| Reference number(s) |
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| 3826-A |

# JURISDICTION SPECIFIC MEDICARE PART B

## SOLIRIS (eculizumab)

### POLICY

#### I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Paroxysmal Nocturnal Hemoglobinuria (PNH)
B. Atypical Hemolytic Uremic Syndrome (aHUS)
C. Generalized Myasthenia Gravis (gMG)
D. Neuromyelitis Optica Spectrum Disorder (NMOSD)
E. Dense Deposit Disease

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration
C. For paroxysmal nocturnal hemoglobinuria, the medical record supporting the diagnosis (i.e., flow cytometry results, evidence of hemolysis, history of major adverse vascular event from thromboembolism), if applicable
D. For continuation of eculizumab following an initial trial to treat atypical hemolytic uremic syndrome, the medical record reflecting that there was a clinical improvement.
E. For dense deposit disease, the medical record documenting elevated serum levels of sC5b-9 (serum membrane attack complex)
F. Medical record documenting either immunization with a meningococcal vaccine at least two weeks prior to the first dose of Soliris or that the risks of delaying eculizumab outweighed the risk of meningococcal infection





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| 3826-A |

## III. CRITERIA FOR APPROVAL

### A. Paroxysmal Nocturnal Hemoglobinuria

Authorization of 12 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when both of the following criteria are met:

1. The diagnosis was confirmed by one of the following:
   i. Flow cytometry and either of the following:
      a. Evidence of clinically significant hemolysis
      b. Documented history of a major adverse vascular event (MAVE) from thromboembolism.
   ii. The member does not meet documentation requirements above and Soliris treatment was started prior to October 1st, 2015.
2. The member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

### B. Atypical Hemolytic Uremic Syndrome

Authorization of 12 weeks may be granted as an initial trial for the treatment of atypical hemolytic uremic syndrome (aHUS) when all of the following criteria are met:

1. The member has no signs of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
2. The member meets either of the following:
   i. Thrombotic thrombocytopenic purpura was ruled out (e.g., the member had a normal ADAMTS 13 activity and no evidence of ADAMTS 13 inhibitor).
   ii. Thrombotic thrombocytopenic purpura could not be ruled out by laboratory and clinical evaluation and a trial of plasma exchange did not result in clinical improvement.
3. The member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

Authorization of 12 months may be granted following an initial trial for the treatment of atypical hemolytic uremic syndrome (aHUS) when all of the following criteria are met:

1. The member has received 6 to 12 weeks of eculizumab.
2. The medical records reflect that there has been a clinical improvement (e.g., increased platelet count or laboratory evidence of reduced hemolysis).
3. The member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

### C. Generalized Myasthenia Gravis

Authorization of 12 months may be granted for treatment of generalized myasthenia gravis (gMG) when the member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

### D. Neuromyelitis Optica Spectrum Disorder

Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when the member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

### E. Dense Deposit Disease

Authorization of 12 months may be granted for treatment of biopsy proven dense deposit disease when both of the following criteria are met:

1. Serum levels of sC5b-9 (serum membrane attack complex) are elevated.
2. The member was immunized with a meningococcal vaccine at least two weeks prior to administration of the first dose of eculizumab or the risks of delaying eculizumab outweighed the risk of meningococcal infection.

## IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 11, 2021.
2. Billing and Coding: Eculizumab (A54548) Version R3. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 11, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 11, 2021.
4. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; November 2020.

 