I. Policy:
Ultomiris (Ravulizumab-cwvz)

II. Purpose/Objective:
To provide a policy of coverage regarding Ultomiris (Ravulizumab-cwvz)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Ultomiris (Ravulizumab-cwvz) 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.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Ultomiris (Ravulizumab-cwvz) will be considered medically necessary when ALL of the following criteria are met:

- Prescription is written by a hematologist AND
- Medical record documentation of 18 years of age or older AND
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation of patient being vaccinated with the meningococcal vaccine
- Physician documentation of one of the following:
  - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment OR
  - there is a significant adverse impact on the insured individual’s health such as end organ damage or thrombosis without other cause.

Authorization Duration: Initial Approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation:
  - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
  - Reduced need or elimination of transfusion requirements OR
  - Stabilization of hemoglobin levels

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/21/19
Revised: 7/10/19 (Hgb level per DHS)
Reviewed: 2/1/20