

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

\*FHK- Florida Healthy Kids

## Ultomiris (ravulizumab-cwvz)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Ultomiris (ravulizumab-cwvz)

### 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 (Hillmen 2006):
  - A. Hemoglobin (Hgb) less than or equal to 7 g/dL or symptoms of anemia with Hgb less than or equal to 9 g/dL; **OR**
  - B. Lactate dehydrogenase greater than 1.5 times the upper limit of normal;

#### **OR**

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New Program Date 01/17/2019

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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- V. Individual has a documented history of a major adverse vascular event from thromboembolism.

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.: 2018. 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: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Hillmen P, Young NS, Schubert J, et al. The complement inhibitor eculizumab in paroxysmal nocturnal hemoglobinuria. N Engl J Med. 2006; 355(12):1233-1243.
6. Parker CJ, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005; 106(12):3699-3709.

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