Ultomiris® (ravulizumab-cwvz) Intravenous Injection

When requesting Ultomiris (ravulizumab-cwvz) intravenous injection, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Paroxysmal Nocturnal Hemoglobinuria
Ultomiris is indicated for the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).

Atypical Hemolytic Uremic Syndrome
Ultomiris is indicated for the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy (TMA).

Generalized Myasthenia Gravis
Ultomiris is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (ACHR) antibody-positive.

Neuromyelitis Optica Spectrum Disorder
Ultomiris is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Coverage Guidelines

Paroxysmal Nocturnal Hemoglobinuria (PNH)

The individual must meet both of the following criteria for initial authorization:

- Diagnosis of PNH was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least 2 cell lineages;
- Ultomiris is prescribed by or in consultation with a hematologist.

The individual must meet both of the following criteria for re-authorization:

- Is continuing to receive benefits from Ultomiris therapy (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reduction in hemolysis);
- Ultomiris is prescribed by or in consultation with a hematologist.

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

Atypical Hemolytic Uremic Syndrome (aHUS)

The individual must meet both of the following criteria for authorization:

- Does not have Shiga toxin *Escherichia coli* related hemolytic uremic syndrome;
- Ultomiris is prescribed by or in consultation with a nephrologist.

Approval duration: 12 months

Generalized Myasthenia Gravis (gMG)

The individual must meet all of the following criteria for initial authorization:

- Has a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive generalized myasthenia gravis;
- Is 18 years of age or older;
- Has Myasthenia Gravis Foundation of America classification of II to IV;
- Has Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or higher;
- Has received or is currently receiving pyridostigmine unless failed, contraindicated or intolerant to pyridostigmine;
- Has received or is currently receiving two different immunosuppressive therapies for at least one year unless failed, contraindicated or intolerant to two different immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, methotrexate , tacrolimus, cyclophosphamide);
- Has evidence of unresolved symptoms of generalized myasthenia gravis (e.g., difficulty swallowing, difficulty breathing, or a functional disability [e.g., double vision, speech, impairment of mobility]);
- Ultomiris is prescribed by or in consultation with a neurologist.

The individual must meet all of the following criteria for re-authorization:

- Is 18 years of age or older;
- Is continuing to receive benefits from Ultomiris therapy (e.g., reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, or respiratory functions);
- Ultomiris is prescribed by or in consultation with a neurologist.

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

Neuromyelitis Optica Spectrum Disorder (NMOSD)

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Neuromyelitis optica spectrum disorder diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody;
- Ultomiris is prescribed by or in consultation with a neurologist.

The individual must meet all of the following criteria for re-authorization:

- Is 18 years of age or older;
- Neuromyelitis optica spectrum disorder diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody;
- Is continuing to receive benefit from Ultomiris therapy (e.g., reduction in relapse rates, reduction in symptoms [e.g., pain, fatigue, motor function], or a slowing progression in symptoms);
- Ultomiris is prescribed by or in consultation with a neurologist.

Approval Duration (initial & renewal): 12 months

Dosing Recommendations

The recommended intravenous Ultomiris loading and maintenance dosing is based on the patient's body weight, with maintenance doses administered every 4 or 8 weeks, starting 2 weeks after loading dose.

Indications	Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg) and Dosing Interval	
PNH **aHUS**	5 to less than 10	600	300	Every 4 weeks
	10 to less than 20	600	600	Every 4 weeks
	20 to less than 30	900	2,100	Every 8 weeks
	30 to less than 40	1,200	2,700	Every 8 weeks
PNH **aHUS** **gMG** **NMOSD**	40 to less than 60	2,400	3,000	Every 8 weeks
	60 to less than 100	2,700	3,300	Every 8 weeks
	100 or greater	3,000	3,600	Every 8 weeks

References

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