Medical Policy:

Eculizumab: Soliris, Bkemv, Epsyqli Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.105	March 31, 2025	October 2, 2019

Definitions

Eculizumab is a monoclonal antibody that binds with high affinity to compliment protein C5, which inhibits its cleavage to C5a and C5b and prevents the generation of the terminal complement complex C5b-9. In patients with paroxysmal nocturnal hemoglobinuria (PNH), eculizumab inhibits terminal complement mediated intravascular hemolysis and in patients with acquired hemolytic uremic syndrome, eculizumab inhibits complement-mediated thrombotic microangiopathy. The precise mechanism by which eculizumab exerts its therapeutic effect in neuromyelitis optica spectrum disorder (NMOSD) is unknown, but is presumed to involve inhibition of aquaporin-4-antibody induced terminal complement C5b-9 deposition

Length of Authorization

PNH and aHUS: Coverage will be provided for twelve months and may be renewed.

gMG and NMOSD: Initial coverage will be provided for 6 months and may be renewed annually thereafter.

Dosing Limits [Medical Benefit]

A. Max Units (per dose and over time):

Indication	Loading Doses	Maintenance Dose
PNH	60 billable units Days 1, 8, 15, & 22; then 90 billable units Day 29	90 billable units every 14 days
aHUS, gMG, NMOSD	90 billable units Days 1, 8, 15, & 22; then 120 billable units Day 29	120 billable units every 14 days

Guideline

I. INITIAL APPROVAL CRITERIA

****For Medicare members: Soliris- please refer to our separate LCD/NCD Medicare criteria**

Eculizumab must be requested by one of the following specialists:

- PNH – Hematologist; **OR**
- Atypical hemolytic uremic syndrome – Hematologist or Nephrologist; **AND**

- Patient does not have a systemic infection; **AND**
- Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of Eculizumab therapy or revaccinated according to current medical guidelines for vaccine use; **AND**
- Prescriber is enrolled in the Eculizumab Risk Evaluation and Mitigation Strategy (REMS) program; **AND**

Coverage is provided in the following conditions:

1. **Paroxysmal Nocturnal Hemoglobinuria (PNH) †**

   A. Patient is 18 years or older; **AND**

   B. Diagnosis must be accompanied by detection of PNH clones by flow cytometry diagnostic testing; **AND**

      i. Demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes); **AND**

   C. Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥1.5 x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):

      i. Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms

      ii. Presence of a thrombotic event related to PNH

      iii. Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension)

      iv. Patient is pregnant and potential benefit outweighs potential fetal risk

      v. Patient has disabling fatigue

      vi. Patient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; **AND**

D. Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement and history of thrombotic events

2. **Atypical Hemolytic Uremic Syndrome (aHUS) †**

A. Patient is 2 months or older; **AND**

B. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level > 10%); **AND**

C. Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); **AND**

D. Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**

E. Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), *Streptococcus pneumoniae* or Influenza A (H1N1) infection, or cobalamin deficiency; **AND**

F. Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement

3. **Generalized Myasthenia Gravis (gMG) †**

A. Patient is 18 years or older; **AND**

B. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; **AND**

C. Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**

D. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**

E. Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; **AND**

F. Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); **AND**

G. Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

4. **Neuromyelitis Optica Spectrum Disorder (NMOSD) †**

A. Patient is 18 years or older; **AND**

B. Submission of medical records (e.g. chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming **all** of the following; **AND**

C. Past medical history of **ONE** of the following:

i. Optic neuritis ; **OR**
ii. Acute myelitis ; **OR**
iii. Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting ; **OR**
iv. Acute brainstem syndrome; **OR**
v. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
vi. Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**

D. Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; **AND**
E. Diagnosis of multiple sclerosis or other diagnoses have been ruled out; **AND**
F. Patient has an Expanded Disability Status Score (EDSS) of ≤7.0 (.e. presence of at least limited ambulation with aid); **AND**
G. Patient is receiving concurrent corticosteroid therapy of 20mg per day or less and those receiving immunosuppressive therapy (e.g. azathioprine, glucocorticoids, mycophenolate etc.) are on a stable dose regimen; **AND**
H. Patient has not received therapy with rituximab or mitoxantrone in the last 3 months; **AND**
I. Patient has not received intravenous immune globulin (IVIG) in the last 3 weeks; **AND**
J. **One** of the following:
i. History of at least two relapses during the previous 12 months prior to initiating Eculizumab
ii. History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Eculizumab; **AND**
K. Eculizumab is initiated and titrated according to the US FDA labeled dosing for NMOSD, up to maximum of 1200mg every 2 weeks; **AND**
L. Prescribed by a neurologist

† FDA Approved Indication(s)

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet the criteria identified above; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, thrombotic microangiopathy complications (TMA), etc.; **AND**
3. Disease response indicated by one or more of the following**:**

A. **PNH**

i. Patient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) OR experienced a spontaneous disease remission OR received curative allogeneic stem cell transplant; **AND**

a. Decrease in serum LDH from pretreatment baseline
b. Stabilization/improvement in hemoglobin level from pretreatment baseline
c. Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

d. Reduction in thromboembolic events

B. **aHUS**

i. Decrease in serum LDH from pretreatment baseline

ii. Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline

iii. Increase in platelet count from pretreatment baseline

iv. Decrease in plasma exchange/infusion requirement from pretreatment baseline

C. **gMG**

i. Patient has had an improvement (i.e., reduction) of at least 1-point from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score [Δ]; **AND**

ii. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline

[Δ May substitute an improvement of at least 1-point from baseline in the Quantitative Myasthenia Gravis (QMG) total score, if available]

D. **NMOSD**

i. Patient has stabilization and/or improvement of neurologic symptoms as evidenced by a decrease in acute relapses, EDSS, hospitalizations, or plasma exchange treatment

III. DOSAGE/ADMINISTRATION

Indication	Dose*
Paroxysmal nocturnal hemoglobinuria (PNH)	Loading dose: – 600 mg intravenously every 7 days for the first 4 weeks, followed by 900 mg intravenously for the fifth dose 7 days later Maintenance dose: – 900 mg intravenously every 14 days
Atypical hemolytic uremic syndrome (aHUS)	**Adults** Loading dose: – 900 mg intravenously every 7 days for the first 4 weeks, followed by 1,200 mg intravenously for the fifth dose 7 days later Maintenance dose: – 1200 mg intravenously every 14 days **Patients < 18 years** 5 kg - <10 kg: – 300 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 3 weeks 10 kg - <20 kg: – 600 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 2 weeks 20 kg -<30 kg: – 600 mg weekly x 2 doses, 600 mg at week 3, then 600 mg every 2 weeks 30 kg - <40 kg: – 600 mg weekly x 2 doses, 900 mg at week 3, then 900 mg every 2 weeks ≥ 40 kg: – 900 mg weekly x 4 doses, 1200 mg at week 5, then 1200 mg every 2 weeks
Generalized Myasthenia Gravis (gMG) and Neuromyelitis Optica Spectrum Disorder (NMOSD)	Loading dose: – 900 mg intravenously every 7 days for the first 4 weeks, followed by 1,200 mg intravenously for the fifth dose 7 days later Maintenance dose: – 1200 mg intravenously every 14 days

Dose Adjustment for aHUS (adult and pediatric patients) and gMG (adult patients) in case of Plasmapheresis, Plasma Exchange or Fresh Frozen Plasma Infusion			
Type of Plasma Intervention	**Most Recent Eculizumab Dose**	**Supplemental Eculizumab With Each Plasma Intervention**	**Timing of Supplemental Eculizumab Dose**
Plasmapheresis or plasma exchange (PE)	300 mg	300 mg per each plasmapheresis or PE	Within 60 minutes after each plasmapheresis or PE
	≥ 600 mg	600 mg per each plasmapheresis or PE	
Fresh frozen plasma infusion (FFP)	≥ 300 mg	300 mg per each infusion of FFP	60 minutes prior to each infusion of FFP

Doses should be administered at the above intervals, or within two days of these time points.

Limitations/Exclusions

1. Eculizumab is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.
2. Patients with unresolved serious Neisseria meningitidis infection
3. Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying Eculizumab treatment outweigh the risks of developing a meningococcal infection.
4. Will not be used in combination with other immunomodulatory biologic therapies (e.g., efgartigimod, efgartigimod-hyaluronidase, ravulizumab, pegcetacoplan, satralizumab, tocilizumab, inebilizumab, rozanolixizumab, rituximab, zilucoplan, pozelimab, etc.) *[Note: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan]*

Applicable Procedure Codes

Code	Description
J1300	Injection, eculizumab, 10 mg
Q5139	Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg
Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg

Applicable NDCs

Code	Description
25682-0001-xx	Soliris 300 mg/30 mL single-use vials for injection
55513-0180-xx	Bkemv 300 mg/30 mL single dose vial for injection (Soliris Biosimilar)
51759-0208-XX	Epysqli 300 mg/30 mL single dose vial for injection

ICD-10 Diagnoses

Code	Description
D59.32	Hemolytic-uremic syndrome
D59.39	Other Hemolytic-Uremic Syndrome

