Pharmacy Drug Policy & Procedure

Policy Name:	Soliris (eculizumab)	Policy #:	1506P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Soliris.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Soliris under the specialty medical benefit when the following criteria have been met.

Criteria

1. 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.

2. 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

3. 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,

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

4. 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

5. Exclusion Criteria

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

6. Approval Period

6.1 Initial Approval: 12 months

6.2 Reapproval: 12 months with documented improvement (e.g., improvement in hemolytic parameters and/or improvement in clinical symptoms)

HCPCS Codes	
J1300	Injection, eculizumab, 10mg (Soliris)
Q5139	Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg

References

1. Soliris (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals Inc; September 2024.
2. Hillmen P, Muus P, Dührsen U, et al. Effect of the complement inhibitor eculizumab on thromboembolism in patients with paroxysmal nocturnal hemoglobinuria. Blood. 2007;110:4123–4128.
3. Noris M, Remuzzi G. Atypical hemolytic-uremic syndrome. N Engl J Med. 2009;361:1676–87.

4. Sherman E, Han MH. Acute and Chronic Management of Neuromyelitis Optica Spectrum Disorder. Curr Treat Options Neurol 2015; 17:48.
5. Kessler, R.A., Mealy, M.A. & Levy, M. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Curr Treat Options Neurol 18, 2 (2016).
6. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021;96(3):114-122.

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