Mass General Brigham
Health Plan

Ultomiris® (ravulizumab-cwvz)
Effective 11/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Ultomiris (ravulizumab) is a complement inhibitor indicated for the treatment of:

- Adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
- Adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)*
- Adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody-positive
- Adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody-positive

**Limitation of use: Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS).*

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when the following diagnosis-specific criteria are met and documentation has been submitted:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

1. The member has a diagnosis of paroxysmal nocturnal hemoglobinuria confirmed by flow cytometry

Atypical Hemolytic Uremic Syndrome (aHUS)

1. The member has a diagnosis of atypical hemolytic uremic syndrome (aHUS)

Generalized myasthenia gravis (gMG)

1. The member has a diagnosis of generalized myasthenia gravis (gMG) with both of the following:
    a. Myasthenic Gravis Foundation of America (MGFA) clinical classification II to IV
    b. MG activities of daily living (MG-ADL) total score ≥ 6
2. Anti-acetylcholine receptor (AchR) antibody positive
3. The member meets ONE of the following:
    a. Member has had an inadequate response to at least two immunosuppressive therapies listed below:
        i. azathioprine
        ii. cyclosporine
        iii. mycophenolate mofetil
        iv. tacrolimus
        v. methotrexate
        vi. cyclophosphamide
        vii. rituximab
    b. Member has had an inadequate response to chronic IVIG

Neuromyelitis Optica Spectrum Disorder (NMOSD)

1. Member has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
2. Anti-aquaporin-4 (AQP4) antibody positive confirmed by use of immunoassay

Continuation of Therapy

Authorization for continued treatment may be granted when the following diagnosis-specific criteria are met:

Atypical hemolytic uremic syndrome

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, platelet counts).

Paroxysmal nocturnal hemoglobinuria

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, improvement in hemoglobin levels, decreased number of red blood cell transfusions)

Generalized myasthenia gravis (gMG)

1. Prescriber submits documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis [QMG] total score).

Neuromyelitis optical spectrum disorder (NMOSD)

1. Prescriber submits documentation of a positive response to therapy (e.g., reduction in number of relapses).

Limitations

1. Initial and reauthorization approvals will be granted for 12 months

References

1. Kulasekararaj AG, Hill A, Rottinghaus ST, et al. Ravulizumab (ALXN1210) vs eculizumab in C5-inhibitor-experienced adult patients with PNH: the 302 study. Blood 2019; 133:540

2. Lee JW, Sicre de Fontbrune F, Wong Lee L, et al. Ravulizumab (ALXN1210) vs eculizumab in adult patients with PNH naive to complement inhibitors: the 301 study [published online December 3, 2018]. *Blood*. doi: 10.1182/blood-2018-09-876136
3. McNamara LA, Topaz N, Wang X, et al. High Risk for Invasive Meningococcal Disease Among Patients Receiving Eculizumab (Soliris) Despite Receipt of Meningococcal Vaccine. MMWR Morb Mortal Wkly Rep 2017; 66:734
4. Röth A, Rottinghaus ST, Hill A, et al. Ravulizumab (ALXN1210) in patients with paroxysmal nocturnal hemoglobinuria: results of 2 phase 1b/2 studies. *Blood Adv*. 2018;2(17):2176-2185. doi: 10.1182/bloodadvances.2018020644
5. Ultomiris (ravulizumab-cwvz) [prescribing information]. Boston, MA: Alexion Pharmaceuticals; June 2024.

Review History

09/18/2019 – Reviewed

01/22/2020 – Added indication of atypical hemolytic uremic syndrome.

08/14/2024 – Reviewed and updated at August P&T. Added approval criteria for generalized myasthenia gravis and neuromyelitis optica spectrum disorder. Updated initial criteria for aHUS to require diagnosis. Updated initial criteria for PNH to require diagnosis of PNH as confirmed by flow cytometry. Added reauthorization criteria requiring documentation of a positive response to therapy. Effective 11/01/2024.