

SOLIRIS (eculizumab)
BKEMV* (eculizumab-aeeb)
EPYSQLI* (eculizumab-aagh)

*These medications are included in this policy but are not available on the market as of yet

Pre - PA Allowance

None

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 MG-Activities of Daily Living (MG-ADL) total score ≥ 6 (http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf)
 - e. Patient has had an inadequate treatment response, intolerance, or contraindication to an acetylcholinesterase inhibitor and at least **ONE** immunosuppressive therapy either in combination or as monotherapy, such as:
 - i. azathioprine
 - ii. cyclosporine
 - iii. mycophenolate mofetil
 - iv. tacrolimus

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- v. methotrexate
 - vi. 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 Limits

Duration 6 months

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)

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3. Generalized myasthenia gravis (gMG)
 - a. 6 years of age or older
 - b. Decrease of MG-ADL total score from baseline of ≥ 2 points
(http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.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

Prior – Approval *Renewal* Limits

Duration 12 months

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



**BlueCross.
BlueShield.**

Federal Employee Program.

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Appendix 3 - List of PA C5 complement inhibitors for gMG

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris

Appendix 4 - List of PA C5 complement inhibitors for NMOSD

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris