Soliris (eculizumab) is a 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. Member has diagnosis of aHUS supported by the absence of Shiga toxin-producing E. coli infection and with ADAMTS13 activity level >5% documented in chart notes; AND
2. Member has ALL of the following documented in chart notes:
   a) Platelet count ≤150 x 10^9/L;
   b) Evidence of hemolysis (e.g., an elevation in serum Lactic Acid Dehydrogenase (LDH));
   c) Serum creatinine above the upper limits of normal, without the need for chronic dialysis; AND
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); AND
4. Member does not have ANY of the following:
   a) History of malignancy within 5 years;
   b) HIV;
   c) Infection-related or identified drug exposure-related hemolytic-uremic syndrome (HUS);
   d) HUS related to bone marrow transplant (BMT) or to vitamin B12 deficiency;
   e) Systemic Lupus Erythematosus (SLE) or antiphospholipid antibody positivity or syndrome;
   f) Member is on chronic intravenous immunoglobulin (IVIG) within 8 weeks or chronic Rituximab therapy within 12 weeks.
5. Dosage allowed: 3,600 mg/28 days for initial fill, then 2,400 mg/28 days for subsequent fills.

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

For reauthorization:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has an increase in mean platelet counts from baseline and signs of complement-mediated thrombotic microangiopathy (TMA) activity were reduced with Soliris (eculizumab) therapy.

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 with diagnosis of gMG as confirmed by ALL of the following criteria documented in chart notes:
   a) Positive serologic test for anti-AChR antibodies;
   b) MG-Activities of Daily Living (MG-ADL) total score ≥ 6;
   c) Failed treatment with any **one** of the following:
      i) At least 2 immunosuppressive therapies (e.g. corticosteroid, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) over 1 year or more; **OR**
      ii) At least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); **AND**
2. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); **AND**
3. Member does **not** have a history of thymectomy (within the past 2 months) or thymus cancer; **AND**
4. Member did **not** use:
   a) Rituximab within 6 months prior to therapy; **OR**
   b) IVIG or PE within 4 weeks prior to therapy.
5. **Dosage allowed:** 900 mg 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 12 months.*

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; **AND**
2. Chart notes have been provided that show the member is stable or has shown improvement in MG-ADL score while on Soliris (eculizumab) therapy.

*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 with diagnosis of PNH as confirmed by flow cytometry (PNH type III red cells or GPI-AP-deficient polymorphonuclear cells (PMNs)); **AND**
2. Medication is prescribed by a hematologist or nephrologist; **AND**
3. Member has received vaccination against Neisseria meningitidis (i.e. Menactra®, Menveo®, MenHibrix®); **AND**
4. Member has **LDH** levels >1.5 times the upper limit of normal documented in chart notes; **AND**
5. Member has **one** or more of the following documented in chart notes:
   a) History of at least 1 blood transfusion within the past 24 months due to anemia or anemia related symptoms or personal beliefs precluding transfusion;
   b) Presence of organ damage due to chronic hemolysis.
6. **Dosage allowed:** 2,400 mg/28 days for initial fill then 1,800 mg/28 days for subsequent fills.

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

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; **AND**
2. Chart notes have been provided that show the member is stable or has shown improvement on Soliris (eculizumab) therapy.

*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 the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

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<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tr>
<td>11/14/2017</td>
<td>New policy for Soliris created.</td>
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References: