Market Applicability													
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Ultomiris (ravulizumab-cwvz)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Ultomiris (ravulizumab-cwvz) 300 mg/30 mL vial*	12 vials per 56 days

*Initiation of therapy: May approve 10 (ten) additional vials (300 mg/mL) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Requests for Ultomiris (ravulizumab-cwvz) in paroxysmal nocturnal hemoglobinuria (PNH) may be approved if the following criteria are met:

I. Individual has PNH as documented by flow cytometry, including the presence of (Parker 2005):
   A. PNH type III red cells clone or a measurable granulocyte or monocyte clone; **OR**
   B. Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs);

AND

II. Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris (ravulizumab-cwvz), unless the clinical record documents the risks of delaying Ultomiris (ravulizumab-cwvz) outweigh the risk of meningococcal infection;

AND

III. Individual has no evidence of an active meningococcal infection;

AND

IV. Individual has (Lee 2018):
   A. Lactate dehydrogenase greater than 1.5 times the upper limit of normal; **OR**

Market Applicability													
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

B. One or more PNH-related sign or symptom (such as but not limited to anemia or history of major adverse vascular event from thromboembolism).

Note: Ultomiris (ravulizumab-cwvz) has a black box warnings for serious meningococcal infections. Life-threatening and fatal meningococcal infections have occurred in patients treated with Ultomiris (ravulizumab-cwvz) and meningococcal infection may become rapidly life-threating or fatal if not recognized and treated early. Individuals should be immunized with meningococcal vaccines at least 2 weeks prior to initiation of therapy unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection. The FDA has required the manufacturer to develop comprehensive risk management programs that includes the enrollment of prescribers in the Ultomiris REMS Program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's websites: http://www.ultomirisrems.com.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 28, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Parker CJ, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005; 106(12):3699-3709.
6. Lee JW, Fontbrune FS, et al. Ravulizumab vs Eculizumab in Adult Patients with PNH Naïve to Complement Inhibitors: The 301 Study. Blood 2018; prepublished online December 3, 2018; DOI 10.1182/blood-2018-09-876136.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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