Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	**Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection), Fabhalta (iptacopan), Voydeya (danicopan), 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	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, criteria will be approved as follows: **Initial Requests** • **3 months:** • ~~For~~ Soliris (eculizumab), Ultomiris (ravulizumab), ~~and Empaveli (pegcetacoplan): the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months.~~ • **6 months: Fabhalta (iptacopan)** • **12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol)** **Reauthorization** • **6 months: Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan)** • **12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan)** **No Reauthorization** • **Izervay (avacincaptad pegol)** ~~For Syfovre (pegcetacoplan injection): initial and reauthorization requests will be approved for up to 12 months~~ ~~For Fabhalta (iptacopan): initial request will be approved for up to a 6 month duration; reauthorization requests will be approved for up 12 months~~
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • 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**

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	• For Fabhalta (iptacopan), Soliris (eculizumab), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan**), and Voydeya (danicopan)**
	  ○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.
	
	Paroxysmal Nocturnal Hemoglobinuria (PNH):
	• Documentation of diagnosis by high sensitivity flow cytometry
	• Hemoglobin (Hgb) < 10.5 g/dL for Empaveli (pegcetacoplan), or HgB < 10 g/dL for Fabhalta (iptacopan)
	• **For Voydeya (danicopan):**
	  ○ **Member has been receiving Soliris (eculizumab) or Ultomiris (ravulizumab) therapy for at least 6 months**
	  ○ **Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10^9/liter] despite treatment with Soliris (eculizumab) or Ultomiris (ravulizumab)**
	  ○ **Voydeya (danicopan) will be used as add-on therapy to Soliris (eculizumab) or Ultomiris (ravulizumab)**
	
	Generalized Myasthenia Gravis (gMG):
	• The request is for Soliris (eculizumab) or Ultomiris (ravulizumab)
	• 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:
	  ○ Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR**
	  ○ Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR**
	  ○ Has a documented history of contraindications or intolerance to ISTs
	
	Neuromyelitis Optica Spectrum Disorder (NMOSD)

Revision/Review Date **7/2024** ~~4/2024~~	• 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** ~~≥ 60 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) ≥ 24 letters 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 **Re-Authorization:** • **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, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lessions, 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.**