**eculizumab**

**Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a

preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

*MCG Care Guidelines, 19th edition, 2015*

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first 4 infusions) of the requested drug or is being re-initiated on the requested drug after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on the requested drug based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on the requested drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

**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 or BKEMV: ***Effective 1/1/2026 and after***, will require an intolerable side effect to preferred eculizumab product (e.g. Epysqli) that is not expected with the requested drug or contraindication to 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 or BKEMV: ***Effective 1/1/2026 and after***, will require an intolerable side effect to preferred eculizumab product (e.g. Epysqli) that is not expected with the requested drug or contraindication to 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 or BKEMV: ***Effective 2/1/2026 and after,*** will require an intolerable side effect to preferred eculizumab product (e.g. Epysqli) that is not expected with the requested drug or contraindication to Epysqli
5. Meets ONE of the following:
    1. Patient has had an inadequate response or intolerance to rituximab
    2. Patient has not been treated with rituximab AND has a contraindication to 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 (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
4. Request for Soliris or BKEMV: ***Effective 1/1/2026 and after***, will require an intolerable side effect to preferred eculizumab product (e.g. Epysqli) that is not expected with the requested drug or contraindication to 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 and BKEMV will require pre-requisite therapy requirement with biosimilar Epysqli (Rationale: (Rationale: more cost-effective therapeutic available)

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