## 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.**



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**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, intolerable side effect, or contraindication to two or more immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, methotrexate, cyclophosphamide and tacrolimus)
6. Request for Soliris: Intolerable side effect to preferred eculizumab product (e.g. BKEMV, Epysqli) that is not expected with the requested drug or contraindication to BKEMV and 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: 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


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**Review History**

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- no clinical changes following revision

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