Mass General Brigham
Health Plan

Complement Inhibitors and Miscellaneous Immunosuppressive Agents
Ultomiris (ravulizumab-cwvz)
Effective 02/18/2025

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		
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Ultomiris (ravulizumab-cwvz) is indicated for the treatment of aHUS, generalized MG, and PNH. They are monoclonal antibodies that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all of the following criteria are met:

Atypical hemolytic-uremic syndrome (aHUS)
1. Diagnosis of atypical hemolytic uremic syndrome (aHUS)
2. Prescriber is a hematologist or nephrologist or consult notes from specialist are provided
3. Appropriate dosing

Generalized Myasthenia Gravis (MG)
1. Diagnosis of generalized myasthenia gravis (MG)
2. Member is ≥ 18 years of age
3. Member is AchR antibody positive
4. Prescriber is a neurologist or consult notes from a neurology office are provided
5. Inadequate response, adverse reaction, or contraindication to pyridostigmine
6. **ONE** of the following:
    a. **BOTH** of the following:
        i. Member has severe disease requiring faster onset medication

ii. Inadequate response, adverse reaction or contraindication to IVIG or plasmapheresis with glucocorticoids

b. Inadequate response or adverse reaction to **TWO** of the following or contraindication to **ALL** of the following immunosuppressant trials:
   i. azathioprine
   ii. cyclosporine
   iii. glucocorticoids (e.g., prednisone)
   iv. mycophenolate
   v. tacrolimus

7. Appropriate dosing

Neuromyelitis optica spectrum disorder (NMOSD)

1. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
2. Prescriber is a neurologist or consult notes from specialist are provided
3. Positive serologic test for anti-aquaporin-4 (AQP4)
4. Member is ≥ 18 years of age
5. Appropriate dosing

Paroxysmal nocturnal hemoglobinuria (PNH)

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
2. Prescriber is a hematologist or consult notes from specialist are provided
3. Appropriate dosing

Continuation of Therapy

For aHUS/PNH: Reauthorization by prescriber will infer a positive response to therapy.
For generalized myasthenia gravis: Prescriber must provide documentation of positive response to therapy.

Limitations

1. Initial approvals will be granted for the following:
   a. PNH/aHUS: 1 year
   b. MG: 6 months
2. Reauthorizations will be granted for 1 year

References

1. Ultomiris (ravulizumab-cwvz) [prescribing information]. Boston, MA: Alexion Pharmaceuticals; December 2018
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. 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
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. 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

Review History
09/18/2019 – Reviewed
01/22/2020 – Added indication of atypical hemolytic uremic syndrome
02/08/2023 - Reviewed and updated for Feb P&T; matched MH UPPL criteria. Added indication of generalized myasthenia gravis. Updated initial approval durations. Effective 4/1/23.
09/13/23 – Reviewed and updated for P&T. Added step through requirement of pyridostigmine. Added reauthorization criteria. Trial with Vyvgart was removed due to Ultomiris being MBO and is not subject to MH's unification requirements. Effective 10/2/23.
01/2025 – Reviewed and updated for P&T. Criteria for myasthenia gravis indications now includes severity of disease and trial with IVIG or plasmapheresis with glucocorticoids. Effective 2/18/25