Mass General Brigham
Health Plan

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

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

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.