Eculizumab (Soliris®)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J1300 per 10 mg

Conditions listed in policy (*see criteria for details*)

- Atypical hemolytic uremic syndrome (aHUS)
- Generalized myasthenia gravis (gMG)
- Neuromyelitis optica spectrum disorder (NMOSD)
- Paroxysmal nocturnal hemoglobinuria (PNH)

AHFS therapeutic class: Complement inhibitor

Mechanism of action: Complement inhibitor

(1) Special Instructions and pertinent Information

Please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal ASO, Shared Advantage, and HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physicians' 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.

ADMINISTRATION OF SOLIRIS 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) with Soliris or is being re-initiated on Soliris 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 Soliris based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Soliris 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Soliris® (eculizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Atypical hemolytic uremic syndrome (aHUS)

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

- Up to 900 mg 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 <40kg:

- **30kg to <40kg**: Up to 600mg 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 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 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 for first week, followed by 300 mg for the second dose 7 days later, then 300 mg every 21 days thereafter

Coverage Period
Cover yearly based upon patient's continued response to therapy

ICD-10:
D59.3

Generalized myasthenia gravis (gMG)

1. Prescribed by or in consultation with a neurologist, **AND**
2. Positive serologic test for anti-AChR antibodies, **AND**
3. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6, **AND**
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, **AND**
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 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: 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), then yearly based on continued response.

ICD-10:
G70.00, G70.01

Neuromyelitis optica spectrum disorder (NMOSD)

1. Prescribed by or in consultation with by a neurologist, **AND**
2. Attestation of anti-aquaporin-4 (AQP4) antibody positivity, **AND**
3. ***Effective 1/28/2024 and after***: Not being used in combination with another drug therapy for NMOSD (e.g., rituximab, inebilizumab, satralizumab), **AND**
4. Meets one of the following:
    a. Patient has had an inadequate response or intolerance to rituximab, OR
    b. Either of the following:
        i. ***Through 12/31/2023***: Patient has not been treated with rituximab AND has a contraindication to Ruxience and Riabni, or
        ii. ***Effective 1/1/2024 and after***: Patient has not been treated with rituximab AND has a contraindication to Ruxience and Truxima

Covered Doses
Up to 900 mg given intravenously 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: Yearly, with documented reduction in frequency of NMO attacks from baseline

ICD-10:
G36.0

Paroxysmal nocturnal hemoglobinuria (PNH)

Covered Doses
Up to 600 mg every 7 days 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
Cover yearly based upon patient's continued response to therapy

ICD-10:
D59.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Soliris® (eculizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
300 mg (single-use vials - 30 mL of 10 mg/mL sterile, preservative-free solution)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- Soliris® (eculizumab) [Prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc., 11/2020.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 3Q2023
Changes from previous policy version:

- Section (2): Neuromyelitis optica spectrum disorder (NMOSD) –
  - ***Effective 1/28/2024* and after**, combination use with other drug therapies indicated for neuromyelitis optica spectrum disorder will be managed
    Rationale: Soliris prescribing information
  - ***Effective 1/1/2024 and after***, the preferred rituximab drugs will be Ruxience and Truxima

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee