Eculizumab:
Soliris®; Bkemv™; Epysqli®
(Intravenous)

Document Number: IC-P0114

Last Review Date: 09/04/2025
Date of Origin: 06/21/2011
Dates Reviewed: 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 10/2017, 03/2018, 06/2018, 10/2018, 02/2019, 08/2019, 8/2020, 09/2020, 10/2021, 06/2022, 09/2023, 05/2024, 06/2024, 08/2024, 04/2025, 09/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Indication	Loading Doses	Maintenance Dose
PNH	300 billable units (600 mg) Days 1, 8, 15, & 22; then 450 billable units (900 mg) Day 29	450 billable units (900 mg) every 14 days
aHUS, gMG, NMOSD	450 billable units (900 mg) Days 1, 8, 15, & 22; then 600 billable units (1200 mg) Day 29	600 billable units (1200 mg) every 14 days

III. Initial Approval Criteria

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Preferred Target Agent(s)	Non-Preferred Target Agent(s)
Epysqli (eculizumab-aagh)	Soliris (eculizumab) Bkemv (eculizumab-aeeb)

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
  - The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:
    - The patient has a positive serological test for anti-AChR antibodies (medical records required); **AND**
    - The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
    - The patient has a MG-Activities of Daily Living total score of greater than or equal to 6; **AND**
    - ONE of the following:
      - The patient's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued; **OR**
      - Discontinuation of the offending agent is NOT clinically appropriate; **AND**
    - ONE of the following:
      - The patient has tried and had an inadequate response after at least a 1-year total trial to at least TWO immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) (either combination or monotherapy); **OR**
      - The patient has an intolerance or hypersensitivity to at least TWO immunosuppressive therapies; **OR**
      - The patient has tried and had an inadequate response after at least a 1-year total trial to treatment to at least ONE immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) AND ONE of the following:
        - The patient required chronic intravenous immunoglobulin (IVIG) (i.e., at least every 3 months over 12 months without symptom control); **OR**
        - The patient required chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control); **OR**
      - The patient has an intolerance or hypersensitivity to at least ONE immunosuppressant AND plasmapheresis/plasma exchange; **OR**
      - The patient has an FDA labeled contraindication to ALL immunosuppressive therapies and plasmapheresis/plasma exchange; **AND**
    - If the client has preferred agent(s), then ONE of the following:
      - The requested agent is a preferred agent; **OR**

- The requested agent is a non-preferred agent AND the patient has ONE of the following:
  - Tried and had an inadequate response to ONE of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **OR**
  - An intolerance or hypersensitivity to ONE of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **OR**
  - An FDA labeled contraindication to ALL of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **AND**
- The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **OR**

– The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) AND ALL of the following:
- The diagnosis was confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (lab tests required); **AND**
- If the client has preferred agent(s), then ONE of the following:
  - The requested agent is a preferred agent; **OR**
  - The requested agent is a non-preferred agent AND the patient has ONE of the following:
    - The patient has ONE of the following:
      - Tried and had an inadequate response to TWO of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), Empaveli (pegcetacoplan); **OR**
      - Tried and had an inadequate response to ONE preferred agent and an intolerance or hypersensitivity to ONE of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), Empaveli (pegcetacoplan); **OR**
      - An intolerance or hypersensitivity to TWO of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), Empaveli (pegcetacoplan); **OR**
    - The patient has an FDA labeled contraindication to ALL of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), Empaveli (pegcetacoplan); **OR**

