Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection) , Izervay (avacincaptad pegol injection)
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, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the criteria will be approved as follows: For Soliris (eculizumab), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan): initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. For Syfovre (pegcetacoplan injections): initial and reauthorization requests will be approved for up to 12 months. For Izervay (avacincaptad pegol injection): initial request will be approved for up to 12 month duration with no reauthorization
Other Criteria	**Initial Authorization:** • 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** • For Soliris (eculizumab), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan) o Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; **AND** o Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.

	Paroxysmal Nocturnal Hemoglobinuria (PNH): • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL • If the request is for Empaveli (pegcetacoplan), documented trial and failure of, contraindication to, or medical reason for not using Soliris (eculizumab) or Ultomiris (ravulizumab) **Generalized Myasthenia Gravis (gMG):** • Refer to the "Myasthenia Gravis Agents" policy **Neuromyelitis Optica Spectrum Disorder (NMOSD)** • Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy **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 **Geographic Atrophy (GA):** • If the request is for Syfovre (pegcetacoplan injection), member must be ≥ 60 years of age • If the request is for Izervay (avacincaptad pegol injection), member must be ≥ 50 years of age • Diagnosis of GA secondary to age-related macular degeneration (AMD) • Absence of choroidal neovascularization (CNV) in treated eye • Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size ≥ 2.5 and ≤ 17.5 mm^2 with at least 1 lesion ≥ 1.25 mm^2 **<u>Re-Authorization:</u>** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • 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,

Revision/Review Date 10/2023	slowing of growth rate of GA lesions, etc.); **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 condition; **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.**