce hemolysis.

Eculizumab (Soliris®) was approved by the FDA on September 23, 2011, for treatment of atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Black Box Warnings

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.
The following statements were taken from the product prescribing information at the time this policy was updated:

LIMITATIONS OF USE

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

PEDIATRIC USE

Use of eculizumab (Soliris®) in PNH: The safety and effectiveness have not been established in the pediatric population.

Use of eculizumab (Soliris®) in aHUS: Four clinical studies assessing the safety and effectiveness of eculizumab (Soliris®) for the treatment of aHUS included a total of 47 pediatric patients (ages 2 months to 17 years). The safety and effectiveness in the pediatric population is similar to that of the adult population.

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.

Contraindications

Use of eculizumab (Soliris®) in PNH: The safety and effectiveness have not been established in the pediatric population.

When services are not covered

For conditions other than those listed above scientific evidence has not been established. When criteria are not met, the prior authorization request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their profession judgement, the requested medication is medically necessary.

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.

Place of Service:

The place of service for the administration of Soliris is outpatient.

Length of Coverage

Coverage will be provided for 12 months for patients who meet the medical necessity guidelines for paroxysmal nocturnal hemoglobinuria (PNH) when the following criteria are met:

- The patient has been revaccinated for meningococcal infections according to standard vaccination schedules
- Monitoring of LDH is done at least annually
- Monitoring of hemoglobin is done at least annually
- Documentation that there has been a decrease in the number of PNH exacerbations while on Soliris®

Coverage will be provided for an initial 6 weeks for atypical hemolytic uremic syndrome (aHUS). Coverage will be renewed in 12 month increments when the following medical are met:

- The patient has been revaccinated for meningococcal infection according to the standard vaccination schedules
- Monitoring for symptoms of thrombotic microangiopathy
- Monitoring of platelet count at least annually
- Monitoring of serum creatinine at least annually
- Monitoring of LDH level at least annually
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When the above criteria for PNH and aHUS are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgement, the requested medication is medically necessary.

CODING REQUIREMENTS:

Diagnosis and Procedure Codes

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

CPT Code	Description
J1300	Injection, Eculizumab, 10 mg

Policy Source(s)

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Brodsky, RA. Treatment and Prognosis of Paroxysmal Nocturnal Hemoglobinuria. *UpToDate*. Updated 09/21/2015