D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis Optica Spectrum Disorder (NMOSD)
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/31/2025	Revision: Added Epysqli to policy.
EmblemHealth & ConnectiCare	03/25/2025	Revision: Added Bkemv to policy. NMOSD: Initial Criteria: Removed (and added reference under limitations/exclusions for all indications) "Patient is not receiving Soliris/Bkemv in combination with any of the following: Anti-CD20-directed antibody (e.g. rituximab); AND Anti-IL6 therapy (e.g., Actemra (tocilizumab), satralizumab); AND Anti-CD19-directed antibody (e.g. inebilizumab)" Renewal Criteria: PNH: Added: "Patient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) OR experienced a spontaneous disease remission OR received curative allogeneic stem cell transplant; AND" gMG: removed: "Improvement of at least 3-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; OR Improvement of at least 5-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score" Added: " Patient has had an improvement (i.e., reduction) of at least 1-point from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score [Δ]; AND Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline [Δ May substitute an improvement of at least 1-point from baseline in the Quantitative Myasthenia Gravis (QMG) total score, if available]" Limitations/Exclusions: Added: "Will not be used in combination with other immunomodulatory biologic therapies (e.g., efgartigimod, efgartigimod-hyaluronidase, ravulizumab, pegcetacoplan, satralizumab, tocilizumab, inebilizumab, rozanolixizumab, rituximab, zilucoplan, pozelimab, etc.) *[Note: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan"* Updated ICD-10 Codes
EmblemHealth & ConnectiCare	6/14/2024	Revision: Initial Criteria: NMOSD Removed: "History of failure of, contraindication, or intolerance to rituximab **OR** inebilizumab therapy; **AND "**
EmblemHealth & ConnectiCare	4/8/2024	Added Statement: **For Medicare members: Soliris- please refer to our separate LCD/NCD Medicare criteria
EmblemHealth & ConnectiCare	1/4/2024	Annual Review: Initial Criteria: Paroxysmal Nocturnal Hemoglobinuria (PNH) † Added: "Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥1.5 x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence): Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms, Presence of a thrombotic event related to PNH, Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension), Patient is pregnant and potential benefit outweighs potential fetal risk, Patient has disabling fatigue, Patient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; AND" Removed: "Patient has ONE of the following indications for therapy: Presence of a thrombotic event; OR Presence of organ damage secondary to chronic hemolysis,

		OR Patient is pregnant and potential benefit outweighs potential fetal risk, OR Patient has disabling fatigue; OR Patient has abdominal pain (requiring admission or opioid analgesics), dysphagia, or erectile dysfunction; AND" Added:" and history of thrombotic events" to the statement: Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement and history of thrombotic events Atypical Hemolytic Uremic Syndrome (aHUS) † Added: "Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); AND" Generalized Myasthenia Gravis (gMG) † Added: "Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); AND" Removed: "Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND" Added: "Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); AND" RENEWAL CRITERIA PNH Added: "Stabilization/improvement in hemoglobin level from pretreatment baseline" and "Reduction in thromboembolic events" NMOSD Added: "Patient has stabilization and/or improvement of neurologic symptoms as evidenced by a decrease in acute relapses, EDSS, hospitalizations, or plasma exchange treatment" Removed: "Reduction in the number and/or severity of relapses or signs and symptoms of NMOSD Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting Soliris. Note: Add on, dose escalation of IST, or additional rescue therapy will be considered as treatment and failure. AND Soliris is dosed according to the FDA labeled dosing for NMOSD: up to a maximum of 1200mg every 2 weeks; and Prescribed by a neurologist; and Patient is not receiving Soliris in combination with any of the following: Disease modifying therapies for the treatment of multiple sclerosis (e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.) Anti-IL6 therapy [e.g., Actemra (tocilizumab)] AND Reauthorization will be for no more than 12 months "
EmblemHealth & ConnectiCare	4/28/2023	Annual Review: PNH Initial Criteria- Removed: i. Patient is transfusion dependent ii.Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms Added: i. "Patient has disabling fatigue ii.Patient has abdominal pain (requiring admission or opioid analgesics), dysphagia, or erectile dysfunction" NMODS Initial Criteria- Removed: "Patient has not failed a previous course of Soliris therapy; AND" "A. Patient is not receiving Soliris in combination with any of the following: a.Disease modifying therapies for the treatment of multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.)" Added: "Patient has an Expanded Disability Status Score (EDSS) of ≤7.0 (.e. presence of at least limited ambulation with aid); AND" "Patient is receiving concurrent corticosteroid therapy of 20mg per day or less and those receiving immunosuppressive therapy (e.g. azathioprine, glucocorticoids, mycophenolate etc.) are on a stable dose regimen; AND"

		"Patient has not received therapy with rituximab or mitoxantrone in the last 3 months; AND" "Patient has not received intravenous immune globulin (IVIG) in the last 3 weeks; AND" "Anti-CD20-directed antibody (e.g. rituximab); AND Anti-CD19-directed antibody (e.g. inebilizumab)" Added "inebilizumab" to the statement History of failure of, contraindication, or intolerance to rituximab OR inebilizumab therapy;" PNH Renewal Criteria- Removed: " Stabilization/improvement in hemoglobin level from pretreatment baseline" gMG Renewal Criteria – Updated to add "OR" to the Statement "i. Improvement of at least 3-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; **OR** ii. Improvement of at least 5-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score"
EmblemHealth & ConnectiCare	1/12/2023	Transfer to New Template
EmblemHealth & ConnectiCare	04/16/2020	Added two contraindications to Limitations/Exclusions per FDA Label: 1. Patients with unresolved serious Neisseria meningitidis infection 2. Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection.
EmblemHealth & ConnectiCare	10/02/2019	Added the new indication for Neuromyelitis Optica Spectrum Disorder (NMOSD), added the criteria and it's diagnosis code G36.0

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