Eculizumab (Soliris, Epysqli, Bkemv) – PA Criteria

HCPC: J1299 eculizumab (Soliris), Q5151 eculizumab-aagh (Epysqli), Q5152 eculizumab-aeeb (Bkemv)

Preferred Products (clinical criteria only)	Non-Preferred Products
Epysqli (eculizumab-aagh)	Soliris (eculizumab)
	Bkemv (eculizumab-aeeb)

Eculizumab (Soliris, Epysqli, Bkemv) is a C5 Complement Inhibitor indicated for the treatment of anti-ACHR+ generalized myasthenia gravis (gMG), anti-AQP4 antibody positive Neuromyelitis Optica Spectrum Disorder (NMOSD), atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Claim is for a preferred product or individual has already stepped through a preferred product (≥3 month trial) unless otherwise specified per indication
  - Therapy meets the following criteria as specified per indication
    - For gMG **(must meet all)**:
      - Therapy is requested by or in consultation with a neurologist
      - Individual is ≥ 6 years of age (Soliris only for patients <18 years of age)
      - Individual has a documented diagnosis of gMG with labs confirming presence of anti-ACHR antibodies
      - Individual has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II-IV disease
      - Documentation is submitted indicating the patient's baseline Quantitative Myasthenia Gravis (QMG) score
      - MG-Activities of Daily Living (MG-ADL) total score of ≥6
      - Documentation is provided indicating inadequate response or contraindication to pyridostigmine and corticosteroids
      - Individual has failed treatment with at least 2 immunosuppressive therapies (ex., azathioprine, cyclosporine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus etc.) over the course of the last 12 months OR has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
      - Documentation is provided indicating previous failure, contraindication or intolerance to Efgartigimod alfa (Vyvgart) and Ravulizumab (Ultomiris)
      - Therapy is not prescribed in combination with other biologics for gMG (e.g. Ultomiris, Zilbrysq, Rystiggo, Vyvgart, Vyvgart Hytrulo, etc.)
      - Approval duration: 6 months
    - For NMOSD **(must meet all)**:
      - Requested therapy is for Soliris only
      - Therapy is requested by or in consultation with a neurologist
      - Individual is ≥18 years of age
      - Individual has a documented diagnosis of NMOSD with presence of seropositive aquaporin-4 (AQP4) antibodies
      - Individual has symptoms consistent with at least **one** core clinical characteristic below:
        - Optic neuritis
        - Acute myelitis

- Area postrema syndrome or episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy
- Acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

- Documentation is provided indicating previous failure, contraindication, or intolerance to **at least two** of the following therapies (with at least one of them being a C5 complement inhibitor):
  - Rituximab
  - Tocilizumab
  - Inebilizumab (Uplizna)
  - Satralizumab-mwge (Enspryng)
  - Ravulizumab (Ultomiris)
- Documentation is provided indicating at least 2 relapses in last 12 months or 3 relapses in the last 24 months with at least 1 relapse in the last 12 months
- Therapy is not being used in combination with other biologics for NMOSD (e.g. inebilizumab, rituximab, satralizumab, tocilizumab, etc.)
- Individual has an Expanded Disability Status Score (EDSS) score documented at baseline
- Approval duration: 6 months

- For aHUS **(must meet all)**:
- ***Retrospective authorization will be accepted for this medication when used for aHUS (when all below criteria are met) in efforts to prevent delay of care***
  - Therapy is requested by or in consultation with a hematologist or nephrologist
  - Individual has a documented diagnosis of aHUS that is not Shiga toxin E. coli related
  - Individual is ≥ 5 kg
  - Documentation is provided indicating baseline values for the following:
    - Serum lactate dehydrogenase (LDH)
    - Serum creatinine/eGFR
    - Platelet count
    - Frequency of plasma exchange/infusion requirement
  - Individual has documented failure or contraindication to Ravulizumab (Ultomiris)
  - Therapy is not prescribed in combination with other biologics for aHUS (e.g.Ultomiris)
  - Approval duration: 6 months
- For PNH **(must meet all)**:
  - Therapy is requested by or in consultation with a hematologist, oncologist, or immunologist
  - Individual is ≥ 18 years of age
  - Individual has a documented diagnosis of PNH confirmed by flow cytometry
  - Individual is transfusion dependent (requiring ≥ 4 transfusions in past 12 months) as a result of PNH and documentation is provided indicating the frequency of transfusions
  - Documentation is provided indicating baseline values for hemoglobin and lactate dehydrogenase (LDH)
  - Documentation of one or more of the following indicating systemic complications: abdominal pain, dysphagia/odynophagia, shortness of breath, chest pain/pressure, hemoglobinuria, end organ damage, thrombosis, etc.

- Documentation is provided indicating previous failure (≥3 months), contraindication, or intolerance to ravalizumab (Ultomiris)
- Therapy is not prescribed in combination with other biologics for PNH (e.g. Ultomiris, Piasky, Fabhalta, Empaveli)
- Approval duration: 6 months

- **Continuation of Therapy (must meet all):**
  - Therapy is not prescribed in combination with other biologics for the requested indication
  - Therapy meets the following criteria as specified per indication
    - For gMG renewal (must meet all):
      - Improvement (reduction in score) in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score from pretreatment baseline
      - Improvement in the Quantitative Myasthenia Gravis (QMG) total score
      - Approval duration: 1 year
    - For NMOSD renewal (must meet all):
      - Individual has had a positive clinical response with reduction in number and/or severity of relapses or signs and symptoms of NMOSD
      - Documentation is provided indicating recent (within 2 months) EDSS
      - Approval duration: 1 year
    - For aHUS renewal (must meet all):
      - Individual has had a positive clinical response as indicated by **one or more** of the following:
        - Decrease in serum LDH from pretreatment baseline
        - Stabilization/improvement in renal function (serum creatinine/eGFR) from pretreatment baseline
        - Increase in platelet count from pretreatment baseline
        - Decrease in plasma exchange/infusion requirement from pretreatment baseline
      - Approval duration: 1 year
    - For PNH renewal (must meet all):
      - Individual has had a positive clinical response as indicated by **one or more** of the following:
        - Stabilization or decrease in serum LDH from pretreatment baseline
        - Stabilization/improvement in hemoglobin level from pretreatment baseline
        - Decrease in packed RBC transfusion requirement from pretreatment baseline
      - Approval duration: 1 year