Pharmacy Medical Necessity Guidelines: Soliris® (eculizumab)

Effective: August 7, 2018

Prior Authorization Required: √

<table>
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<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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<td>MED Department to Review</td>
<td>MM/ PRECERT</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
- All plans except Tufts Health Public Plans: Precert: 617.972.9409
- Tufts Health Public Plans: MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Soliris (eculizumab) is a complement inhibitor indicated for the treatment of:

- **Paroxysmal Nocturnal Hemoglobinuria (PNH)**
  - Patients with PNH to reduce hemolysis

- **Atypical Hemolytic Uremic Syndrome (aHUS)**
  - Patients with aHUS to inhibit complement-mediated thrombotic microangiopathy. Soliris is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome

- **Generalized Myasthenia Gravis (gMG)**
  - Adult patients with gMG who are anti-acetylcholine receptor antibody positive

**COVERAGE GUIDELINES**

The plan may authorize coverage of Soliris (eculizumab) for Members when all of the following criteria are met:

**Paroxysmal Nocturnal Hemoglobinuria (PNH)**

1. Documented diagnosis of paroxysmal nocturnal hemoglobinuria
2. The prescribing physician is a hematologist or nephrologist
3. The Member has been vaccinated against meningococcal infection (at least 2 weeks prior to eculizumab treatment, if not previously vaccinated)

**Dosing Recommendations:**

- Initial: 600 mg intravenously (IV) once weekly (±2 days) for 4 weeks, followed by 900 mg IV for 1 week (±2 days) later
- Maintenance: 900 mg every 2 weeks (±2 days) thereafter

**Atypical Hemolytic Uremic Syndrome (aHUS)**

1. Documented diagnosis of atypical hemolytic uremic syndrome
2. The prescribing physician is a hematologist or nephrologist
3. The Member has been vaccinated against meningococcal infection (at least 2 weeks prior to eculizumab treatment, if not previously vaccinated)
**Generalized Myasthenia Gravis (gMG)**

1. Documented diagnosis of generalized myasthenia gravis  
   **AND**
2. Documentation of a positive serologic test for anti-acetylcholine antibodies  
   **AND**
3. Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis  
   **AND**
4. Documentation of a Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6  
   **AND**
5. The prescribing physician is a neurologist  
   **AND**
6. Documentation of at least one of the following:
   a. At least a 12 month previous trial of two or more immunosuppressive therapies (either in combination or as monotherapy) (e.g., azathioprine, cyclophosphamide, methotrexate)
   b. Previous trial of one immunosuppressive therapy with required chronic plasmapheresis, plasma exchange, or intravenous immunoglobulin  
   **AND**
7. The Member has been vaccinated against meningococcal infection (at least 2 weeks prior to eculizumab treatment, if not previously vaccinated)

**LIMITATIONS**

1. Soliris (eculizumab) will not be approved for other types of hemolytic uremic syndrome including Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
2. For the diagnosis of generalized myasthenia gravis, initial approval of Soliris (eculizumab) will be authorized for 6 months. Subsequent 12 month authorizations will require documentation from a neurologist of a decrease in the MG-ADL total score from baseline.

**CODES**
The following HCPCS/CPT code(s) are:

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<thead>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>J1300</td>
<td>Injection, eculizumab, 10 mg</td>
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**REFERENCES**


**APPROVAL HISTORY**

November 13, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 11, 2008: No changes
- November 10, 2009: No changes
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
- September 14, 2010: No changes
- September 13, 2011: No changes
- November 15, 2011: Added coverage guidelines for atypical Hemolytic Uremic Syndrome
- February 14, 2012: Added nephrologist to prescribing specialists
- January 15, 2013: No changes
- November 5, 2013: No changes
- November 4, 2014: No changes
- November 10, 2015: No changes
- January 1, 2016: Administrative change to rebranded template
- April 12, 2016: Effective 10/1/2016, MNG applies to Tufts Health Together.
- December 12, 2017: Updated Medical Necessity Guidelines to include coverage criteria for the new indication myasthenia gravis.
- August 7, 2018: No changes

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.