blue california
Promise Health Plan

eculizumab

Medical Benefit Drug Policy

eculizumab (Soliris)
eculizumab-aeeb (BKEMV)
eculizumab-aagh (Epysqli)

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

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 condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

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.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Atypical Hemolytic Uremic Syndrome (aHUS)

Meets medical necessity if all the following are met:

Initial

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)
3. Request for Soliris: Intolerable side effect to eculizumab biosimilars (e.g. BKEMV, Epysqli) that is not expected with the requested drug or contraindication to all biosimilars (e.g. BKEMV, Epysqli)

Reauthorization

1. Prescribed by or in consultation with a hematologist or nephrologist
2. Patient has continued response to therapy

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:

Yearly

ICD-10:

D59.30

Generalized Myasthenia Gravis (gMG)

Meets medical necessity if all the following are met:

Initial

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
6. Request for Soliris: Intolerable side effect to eculizumab biosimilars (e.g. BKEMV, Epysqli) that is not expected with the requested drug or contraindication to all biosimilars (e.g. BKEMV, Epysqli)

Reauthorization
1. Meets ONE of the following:
   a. 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)
   b. Reduction in signs and symptoms of myasthenia gravis

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

ICD-10:
G70.00, G70.01

Neuromyelitis Optica Spectrum Disorder (NMOSD)
Meets medical necessity if all the following are met:
Initial
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. Request for Soliris: ***Effective 2/1/2026 and after,*** will require an intolerable side effect to eculizumab biosimilars (e.g. BKEMV, Epysqli) that is not expected with the requested drug or contraindication to all biosimilars (e.g. BKEMV, Epysqli)
5. 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 Riabni, Ruxience and Truxima

Reauthorization
1. Documented reduction in frequency of NMO attacks from baseline
2. Prescribed by or in consultation with a neurologist
3. Not being used in combination with another drug therapy for NMOSD

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:
Yearly

ICD-10:
G36.0

Paroxysmal Nocturnal Hemoglobinuria (PNH)
Meets medical necessity if all the following are met:
Initial
1. Age is consistent with the FDA-approved indication
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
4. Request for Soliris: Intolerable side effect to eculizumab biosimilars (e.g. BKEMV, Epysqli) that is not expected with the requested drug or contraindication to all biosimilars (e.g. BKEMV, Epysqli)

Reauthorization
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

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:
Yearly

ICD-10:
D59.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. BKEMV (eculizumab-aeeb) [Prescribing information]. Amgen, Inc.,Thousand Oaks, CA: 10/2024.

3. 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.
4. Epysqli (eculizumab-aagh) [Prescribing information]. Samsung Bioepis Co., Ltd., Yeonsu-gu, Incheon, Republic of Korea: 7/2024.
5. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
6. 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.
7. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
8. 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.
9. Soliris (eculizumab) [Prescribing information]. Alexion Pharmaceuticals, Inc., Boston, MA: 2/2025.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- Neuromyelitis Optica Spectrum Disorder:
  - Biosimilars Bkemv and Epysqli will be covered for this indication (Rationale: Biosimilar is highly similar to reference product that is already approved by the FDA)
  - ***Effective 2/1/2026 and after***, request for Soliris will require pre-requisite therapy requirement with biosimilars BKEMV and Epysqli (Rationale: (Rationale: more cost-effective therapeutic available)

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