

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Ultomiris is a complement inhibitor indicated for the treatment of multiple indications involving the complement system including neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive, generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor antibody-positive (AChR-Ab+), atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH).
Exclusion Criteria	None.
Required Medical Information	<p>For neuromyelitis optica spectrum disorder (NMOSD):</p> <ol style="list-style-type: none"> 1. Patient has anti-aquaporin-4 (AQP4) antibody positive disease; 2. Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions; 3. Ultomiris will not be used in combination with Soliris, Uplizna, Enspryng, or other medications for NMOSD; 4. Must have an Expanded Disability Status Scale (EDSS) score of ≤ 7; Medical records supporting the request must be provided; <p>For reauthorization: Ultomiris must not be used in combination with Soliris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); AND Documentation of a decrease in relapse rate must be provided.</p> <p>For myasthenia gravis:</p> <ol style="list-style-type: none"> 1. Must have a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of six or more; 2. Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive; 3. Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soloris, Rystiggo, or Zilbrysq. (Ultomiris has not been studied and there is no data to support use in combination with other medications used to treat MG); 4. Medical records supporting the request must be provided; <p>For reauthorization, must have documentation of improvement in the MG-ADL total score from baseline - must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soloris, Rystiggo, or Zilbrysq.</p> <p>For paroxysmal nocturnal hemoglobinuria (PNH):</p> <ol style="list-style-type: none"> 1. Must have diagnosis confirmed by flow cytometry; 2. Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain); 3. Must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli. (Ultomiris has not been studied and there is no data to support use in combination with other medications used for PNH); 4. Medical records supporting the request must be provided;

	For reauthorization: Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - AND - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline - AND - must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli.						
Age Restriction	None						
Prescriber Restrictions	For NMSOD: Must be prescribed by or in consultation with a neurologist.						
Coverage Duration	One year (initial); two years (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 793 1511 968"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J1303</td> <td>Ultomiris (ravulizumab-cwvz)</td> <td>Billing unit: 10 mg 300 mg/3 mL, 1100 mg/11 mL SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J1303	Ultomiris (ravulizumab-cwvz)	Billing unit: 10 mg 300 mg/3 mL, 1100 mg/11 mL SDV
HCPCS	Description	Billing Units/How Supplied					
J1303	Ultomiris (ravulizumab-cwvz)	Billing unit: 10 mg 300 mg/3 mL, 1100 mg/11 mL SDV					

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025