        - The patient is currently treated with the requested agent (medical records including last date of infusion required); **AND**
    - The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Fabhalta (iptacopan), or Piasky (crovalimab-akkz); **OR**
- The patient has a diagnosis of atypical Hemolytic Uremic Syndrome (aHUS) AND ALL of the following:
    - The diagnosis was confirmed by ONE of the following: (medical records required)
        - Genetic mutation (e.g., *CFH, CD46, CFI, C3, CFB, THBD, CFHR1, CFHR3, CFHR5*); **OR**
        - Antibodies to complement factors; **OR**
        - A differential diagnosis of complement-mediated HUS has been demonstrated (i.e., screening for Shiga toxin-producing E. coli [STEC] for STEC-HUS, pneumococcal culture of blood/sputum/cerebrospinal or pleural fluid for pneumococcal-associated HUS, ADAMTS13 less than 10% activity for thrombotic thrombocytopenic purpura [TTP], screening for defective cobalamin metabolism); **AND**
    - The patient is negative for Shiga toxin-producing *E. coli* (STEC); **AND**
    - If the client has preferred agent(s), then ONE of the following:
        - The requested agent is a preferred agent ; **OR**
        - The requested agent is a non-preferred agent AND the patient has ONE of the following:
            - Tried and had an inadequate response to Ultomiris (ravulizumab-cwvz); **OR**
            - An intolerance or hypersensitivity to Ultomiris (ravulizumab-cwvz); **OR**
            - An FDA labeled contraindication to Ultomiris (ravulizumab-cwvz); **OR**
- The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND ALL of the following:
    - The patient is anti-aquaporin-4 (AQP4) antibody positive (lab test required); **AND**
    - The diagnosis was confirmed by at least ONE of the following:
        - Optic neuritis; **OR**
        - Acute myelitis; **OR**
        - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; **OR**
        - Acute brainstem syndrome; **OR**
        - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
        - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**
    - The patient has had at least ONE discrete clinical attack of CNS symptoms; **AND**
    - Alternative diagnoses (e.g., multiple sclerosis, ischemic optic neuropathy) have been ruled out; **AND**

- If the client has preferred agent(s), then ONE of the following:
  - The requested agent is a preferred agent; **OR**
  - The requested agent is a non-preferred agent AND the patient has ONE of the following:
    - Tried and had an inadequate response to ONE of the following preferred agent(s); Enspryng (satralizumab-mwge), Ultomiris (ravulizumab-cwvz), Uplizna (inebilizumab-cdon); **OR**
    - An intolerance or hypersensitivity to ONE of the following preferred agent(s); Enspryng (satralizumab-mwge), Ultomiris (ravulizumab-cwvz), Uplizna (inebilizumab-cdon); **OR**
    - An FDA labeled contraindication to ALL of the following preferred agent(s); Enspryng (satralizumab-mwge), Ultomiris (ravulizumab-cwvz), Uplizna (inebilizumab-cdon); **OR**
  - The patient has severe disease, and it has been determined that Enspryng (satralizumab-mwge), Ultomiris (ravulizumab-cwvz), AND Uplizna (inebilizumab-cdon) would NOT be clinically appropriate for the patient; **OR**
  - The patient is currently using the requested agent (medical records including last date of infusion required); **AND**
- The patient will NOT be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, or Uplizna (inebilizumab-cdon); **OR**

– The patient has another FDA labeled indication for the requested agent and route of administration; **AND**

- If the patient has an FDA labeled indication, then ONE of the following:
  - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
  - There is support for the use of the requested agent for the patient's age for the requested indication; **AND**
- The requested agent is a non-preferred agent AND the patient has ONE of the following:
  - Tried and had an inadequate response to ONE preferred agent; **OR**
  - An intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent; **OR**
  - An FDA labeled contraindication to ALL preferred agent(s) that is NOT expected to occur with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with Ultomiris (ravulizumab-cwvz), Soliris (eculizumab), Bkemv (eculizumab-aeeb), or Epysqli (eculizumab-aagh); **AND**

- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient was previously approved for the requested agent through the plan's Medical Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review); **AND**
- ONE of the following:
  - The patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND BOTH of the following:
    - The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement for RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase [LDH]) (medical records required); **AND**
    - The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Fabhalta (iptacopan), or Piasky (crovalimab-akkz); **OR**
  - The patient has a diagnosis of atypical hemolytic uremic syndrome (aHUS) AND BOTH of the following:
    - The patient has had improvements or stabilization with the requested agent (e.g., improved platelet count, reduction of lactate dehydrogenase [LDH], stabilization/improvement of renal function) (medical records required); **AND**
    - If the client has preferred agent(s), then ONE of the following:
      - The requested agent is a preferred agent; **OR**
      - The requested agent is a non-preferred agent AND the patient has ONE of the following:
        - Tried and had an inadequate response to Ultomiris (ravulizumab-cwvz); **OR**
        - An intolerance or hypersensitivity to Ultomiris (ravulizumab-cwvz); **OR**
        - An FDA labeled contraindication to Ultomiris (ravulizumab-cwvz); **OR**
  - The patient has a diagnosis of generalized myasthenia gravis (gMG) AND ALL of the following:
    - The patient has had improvements or stabilization with the requested agent (e.g., improved MG-ADL total score, improved quantitative myasthenia gravis total score) (medical records required); **AND**
    - If the client has preferred agent(s), then ONE of the following:
      - The requested agent is a preferred agent; **OR**
      - The requested agent is a non-preferred agent AND the patient has ONE of the following:

