Field Name	Field Description
Prior Authorization Group Description	Complement Inhibitors
Drugs	Soliris (eculizumab), Ultomiris (ravulizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • The patient has a confirmed diagnosis that is indicated in the FDA approved package insert OR is a medically-accepted indication; AND • The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; AND • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age and concomitant medical conditions; AND • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; AND • Antimicrobial prophylaxis with oral antibiotics for two weeks will be administered if vaccine is administered less than two weeks before starting Soliris/Ultomiris therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis. **Generalized Myasthenia Gravis (gMG):**

Revision/Review Date 6/2021	• **The request is for Soliris (eculizumab)**
	  o **If the request is for Ultomiris (ravulizumab), do not approve, not indicated for gMG**
	• **Patient has a positive serologic test for anti-AChR antibodies; AND**
	• **Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II,III or IV at initiation of therapy; AND**
	• **Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; AND**
	• **One of the following:**
	  o **Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; OR**
	  o **Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; OR**
	  o **Has a documented history of contraindications or intolerance to ISTs**
	
	Neuromyelitis Optica Spectrum Disorder (NMOSD)
	• **If the request is for Soliris (eculizumab)**
	  o **Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy**
	• **If the request is for Ultomiris (ravulizumab), do not approve; not indicated for NMOSD**
	
	Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)
	• **Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; OR**
	• **Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient**
	
	Re-Authorization:
	• **Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, reduced need for blood transfusions); AND**
	• **The request is for an FDA approved dose; AND**
	• **If the request is for aHUS/Complement Mediated HUS**

	o **Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**