Pharmacy Drug Policy Checklist

POLICY NAME	Soliris (eculizumab)	POLICY #	1506P

Criteria

Coverage Criteria for the Treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH)

- ☐ **1.1** Diagnosis of PNH
- ☐ **1.2** Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Soliris REMS program
- ☐ **1.3** Age 18 years or older
- ☐ **1.4** Lab cultures rule out any unresolved serious Neisseria meningitidis infection, if patient was diagnosed with Neisseria meningitidis infection recently
- ☐ **1.5** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **1.6** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Soliris by both a pharmacist and medical director.

Coverage Criteria for the Treatment of atypical Hemolytic Uremic Syndrome (aHUS)

- ☐ **2.1** Diagnosis of aHUS with evidence of complement gene abnormality or factor antibodies
- ☐ **2.2** Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Soliris REMS program
- ☐ **2.3** Lab cultures rule out any unresolved serious Neisseria meningitidis infection, if patient was diagnosed with Neisseria meningitides recently
- ☐ **2.4** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **2.5** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Soliris by both a pharmacist and medical director

Coverage Criteria for the Treatment of Generalized Myasthenia Gravis (gMG)

- ☐

3.1 Documented diagnosis of generalized myasthenia gravis (gMG) as supported by the following:

- Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV
- Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score greater than or equal to 6

☐ **3.2** Documentation that patient is anti-acetylcholine (AchR)-antibody-positive

☐ **3.3** Prescribed by a neurologist (doctor of the nervous system) or physician specialized in the treatment of gMG in the Soliris REMS program

☐ **3.4** Age 18 years or older

☐ **3.5** Lab cultures rule out any unresolved serious Neisseria meningitidis infection if patient was diagnosed with N meningitides infection recently

☐ **3.6** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

☐ **3.7** Previous trial with at least 1 immunosuppressant (such as azathioprine, mycophenolate, cyclosporine, References methotrexate, etc)

☐ **3.8** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Soliris by both a pharmacist and medical director

Coverage Criteria for the Treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD)

☐ **4.1** Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) with chart notes indicating the member exhibits at least one of the core clinical characteristics:

- Optic neuritis (inflammation of optic nerve)
- Acute myelitis (a type of inflammation of the spinal cord)
- Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome (lesions of the brain stem causing symptoms such as dizziness, vertigo, headache, facial pain, vision disturbances)
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions (resulting from a rare type of central nervous system lesion)
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

☐ **4.2** Documentation that the patient is anti-aquaporin-4 (AQP4) antibody positive

☐ **4.3** Ordered by a neuro-ophthalmologist or specialist in the treatment of NMOSD in the Soliris REMS program

☐ **4.4** Age 18 years or older

☐ **4.5** Documentation that the member has been on a stable dose of immunosuppressive therapy (such as azathioprine, mycophenolate mofetil, oral corticosteroids, etc.)

☐ **4.6** Lab cultures rule out any unresolved serious Neisseria meningitides infection, if patient was diagnosed with N meningitidis infection recently

- [ ] **4.7** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- [ ] **4.8** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Soliris by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- [ ] **5.1** Patients with unresolved Neisseria meningitides infection
- [ ] **5.2** Patients who are not vaccinated against Neisseria meningitides (unless treatment cannot be delayed)
- [ ] **5.3** Not indicated for the treatment of patients with Shiga toxin Escherichia coli-related hemolytic uremic syndrome
- [ ] **5.4** Soliris cannot be used in combination with another terminal complement inhibitor, such as Ultomiris