**PHARMACY POLICY STATEMENT**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Soliris (eculizumab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J1300</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (non-preferred product)</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
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</tbody>
</table>

Soliris (eculizumab) is a non-preferred product and will only be considered for coverage under the medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)**

**For initial authorization:**

1. Medication is prescribed by or in consultation with a hematologist or nephrologist; AND
2. Member has a diagnosis of aHUS supported by ALL of the following:
   a) Thrombocytopenia (platelet count < 150 x 10⁹/L),
   b) Evidence of hemolysis i.e. elevated lactate dehydrogenase (LDH), low haptoglobin count, or presence of fragmented red blood cells or schistocytes on blood smear,
   c) Evidence of renal impairment (e.g. raised SCr or low eGFR); AND
3. Shiga toxin-producing E. coli related HUS (STEC-HUS) has been ruled out; AND
4. ADAMTS13 activity level is > 5% (to rule out TTP); AND
5. Member has tried and failed or is unable to try Ultomiris; AND
6. Member has received meningococcal vaccine.

7. **Dosage allowed:**
   - Pediatrics: See weight-based dosing in package insert.
   - Adults: 900mg weekly x 4 weeks, then 1200mg 1 week later, then 1200mg every 2 weeks thereafter.

   *If member meets all the requirements listed above, the medication will be approved for 6 months.*

**For reauthorization:**

1. Chart notes must demonstrate hematologic normalization as evidenced by increased platelet count or LDH maintained below upper limit of normal; AND
2. Improved or preserved kidney function.

   *If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

**GENERALIZED MYASTHENIA GRAVIS (gMG)**
For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of severe, refractory gMG with documentation of positive serologic test for anti-AChR antibodies\(^25\); AND
4. Member has tried and failed one of the following (unless contraindicated or intolerable):
   i) Corticosteroid and at least 2 other immunosuppressive therapies\(^24\) (e.g. azathioprine [first line], cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) over 1 year or more\(^15\) (total); OR
   ii) At least 1 immunosuppressive therapy and has required plasmapheresis or plasma exchange or intravenous immunoglobulin (IVIG) at least every 3 months over the past year\(^15\); AND
5. Member has received meningococcal vaccine.
6. **Dosage allowed:** 900 mg IV weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

*If member meets all the requirements listed above, the medication will be approved for 6 months.*

For **reauthorization**:
1. Chart notes must demonstrate improvement in activities of daily living, muscle strength, and/or health-related quality of life; fewer exacerbations or hospitalizations, or reduced use of rescue medication.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

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**NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD)**

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of NMOSD and is seropositive for aquaporin-4 (AQP4) IgG antibodies (documentation required); AND
4. Member had had 1 or more relapses within the past year; AND
5. Member has tried and failed at least one of the following for 6 months or longer: azathioprine, mycophenolate, rituximab\(^19,20,21\) (requires prior auth); AND
6. Member has tried and failed Enspryng (requires prior auth) for at least 6 months or has contraindication; AND
7. Member has received meningococcal vaccine.
8. **Dosage allowed:** 900 mg IV weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

*If member meets all the requirements listed above, the medication will be approved for 6 months.*

For **reauthorization**:
1. Chart notes must document disease stabilization, symptom improvement, and/or reduced frequency of relapses.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*
PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

For initial authorization:
1. Member is 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a hematologist; AND
3. Member has a diagnosis of PNH as confirmed by flow cytometry; AND
4. Member has a lactate dehydrogenase (LDH) level >1.5x upper limit of normal (ULN); AND
5. Member has tried and failed or is unable to try Ultomiris; AND
6. Member has received meningococcal vaccine.

7. **Dosage allowed:** 600mg weekly x 4 weeks, then 900mg 1 week later, then 900mg every 2 weeks thereafter.

*If member meets all the requirements listed above, the medication will be approved for 6 months.*

For reauthorization:
1. Clinical evidence of positive response to therapy such as increased hemoglobin level, decreased need for transfusions, normalized LDH levels, improved fatigue.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

CareSource considers Soliris (eculizumab) not medically necessary for the treatment of diseases that are not listed in this document.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>11/14/2017</td>
<td>New policy for Soliris created.</td>
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<tr>
<td>10/26/2019</td>
<td>New diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) added.</td>
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<tr>
<td>10/15/2020</td>
<td>Revised criteria for NMOSD to align with other products. Only require at least 1 relapse in past year. Added trial of a standard therapy. Added trial of Enspryng. Rewarded the criteria for meningitis vaccine. Removed the part about stable immunosuppressive therapy (just assessed for study purpose). Removed restrictions on prior Rituxan, mitoxantrone, IVIG (only applicable to the study design). Changed initial auth duration to 6 months. Edited the renewal criteria to be more appropriate. Also corrected the dose information error. Changed to non-preferred drug status.</td>
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<tr>
<td>02/08/2021</td>
<td>gMG: Updated references. Added specialist requirement. Removed MG-ADL score. Amended prerequisite drugs to more closely match guidelines and literature. Removed clinical trial exclusion criteria. Reduced initial auth duration to 6 months. Revised renewal criteria.</td>
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References:


Effective date: 01/01/2022
Revised date: 06/02/2021