# Eculizumab (Soliris®)

**Goal(s):**

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Eculizumab is approved by the FDA for the following indications:
  - Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-AQP4-IgG-antibody positive
  - Reducing hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)
  - Inhibiting complement-mediated thrombotic microangiopathy in patients with atypical hemolytic uremic syndrome (aHUS)
  - Treatment of generalized myasthenia gravis (MG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- Soliris® (eculizumab) pharmacy and physician administered claims

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; not funded by the OHP. |
| 3. Is this request for continuation of therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Has the patient been vaccinated against *Streptococcus pneumoniae, Haemophilus influenzae* type B, and *Neisseria meningitidis serogroups A, C, W, and Y and serogroup B* according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies?<br><br>Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy. | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the diagnosis one of the following:<br>• Neuromyelitis Optica Spectrum Disorder (NMOSD) in an adult who is anti-aquaporin-4 (AQP4) antibody positive,<br>• Paroxysmal Nocturnal Hemoglobinuria (PNH),<br>OR<br>• atypical Hemolytic Uremic Syndrome (aHUS)? (Note: Eculizumab is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). | **Yes:** Go to #6 | **No:** Go to #7 |
| 6. Does the requested dosing align with the FDA- approved dosing (**Table 1**)? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the request for a diagnosis of myasthenia gravis in an adult patient who is ACh Receptor (AChR) antibody-positive? | **Yes:** Go to # 8 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Has the patient tried:<br>• at least 2 or more immunosuppressant therapies (e.g., glucocorticoids in combination with azathioprine or mycophenolate mofetil or cyclosporine or tacrolimus or methotrexate or rituximab) for 12 months without symptom control<br>OR<br>• at least 1 or more nonsteroidal immunosuppressant with maintenance intravenous immunoglobulin once monthly or plasma exchange therapy (PLEX) over 12 months without symptom control? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there objective documentation of treatment benefit from baseline?<br><br>Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom control or improvement, functional improvement, etc.). | **Yes:** Approve for 12 months<br><br>Document baseline assessment and physician attestation received. | **No:** Pass to RPh. Deny; medical appropriateness |

**Table 1. FDA-Approved Indications and Dosing for Eculizumab[1]**

| | Eculizumab (Soliris®) | | |
|---|---|---|---|
| **FDA-approved Indications** | • Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-AQP4-IgG-antibody<br>• Reducing hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)<br>• Inhibiting complement-mediated thrombotic microangiopathy in patients with atypical hemolytic uremic syndrome (aHUS)<br>• Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive | | |
| **Recommended NMOSD dose in patients 18 yo and older** | 900 mg IV every week x 4 weeks, followed by<br>1200 mg IV for the fifth dose 1 week later, then<br>1200 mg IV every 2 weeks thereafter | | |
| **Recommended PNH dose in patients 18 yo and older** | 600 mg IV every week x 4 weeks, followed by<br>900 mg IV for the fifth dose 1 week later, then<br>900 mg IV every 2 weeks thereafter | | |
| **Recommended aHUS dose in patients less than 18 yo** | **Body Weight**<br>5 kg to 9 kg | **Induction Dose**<br>300 mg weekly x 1 dose | **Maintenance Dose** |

| | | | |
|---|---|---|---|
| | 10 kg to 19 kg<br>20 kg to 29 kg<br>30 kg to 39 kg<br>≥ 40 kg | 600 mg weekly x 1 dose<br>600 mg weekly x 2 doses<br>600 mg weekly x 2 doses<br>900 mg weekly x 4 doses | 300 mg at week 2; then 300mg every 3 weeks<br>300 mg at week 2; then 300mg every 2 weeks<br>600 mg at week 3; then 600mg every 2 weeks<br>900 mg at week 3; then 900 mg every 2 weeks<br>1200 mg at week 5; then 1200 mg every 2 weeks |
| **Recommended aHUS dose in patients 18 yo and older** | 900 mg IV every week x 4 weeks, followed by 1200 mg IV for the fifth dose 1 week later, then 1200 mg IV every 2 weeks thereafter | | |
| **Recommended generalized MG dose** | 900 mg IV every week x 4 weeks, followed by 1200 mg IV for the fifth dose 1 week later, then 1200 mg IV every 2 weeks thereafter | | |
| **Dose Adjustment in Case of Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion** | Dependent on most recent eculizumab dose: refer to prescribing information for appropriate dosing (300 mg to 600 mg) | | |

1. Soliris (eculizumab) Solution for Injection Prescribing Information. Boston, MA: Alexion Pharmaceuticals, Inc. 11/2020.

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*P&T/DUR Review:12/21; 4/21 (DM)*
*Implementation: 5/1/21*