        - Tried and had an inadequate response to ONE of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **OR**
        - An intolerance or hypersensitivity to ONE of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **OR**
        - An FDA labeled contraindication to ALL of the following preferred agent(s); Ultomiris (ravulizumab-cwvz), Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc); **AND**
      - The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **OR**
    - The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND BOTH of the following:
      - The patient has had stabilization or improvement with the requested agent (e.g., decreased relapses, improvement or stabilization of vision or paralysis) (medical records required); **AND**
      - The patient will NOT be using the requested agent in combination with Enspryng (satralizumab-mwge), Rituximab, or Uplizna (inebilizumab-cdon); **OR**
    - The patient has a diagnosis other than PNH, aHUS, gMG, or NMOSD AND the patient has had improvements or stabilization with the requested agent (e.g., improvement or stabilization of symptoms) (medical records required); **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, hematologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The requested agent is a non-preferred agent AND the patient has ONE of the following:
  - Tried and had an inadequate response to ONE preferred agent; **OR**
  - An intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent; **OR**
  - An FDA labeled contraindication to ALL preferred agent(s) that is NOT expected to occur with the requested agent; **AND**
- The patient will NOT be using the requested agent in combination with Ultomiris (ravulizumab-cwvz), Soliris (eculizumab), Bkemv (eculizumab-aeeb), or Epysqli (eculizumab-aagh); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

V. 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 of age** 5 kg - <10 kg: – 300 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 3 weeks thereafter 10 kg - <20 kg: – 600 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 2 weeks thereafter 20 kg - <30 kg: – 600 mg weekly x 2 doses, 600 mg at week 3, then 600 mg every 2 weeks thereafter 30 kg - <40 kg: – 600 mg weekly x 2 doses, 900 mg at week 3, then 900 mg every 2 weeks thereafter ≥ 40 kg: – 900 mg weekly x 4 doses, 1200 mg at week 5, then 1200 mg every 2 weeks thereafter
Generalized Myasthenia Gravis (gMG)	**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 **Pediatric patients ≥ 6 years of age** 5 kg - <10 kg: – 300 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 3 weeks thereafter 10 kg - <20 kg: – 600 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 2 weeks thereafter 20 kg - <30 kg: – 600 mg weekly x 2 doses, 600 mg at week 3, then 600 mg every 2 weeks thereafter

	30 kg - <40 kg: – 600 mg weekly x 2 doses, 900 mg at week 3, then 900 mg every 2 weeks thereafter ≥ 40 kg: – 900 mg weekly x 4 doses, 1200 mg at week 5, then 1200 mg every 2 weeks thereafter
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
** Doses should be administered at the above intervals, or within two days of these time points. For supplemental dose therapy after plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion and intravenous immunoglobulin (IVIg), please refer to the eculizumab package insert for appropriate dosing.*	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1299 – Injection, eculizumab, 2mg; 1 billable unit = 2 mg *(Soliris ONLY)*
- Q5151 – Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg; 1 billable unit = 2 mg
- Q5152 – Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg; 1 billable unit = 2 mg

NDC(s):

- Soliris 300 mg/30 mL single-dose vial for injection: 25682-0001-xx
- Bkemv 300 mg/30 mL single dose vial for injection: 55513-0180-xx
- Epysqli 300 mg/30 mL single dose vial for injection: 71202-0010-xx

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD)

Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.32	Hereditary hemolytic-uremic syndrome
D59.39	Other hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis optica [Devic]
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A54548	National Government Services, Inc

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC