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5.85.011

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	September 8, 2011
Subject:	Soliris	**Page:**	1 of 9

Last Review Date: September 19, 2025

Soliris

Description

Soliris (eculizumab)

Bkemv (eculizumab-aeeb)

Epysqli (eculizumab-aagh)

Bolded medications are the preferred products.

Background

Soliris and its biosimilars are complement inhibitors indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), and neuromyelitis optica spectrum disorder (NMOSD). Soliris and its biosimilars are humanized monoclonal IgG antibodies that binds to complement protein C5, preventing cleavage into C5a and C5b. Blocking the formation of C5b inhibits the subsequent formation of terminal complex C5b-9 or MAC. Terminal complement-mediated intravascular hemolysis is a key clinical feature of paroxysmal nocturnal hemoglobinuria (PNH), blocking the formation of membrane attack complex (MAC) results in stabilization of hemoglobin and a reduction in the need for RBC transfusions. Impairment of complement activity regulation leads to uncontrolled complement activation in atypical hemolytic uremic syndrome (aHUS) (1-4).

Regulatory Status

FDA-approved indications: Soliris and its biosimilars are complement inhibitors indicated for: (1-3)

1. The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
2. The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
    a. Limitation of Use: Soliris and its biosimilar are not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
3. The treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older who are anti-acetylcholine receptor (AchR) antibody positive.
4. The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

The International Consensus Guidance for Management of Myasthenia Gravis recommends the use of chronic IVIG and immunosuppressants (5).

Soliris and its biosimilars include a boxed warning citing the risk of life-threatening and fatal meningococcal infections. Additionally, all patients must be vaccinated with a meningococcal vaccine at least 2 weeks prior to receiving their first dose (1-3).

Soliris and its biosimilars are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the REMS, prescribers must enroll in the program (1-3).

In addition, Soliris and its biosimilars have warnings regarding infusion-related reactions and using caution when administering to patients with any other systemic infection (1-3).

The safety and effectiveness of Soliris and its biosimilars for the treatment of PNH and NMOSD in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Soliris and its biosimilars for the treatment of gMG in pediatric patients less than 6 years of age have not been established. The safety and effectiveness of Soliris and its biosimilars for the treatment of aHUS have been established in pediatric patients (1-3).

Related policies
Empaveli, Enspryng, Fabhalta, Ultomiris, Uplizna, Vyvgart

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Soliris and its biosimilars may be considered **medically necessary** if the conditions indicated below are met.

Soliris and its biosimilars may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)
    a. 18 years of age or older
    b. Documented baseline value for serum lactate dehydrogenase (LDH)
    c. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)
2. Atypical hemolytic uremic syndrome (aHUS)
    a. Documented baseline value for serum lactate dehydrogenase (LDH)
    b. Patient does **NOT** have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
    c. **NO** dual therapy with another Prior Authorization (PA) medication for aHUS (see Appendix 2)
3. Generalized myasthenia gravis (gMG)
    a. 6 years of age or older
    b. Positive serologic test for anti-AChR antibodies
    c. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
    d. Documented baseline score of **ONE** of the following:
        i. MG-Activities of Daily Living (MG-ADL) total score ≥ 6 (*http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf*)
        ii. Quantitative Myasthenia Gravis (QMG) total score > 9 *(https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf)*
    e. Patient has had an inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
        i. acetylcholinesterase inhibitor

ii. azathioprine
iii. cyclosporine
iv. mycophenolate mofetil
v. tacrolimus
vi. methotrexate
vii. cyclophosphamide

f. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for gMG (see Appendix 3)

4. Neuromyelitis optica spectrum disorder (NMOSD)
   a. 18 years of age or older
   b. Anti-aquaporin-4 (AQP4) antibody positive
   c. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for NMOSD (see Appendix 4)

AND ALL of the following:

a. Vaccination against Neisseria meningitidis at least 2 weeks prior to initiation [unless treatment cannot be delayed]
b. Prescriber is enrolled in the Soliris/biosimilar REMS program

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)
   a. 18 years of age or older
   b. Decrease in serum LDH from pretreatment baseline
   c. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)
2. Atypical hemolytic uremic syndrome (aHUS)
   a. Decrease in serum LDH from pretreatment baseline
   b. Patient does **NOT** have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
   c. **NO** dual therapy with another Prior Authorization (PA) medication for aHUS (see Appendix 2)
3. Generalized myasthenia gravis (gMG)
   a. 6 years of age or older
   b. Decrease of MG-ADL or QMG total score from baseline of ≥ 2 points

(http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf)
(https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf)

c. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for gMG (see Appendix 3)

4. Neuromyelitis optica spectrum disorder (NMOSD)
   a. 18 years of age or older
   b. Patient has had fewer relapses while on therapy
   c. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for NMOSD (see Appendix 4)

AND ALL of the following:

a. Absence of unacceptable toxicity from the drug
b. Prescriber is enrolled in the Soliris/biosimilar REMS program

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Soliris and its biosimilars are complement inhibitors indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). Soliris and its biosimilars include a boxed warning citing the risk of life-threatening and fatal meningococcal infections. Soliris and its biosimilars are not indicated for the treatment of patients with Shiga toxin E. coli- related hemolytic uremic syndrome (STEC-HUS). Soliris and its biosimilars are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). In addition, Soliris and its biosimilars have warnings regarding infusion-related reactions and using caution when administering to patients with any other

systemic meningococcal infections. The safety and effectiveness of Soliris and its biosimilars for the treatment of PNH and NMOSD in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Soliris and its biosimilars for the treatment of gMG in pediatric patients less than 6 years of age have not been established. The safety and effectiveness of Soliris and its biosimilars for the treatment of aHUS have been established in pediatric patients (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Soliris and its biosimilars while maintaining optimal therapeutic outcomes.

References

1. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2025.
2. Bkemv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
3. Epysqli [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2025.
4. Soliris. Drug Facts and Comparisons. eFacts [online]. Last updated 2022. Available from Wolters Kluwer Health, Inc.
5. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016; 87(4):419. Epub 2016 Jun 29.

Policy History

Date	Action
September 2011	New policy
January 2012	New FDA-approved diagnosis of aHUS added to criteria
September 2012	Annual editorial and reference update
March 2013	Annual editorial and reference update
March 2014	Annual review and reference update
March 2015	Annual review and reference update
December 2016	Annual editorial review and reference update Policy code changed from 5.10.11 to 5.85.11
September 2017	Annual editorial review and reference update
November 2017	Addition of myasthenia gravis (gMG) and renewal requirements Addition of documented baseline value for serum lactate dehydrogenase (LDH) and decrease of serum LDH from pretreatment baseline
March 2018	Annual review

August 2018	Removal of requirements: documented baseline value for serum lactate dehydrogenase (LDH) from initiation and decrease in serum LDH from pretreatment baseline from renewal for gMG
September 2018	Annual review and reference update
January 2019	Addition of requirement of no dual therapy with another terminal complement inhibitor such as Ultomiris to PNH indication
March 2019	Annual review
June 2019	Annual review
July 2019	Addition of indication: neuromyelitis optica spectrum disorder (NMOSD)
September 2019	Annual review
November 2019	Addition of aHUS requirement of no dual therapy with another terminal complement inhibitor such as Ultomiris and vaccination requirement is only necessary if Soliris treatment can be delayed
December 2019	Annual review
February 2020	Addition of Myasthenia Gravis requirement to t/f IVIG and an immunosuppressant per FEP
March 2020	Annual review
September 2020	Annual review
December 2020	Annual review
June 2021	Addition of Appendices 1 and 2. Updated no dual therapy requirements. MG-ADL link updated
September 2021	Annual review
March 2022	Annual review and reference update
May 2022	Moved requirement of no STEC-HUS under aHUS indication per PI. Added “generalized” to myasthenia gravis indication. MG-ADL link updated. Added no dual therapy with another PA C5 complement inhibitor for gMG and added Appendix 3
June 2022	Annual review
November 2022	Revised to align with BCBS association policy: removed initiation requirement of t/f of chronic IVIG, added t/f of acetylcholinesterase inhibitor, added continuation requirement that patient has had fewer relapses on treatment, revised continuation requirement to specify a ≥ 2 point drop in MG-ADL. Changed policy number to 5.85.011
March 2023	Annual review
June 2023	Annual review
September 2023	Annual review. Association policy alignment: removed gMG requirement for fewer relapses, changed duration of initial approval from 12 months to 6 months

December 2023	Annual review
March 2024	Annual review
April 2024	Added no dual therapy with another PA C5 compliment inhibitor for NMOSD and added Appendix 4
June 2024	Annual review
July 2024	Addition of biosimilar Bkemv
August 2024	Addition of biosimilar Epysqli
September 2024	Annual review
December 2024	Annual review and reference update
April 2025	Per PI update, decreased age for gMG to 6 years of age and older
June 2025	Annual review
September 2025	Annual review and reference update. Per SME, removed double step requirement to t/f immunosuppressive therapy and added QMG score as an optional gMG scoring tool

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.

Appendix 1 - List of PA Medications for PNH

Generic Name	Brand Name
eculizumab	Soliris
iptacopan	Fabhalta
pegcetacoplan	Empaveli
ravulizumab-cwvz	Ultomiris

Appendix 2 - List of PA Medications for aHUS

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris

Appendix 3 - List of PA C5 complement inhibitors for gMG

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris
zilucoplan	Zilbrysq

Appendix 4 - List of PA C5 complement inhibitors for NMOSD

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris