POLICY NAME Soliris (eculizumab) POLICY # 1506P

## Criteria

Coverage Criteria for the Treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH)		
	Diagnosis of PNH	
	Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Soliris REMS program	
	Age 18 years or older	
	Lab cultures rule out any unresolved serious Neisseria meningitidis infection, if patient was diagnosed with Neisseria meningitidis infection recently	
	Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)	
	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)		
(aHl		
(aHl		
(aHU	JS)	
(aHU	Diagnosis of aHUS with evidence of complement gene abnormality or factor antibodies  Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Soliris REMS	
(aHU	Diagnosis of aHUS with evidence of complement gene abnormality or factor antibodies  Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Soliris REMS program  Lab cultures rule out any unresolved serious Neisseria meningitidis infection, if patient was	

Coverage Criteria for the Treatment of Generalized Myasthenia Gravis (gMG)	
	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
	Documentation that patient is anti-acetylcholine (AchR)-antibody-positive
	Prescribed by a neurologist (doctor of the nervous system) or physician specialized in the treatment of gMG in the Soliris REMS program
	Age 18 years or older
	Lab cultures rule out any unresolved serious Neisseria meningitidis infection if patient was diagnosed with N meningitides infection recently
	Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
	Previous trial with at least 1 immunosuppressant (such as azathioprine, mycophenolate, cyclosporine, References methotrexate, etc)
	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
	erage Criteria for the Treatment of Neuromyelitis Optica Spectrum Disorder OSD)
	OSD)  Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) with chart notes indicating the member exhibits at least one of the core clinical characteristics:
	OSD)  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)
	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)
	OSD)  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)
	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,
	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)
	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
	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  Documentation that the patient is anti-aquaporin-4 (AQP4) antibody positive

(such as azathioprine, mycophenolate mofetil, oral corticosteroids, etc.)

diagnosed with N meningitidis infection recently

Lab cultures rule out any unresolved serious Neisseria meningitides infection, if patient was

	Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)		
	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		
Exc	Exclusion Criteria – Any of the following prevents coverage		
	Patients with unresolved Neisseria meningitides infection		
	Patients who are not vaccinated against Neisseria meningitides (unless treatment cannot be delayed)		
	Not indicated for the treatment of patients with Shiga toxin Escherichia coli-related hemolytic uremic syndrome		
	Soliris cannot be used in combination with another terminal complement inhibitor, such as Ultomiris		