eculizumab

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Complement inhibitor
HCPCS:
J1299:Injection, eculizumab, 2 mg
Q5151:Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg
Q5152:Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
How Supplied:
300 mg (single-use vials - 30 mL of 10 mg/mL sterile, preservative-free solution)

Condition(s) listed in policy (see coverage criteria for details)

- Atypical Hemolytic Uremic Syndrome (aHUS)
- Generalized Myasthenia Gravis (gMG)
- Neuromyelitis Optica Spectrum Disorder (NMOSD)
- Paroxysmal Nocturnal Hemoglobinuria (PNH)

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Atypical Hemolytic Uremic Syndrome (aHUS)
Meets medical necessity if all the following are met:
1. Prescribed by or in consultation with a hematologist or nephrologist
2. Not being used for Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

Covered Doses:
For patients 18 years or older and pediatric patients weighing 40 kg and over:

- Up to 900 mg given intravenously (IV) once weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 7 days later, then 1200 mg every 14 days thereafter

For patients < 18 years old and < 40 kg:

- 30kg to <40kg: Up to 600 mg given IV once weekly for the first two weeks, followed by 900 mg for the third dose 7 days later, then 900 mg every 14 days thereafter
- 20kg to <30kg: Up to 600 mg given IV once weekly for the first two weeks, followed by 600 mg for the third dose 7 days later, then 600 mg every 14 days thereafter
- 10kg to <20kg: Up to 600 mg given IV once weekly for the first week, followed by 300 mg for the second dose 7 days later, then 300 mg every 14 days thereafter
- 5kg to <10kg: Up to 300 mg given IV once weekly for first week, followed by 300 mg for the second dose 7 days later, then 300 mg every 21 days thereafter

Coverage Period:
Initial: 1 year
Reauthorization: Yearly when meets the following below

1. Meets ALL of the following:
    1. Prescribed by or in consultation with a hematologist or nephrologist
    2. Patient has continued response to therapy

ICD-10:
D59.30

Generalized Myasthenia Gravis (gMG)
Meets medical necessity if all the following are met:

1. Prescribed by or in consultation with a neurologist
2. Positive serologic test for anti-AChR antibodies
3. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
5. Inadequate response over 1 year or more with 2 or more immunosuppressive therapies (ISTs), or medical rationale why at least two ISTs have not been tried each or in combination, for at least one year

Covered Doses:
Up to 900 mg given intravenously once weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 7 days later, then 1200 mg every 14 days thereafter

Coverage Period:
Initial: 6 months
Reauthorization: Yearly when meets one of the following below

1. ONE of the following:
    1. Patient has demonstrated a MG-ADL total score of at least a 3-point improvement and did not require rescue therapy (e.g. PE, plasmapheresis)
    2. Reduction in signs and symptoms of myasthenia gravis

ICD-10:
G70.00, G70.01

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Meets medical necessity if all the following are met:

For Soliris only:

1. Prescribed by or in consultation with by a neurologist
2. Anti-aquaporin-4 (AQP4) antibody positivity
3. Not being used in combination with another drug therapy for NMOSD (e.g., rituximab, inebilizumab, satralizumab)
4. Meets ONE of the following:
   a. Patient has had an inadequate response or intolerance to rituximab
   b. Patient has not been treated with rituximab AND has a contraindication to Ruxience and Truxima

Covered Doses:

Up to 900 mg given intravenously once weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 7 days later, then 1200 mg every 14 days thereafter.

Coverage Period:

Initial: 1 year

Reauthorization:

1. Yearly if meets ALL of the following:
   a. Documented reduction in frequency of NMO attacks from baseline
   b. Prescribed by or in consultation with a neurologist
   c. Not being used in combination with another drug therapy for NMOSD
   d. Dose does not exceed the FDA-approved maximum

ICD-10:

G36.0

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years and older)
2. Prescribed by or in consultation with a hematologist or oncologist
3. Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

Covered Doses:

Up to 600 mg given intravenously once weekly for the first 4 weeks, followed by up to 900 mg for the fifth dose 7 days later, then up to 900 mg every 14 days thereafter.

Coverage Period:

Initial: 1 year

Reauthorization:

1. Yearly if meets ALL the following:
   1. Prescribed by or in consultation with a hematologist or oncologist
   2. Clinical response from baseline (e.g. increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, etc)
   3. Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

ICD-10:
D59.5

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for BKEMV, Epysqli, and Soliris.
2. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
3. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) - revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management (2024)

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries.
- Support for using biosimilars as step requirement is found in Noridian Health Care Solutions and supported by the FDA. Noridian will accept a biosimilar drug on the same criteria as the drug to which it is a biosimilar unless an article is published to the contrary. Per the FDA, a biosimilar is highly similar to and has no clinically meaningful difference from an existing FDA approved biologic reference drug.
- Support for using rituximab/rituximab biosimilars for NMOSD is found in the recommendations of the Neuromyelitis Optica Study Group (NEMOS; published in 2024). The recommendations include rituximab among first-line antibody treatment options for long-term therapy and state that there is no high-level evidence demonstrating the superiority of one drug over another for AQP4-IgG-positive NMOSD. Furthermore, rituximab has been a mainstay of NMOSD treatment and has been successfully used to treat the disease for over 15 years.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. BKEMV (eculizumab-aeeb) [Prescribing information]. Amgen, Inc.,Thousand Oaks, CA: 10/2024.
6. Damato V, Evoli A, Iorio R. Efficacy and safety of rituximab therapy in neuromyelitis optica spectrum disorders: a systematic review and meta-analysis. *JAMA Neurol.* 2016;73(11):1342-1348.
7. Epysqli (eculizumab-aagh) [Prescribing information]. Samsung Bioepis Co., Ltd., Yeonsu-gu, Incheon, Republic of Korea: 7/2024.
8. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

9. Kumpfel T, Giglhuber K et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. Journal of Neurology (2024) 271:141-176.
10. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
11. Mealy MA, Wingerchuk DM, Palace J, et al. Comparison of Relapse and Treatment Failure Rates Among Patients With Neuromyelitis Optica: Multicenter Study of Treatment Efficacy. JAMA Neurol. 2014 Mar;71(3):324-30.
12. Soliris (eculizumab) [Prescribing information]. Alexion Pharmaceuticals, Inc., Boston, MA: 2/2025.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- New policy

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee