Reference number(s)
3826-A

Jurisdiction Specific Medicare Part B Soliris and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Soliris	eculizumab
Bkemv	eculizumab-aeeb
Epysqli	eculizumab-aagh

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 FDA-labeled indications and recognized compendial (off-label) uses are below:
  - Paroxysmal Nocturnal Hemoglobinuria (PNH)
  - Atypical Hemolytic Uremic Syndrome (aHUS)
  - Generalized Myasthenia Gravis (gMG)
  - Neuromyelitis Optica Spectrum Disorder (NMOSD)
  - Dense Deposit Disease
  - Antibody Mediated Heart Transplant Rejection
  - Antibody Mediated Renal Transplant Rejection
  - Complement C3 Glomerulopathy (C3G) Post-Kidney Transplant
- Compendial Uses – ICD-10 codes supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include within this criteria. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

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

Coverage Criteria

Paroxysmal Nocturnal Hemoglobinuria (PNH)[1-4,6,7]

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

- The diagnosis was confirmed by one of the following:
  - Flow cytometry and either of the following:
    - Evidence of clinically significant hemolysis.
    - Documented history of a major adverse vascular event (MAVE) from thromboembolism.
  - The member does not meet documentation requirements above and Soliris treatment was started prior to October 1st, 2015.
- 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.

Atypical Hemolytic Uremic Syndrome (aHUS)[1-4,6,7]

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:

- The member has no signs of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- The member meets either of the following:
  - Thrombotic thrombocytopenic purpura was ruled out (e.g., the member had normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor).
  - 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.
- 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:

- The member has received 6 to 12 weeks of eculizumab.

- The medical records reflect that there has been a clinical improvement (e.g., increased platelet count or laboratory evidence of reduced hemolysis).
- 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.

Generalized Myasthenia Gravis (gMG)[1-4]

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.

Neuromyelitis Optica Spectrum Disorder (NMOSD)[1-4]

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.

Dense Deposit Disease[1-3]

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

- Serum levels of sC5b-9 (serum Membrane Attack Complex) are elevated.
- 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.

Antibody Mediated Heart Transplant Rejection[1-3,5]

Authorization of 12 months may be granted for treatment of antibody mediated heart transplant rejection 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.

Antibody Mediated Renal Transplant Rejection[1-3,5]

Authorization of 12 months may be granted for treatment of antibody mediated renal transplant rejection 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.

Complement C3 Glomerulopathy (C3G) Post-Kidney Transplant[1-3,5]

Authorization of 12 months may be granted for treatment of complement C3 glomerulopathy (C3G) post-kidney transplant 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.

All Other Indications[2]

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A54548.

Dosage and Administration

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

References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 17, 2025.
2. Billing and Coding: Eculizumab (A54548) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 17, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 17, 2025.
4. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025.
5. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 17, 2025.
6. Bkemv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
7. Epysqli [package insert]. Republic of Korea: Samsung Bioepis Co., Ltd.; February 2025.

