

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**1. Requirements for Prior Authorization of Soliris (eculizumab)**

A. Prescriptions That Require Prior Authorization

All prescriptions for Soliris (eculizumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Soliris (eculizumab), the determination of whether the requested prescription is medically necessary will take into account the following:

1. For the treatment of a diagnosis of atypical hemolytic uremic syndrome (aHUS) – Whether the recipient:
  - a. Has a diagnosis of atypical hemolytic uremic syndrome (aHUS)  
**AND**
  - b. Is prescribed the medication by, or in consultation with, a
    - i. Hematologist/Oncologist OR
    - ii. Nephrologist**AND**
  - c. Received a meningococcal vaccine at least two weeks prior to the first dose  
**AND**
  - d. Received a Streptococcus pneumoniae vaccination  
**AND**
  - e. If under 18 years of age, also received a Haemophilus influenza (Hib) vaccination
2. For the treatment of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) – Whether the recipient:
  - a. Has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry testing  
**AND**
  - b. Is prescribed the medication by, or in consultation with, a Hematologist/Oncologist

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**AND**

- c. Received a meningococcal vaccine at least two weeks prior to the first dose

**AND**

- d. Received a Streptococcus pneumoniae vaccination

**AND**

- e. If under 18 years of age, also received a Haemophilus influenza (Hib) vaccination
3. If the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR SOLIRIS (eculizumab):  
The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Soliris (eculizumab) that were previously approved will take into account the following:

- 1. Documentation from the prescribing provider that the recipient had a positive clinical response and tolerates the therapy.

**OR**

- 2. The recipient does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the recipient.

**C**     Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Soliris (eculizumab). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

**D.**     Dose and Duration of Therapy

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The Department will limit authorization of prescriptions for Soliris (eculizumab) as follows:

1. Up to three (3) months of therapy for an initial request
2. Up to six (6) months for a renewal of a previously approved request

E. References

1. Complement-mediated hemolytic uremic syndrome. UpToDate. Accessed July 29, 2014.
2. Diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. UpTo Date. Accessed July 29, 2014
3. 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.
4. Soliris prescribing information. Alexion Pharmaceuticals, Inc. April 2014.