

**Ultomiris® (ravulizumab-cwvz)**  
**Effective 04/01/2020**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

Ravulizumab is a humanized monoclonal antibody which is a terminal complement inhibitor that specifically binds to the complement protein C5 (with high affinity), inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing generation of the terminal complement complex C5b9. The C5 inhibition of complement-mediated hemolysis achieved by ravulizumab in patients with paroxysmal nocturnal hemoglobinuria is immediate, thorough, and sustained.

Ravulizumab inhibits terminal complement-mediated intravascular hemolysis in paroxysmal nocturnal hemoglobinuria (PNH) and complement-mediated thrombotic microangiopathy in atypical hemolytic uremic syndrome

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Ultomiris, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

#### OR

Authorization of Ultomiris will be granted if the member meets any following criteria and documentation has been submitted:

1. The member has a diagnosis of paroxysmal nocturnal hemoglobinuria
  - a. The member is at least 18 years of age
  - b. The member has received a meningococcal vaccine at least two weeks prior to treatment initiation
  - c. Requested dosing is appropriately weight-based per FDA guidelines
2. The member has a diagnosis of atypical hemolytic uremic syndrome
  - a. The member is at least 1 month of age

- b. The member has received a meningococcal vaccine at least two weeks prior to treatment initiation
- c. Requested dosing is appropriately weight-based per FDA guidelines

#### **Limitations**

1. Approvals will be granted for 12 months

#### **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.

