GCHP Medi-Cal Clinical Guidelines
Eculizumab (Soliris™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy. • Refractory generalized myasthenia gravis (gMS) in adults who are anti-acetylcholine receptor antibody-positive (AChR+). • Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive. • Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Exclusion Criteria	• Unresolved serious Neisseria meningitides infection. • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome. • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative. • Use along with ravulizumab (Ultomiris™) or efgartigimodum alfa-fcab (Vyvgart™). • NMOSD negative AQP4-IgG.
Required Medical Information	**Initial:** • Vaccination against Neisseria meningitides at least two weeks prior to initiation (unless Soliris [eculizumab] treatment cannot be delayed), AND • **Atypical hemolytic uremic syndrome (aHUS)** ○ Documented baseline value for serum lactate dehydrogenase (LDH) AND ○ Has a body weight of at least 5 kg (or 11 lbs) AND ○ Does not have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) AND ○ Not on another terminal complement inhibitor such as Ultomiris (ravulizumab-cwvz). • **Generalized Myasthenia Gravis (gMG)** ○ Positive serologic test for anti-acetylcholine antibodies AND ○ Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV AND ○ Documented baseline MG-Activities of Daily Living (MG-ADL) total score greater than or equal to six AND ○ Inadequate treatment response, intolerance or contraindication to two or more immunosuppressants such as azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, methotrexate, etc. AND ○ Indequate treatment response, intolerance, or contraindication to chronic IVIG therapy.

	• **Neuromyelitis optica spectrum disorder (NMOSD)**
	  ○ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMOIgG antibodies.
	
	• **Paroxysmal nocturnal hemoglobinuria (PNH)**
	  ○ Documented baseline value for serum lactate dehydrogenase (LDH) AND
	  ○ Not on another terminal complement inhibitor such as Ultomiris (ravulizumab-cwvz).
	
	Renewal:
	Significant clinical response as evidenced by
	• **Paroxysmal nocturnal hemoglobinuria (PNH)** – Documentation of a reduction in serum LDH from pretreatment baseline.
	• **Atypical hemolytic uremic syndrome (aHUS)** – Documentation of a reduction in serum LDH from pretreatment baseline.
	• **Myasthenia Gravis (gMG)** – Documentation of reduction of (MG-ADL) total score from baseline.
	• **Neuromyelitis optica spectrum disorder (NMOSD)** – Patient has had fewer relapses while on eculizumab therapy.
	
	Off-label indications: 1) The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2) In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments, or b. There are no FDA-approved drug treatments for the diagnosis.

Age Restriction	aHUS: 2 months of age and older gMS, NMOSD, PNH: 18 years of age and older
Prescriber Restrictions	PNH: Hematologist aHUS: Nephrologist, Hematologist gMS: Neurologist NMOSD: Neurologist, Ophthalmologist *Prescribers must be enrolled in REMS*
Coverage Duration	Initial: Six months; Renewal: 12 months

Other Criteria / Information

Criteria adapted from DHCS March 2024

HCPCS	Description	Dosing, Units
J1300	Injection, eculizumab, 10mg (Soliris™)	**aHUS, gMS, NMOSD (≥ 18 yrs):** 900 mg IV qwk x four doses, then 1,200 mg for the fifth dose on week five, then 1,200 mg q2wks thereafter. **aHUS (≥ two months):** Weight / Induction dose / Maintenance dose ≥ 40kg: 900mg IV weekly x four / 1,200mg at week five then 1,200mg every two weeks 30 to < 40kg: 600mg IV weekly x two / 900mg at week three then 900mg every two weeks 20 to < 30kg: 600mg IV weekly x two / 600mg at week three then 600mg every two weeks 10 to < 20kg: 600mg IV weekly x one / 300mg at week two then 300mg every two weeks 5 to < 10kg: 300mg IV weekly x one / 300mg at week two then 300mg every three weeks **PNH**: 600 mg IV qwk x four doses, then 900 mg for the fifth dose on week five, then 900 mg q2wks thereafter.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025