Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Eculizumab

<table>
<thead>
<tr>
<th>MNG #: 020</th>
<th>☒ SCO ☒ One Care</th>
<th>Prior Authorization Needed? ☒ Yes ☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical:  ☒</td>
<td>Operational: ☒</td>
<td>Informational: ☐</td>
</tr>
<tr>
<td>Medicare Benefit: ☒ Yes ☐ No</td>
<td>Approval Date: 06/06/2019</td>
<td>Effective Date: 09/15/2019</td>
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<tr>
<td>Last Revised Date: 3/26/2020</td>
<td>Next Annual Review Date: 06/06/2020, 3/26/2021</td>
<td>Retire Date:</td>
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OVERVIEW:
Eculizumab (Soliris) is a complement inhibitor approved by the FDA to treat Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Myasthenia Gravis (gMG), and Paroxysmal Nocturnal Hemoglobinuria (PNH).

Ravulizumab-cwvz (Ultomiris) is a complement inhibitor approved by the FDA for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH).

CCA will cover Eculizumab (Soliris) for aHUS and gMG according to the following criteria:

DECISION GUIDELINES:
Clinical Coverage Criteria:

CCA will cover Eculizumab (Soliris) for aHUS and gMG according to the following decision guidelines:

I. **Atypical Hemolytic Uremic Syndrome (aHUS)**
1. Documented diagnosis of atypical hemolytic uremic syndrome
   AND
2. The prescribing physician is a hematologist or nephrologist
   AND
3. The Member has been vaccinated against meningococcal infection (at least 2 weeks prior to eculizumab treatment, if not previously vaccinated).

OR

II. **Generalized Myasthenia Gravis (gMG)**
1. Documented diagnosis of generalized myasthenia gravis
   AND
2. Documentation of a positive serologic test for anti-acetylcholine antibodies
   AND
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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)
   OR
   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)

CCA will cover either eculizumab (Soliris) or Ravulizumab-cwvz (Ultromiris) for PNH according to the following criteria:

1. Documented diagnosis of paroxysmal nocturnal hemoglobinuria

AND

2. The prescribing physician is a hematologist or nephrologist

AND

3. The Member has been vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated).

Note that for all above criteria that specify a specialty, the PCP may prescribe the agent AS LONG AS there is documentation of the active, regular involvement of the appropriate specialist, as documented by up to date office notes or equivalent.

Disclaimer:
This Medical Necessity Guideline is not a rigid rule. As with all of CCA’s criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science.
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indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member’s unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member’s unique clinical circumstances will generally be required.

ATTACHMENTS:

EXHIBIT A:

EXHIBIT B

REVISION LOG:

<table>
<thead>
<tr>
<th>REVISION DATE</th>
<th>DESCRIPTION</th>
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<tr>
<td>06/06/19</td>
<td>MNG reviewed and passed by the Medical Policy Committee</td>
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<tr>
<td>3/26/2020</td>
<td>KH Staff reviewed document and update format,</td>
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APPROVALS:

Stefan Topolski, MD  
CCA Senior Clinical Lead [Print]

Signature  
3/26/2020  
Date

Lori Tishler, MD  
CCA CMO or Designee [Print]

Signature  
06/06/2019  
Date

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