

Complement Inhibitors and Miscellaneous Immunosuppressive Agents
Ultomiris (ravulizumab-cwvz)
Effective 01/01/2026

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	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
- 8. Inadequate response or adverse reaction to ONE or contraindication to ALL of the following:
 - a. Imaavy
 - b. Rystiggo
 - c. Vyvgart
 - d. Vyvgart Hytrulo

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 generalized myasthenia gravis: Prescriber must provide documentation of positive response to therapy.

For all other indications: Reauthorization by prescriber will infer a positive response to therapy.

Limitations

- 1. Initial approvals will be granted for the following:
 - a. PNH/aHUS/NMOSD: 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

11/12/25 – Reviewed and updated for P&T. Step-through with Imaavy, Rystiggo, Vyvgart, or Vyvgart Hytrulo was added in gMG indication. Aligning with MH for HOPA implementation. Effective 1/1/26

