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-acetylcholine 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.

DOSING AND ADMINISTRATION:

**Paroxysmal Nocturnal Hemoglobinuria 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.
### Dosing recommendations in atypical hemolytic uremic syndrome patients < 18 years of age:

<table>
<thead>
<tr>
<th>Patient Body Weight</th>
<th>Induction</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>40kg and over</td>
<td>900mg weekly for 4 doses</td>
<td>1200 mg at week 5; then 1200mg every 2 weeks</td>
</tr>
<tr>
<td>30kg to &lt; 40kg</td>
<td>600mg weekly for 2 doses</td>
<td>900mg at week 3; then 900mg every 2 weeks</td>
</tr>
<tr>
<td>20kg to &lt; 30kg</td>
<td>600mg weekly for 2 doses</td>
<td>600mg at week 3; then 600mg every 2 weeks</td>
</tr>
<tr>
<td>10kg to &lt; 20kg</td>
<td>600mg weekly for 1 dose</td>
<td>300mg at week 2; then 300mg every 2 weeks</td>
</tr>
<tr>
<td>5kg to &lt; 10kg</td>
<td>300mg weekly for 1 dose</td>
<td>300mg at week 2; then 300mg every 3 weeks</td>
</tr>
</tbody>
</table>