Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	 September 23, 2011, June 13, 2012, November 23, 2015, November 14, 2017, July 31, 2019, June 10, 2021

SOLIRIS® (eculizumab)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

- Supporting documentation indicating a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) or atypical hemolytic uremic syndrome (aHUS).
  - Supporting documentation are diagnosis codes in claims medical history, progress notes, and/or discharge notes.
- The prescribing physician must be a hematologist for aHUS or PNH; **OR**
- Supporting documentation indicating a diagnosis of generalized myasthenia gravis (gMG) who are anti-aceytlcholine receptor positive.
- The prescribing physician must be a neurologist for gMG; **OR**
- Supporting documentation indicating a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) who are aquaporin-4 antibody positive.
- The prescribing physician must be a neurologist for NMOSD; **AND**
- Patient must have been vaccinated against meningococcal infection (*Nisseria meningitidis)*. If patient has not been previously vaccinated, then the patient must receive a meningococcal vaccination at least 2 weeks prior to first dose of Soliris®.
  - Verify vaccination via CPT codes in medical claims history, physician progress notes, or vaccination records.

CONTINUATION OF THERAPY:

- Patient has met initial review criteria.
- A clinical response is documented with therapy.

DOSING AND ADMINISTRATION:

- **Paroxysmal Nocturnal Hemoglobinuria (PNH) for patients 18 and older:**
  - 600mg weekly for the first 4 weeks, followed by 900mg for the fifth dose 1 week later, then 900mg every 2 weeks thereafter.
- **Generalized myasthenia gravis or Neuromyelitis optica spectrum disorder for patients 18 years and older:**
  - 900mg weekly for the first 4 weeks, followed by 1200mg for the fifth dose 1 week later, then 1200mg every 2 weeks thereafter.
- **Atypical hemolytic uremic syndrome for patients 18 and older**:
  - 900mg weekly for the first 4 weeks, followed by 1200mg for the fifth dose 1 week later, then 1200mg every 2 weeks thereafter.

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Dosing recommendations in atypical hemolytic uremic syndrome patients < 18 years of age:

Patient Body Weight	Induction	Maintenance
40kg and over	900mg weekly for 4 doses	1200 mg at week 5; then 1200mg every 2 weeks
30kg to < 40kg	600mg weekly for 2 doses	900mg at week 3; then 900mg every 2 weeks
20kg to < 30kg	600mg weekly for 2 doses	600mg at week 3; then 600mg every 2 weeks
10kg to < 20kg	600mg weekly for 1 dose	300mg at week 2; then 300mg every 2 weeks
5kg to < 10kg	300mg weekly for 1 dose	300mg at week 2; then 300mg every 3 weeks