POLICY NUMBER UM ONC_1386	**SUBJECT** Ultomiris™ (ravulizumab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 02/12/20	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 02/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Ultomiris (ravulizumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: http://pathways.newcenturyhealth.com **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Paroxysmal Nocturnal Hemoglobinuria (PNH)**
    a. The member has hemolytic paroxysmal nocturnal hemoglobinuria (PNH) and Ultomiris (ravulizumab) is being used for **ALL** of the following conditions:
        i. The member required no more than 3 blood transfusions within the past 12 months
        ii. Lactate dehydrogenase (LDH) >1.5 x upper limit of normal
        iii. Hemoglobin level < 10 gm/dl within the last 4 weeks (for initial and continuation requests).
3. **Atypical Hemolytic Uremic Syndrome (aHUS)**

a. The member has aHUS and Ultomiris (ravulizumab) is being for **ALL** of the following conditions:
    i. The member is refractory and to at least 4 plasma therapy treatments
    ii. Has a platelet count ≤ 100 x109/L
    iii. Lactate dehydrogenase (LDH) level ≥ ULN
    iv. Creatinine level ≥ ULN.

III. EXCLUSION CRITERIA

1. Ultomiris (ravulizumab) is being used after disease progression with the same regimen or other anti-complement therapies (e.g. eculizumab).
2. Ultomiris (ravulizumab) is not indicated for the treatment of patients with Shiga toxin E. coli-related hemolytic-uremic syndrome (STEC-HUS).
3. Ultomiris (ravulizumab) is being used for the acute correction of anemia or as a substitute for RBC transfusions.
4. The member did not receive meningococcal vaccination, antibiotic prophylaxis, and iron supplementation prior to the first dose of Ultomiris (ravulizumab).
5. The member has active infections, history of meningococcal infections, or prior history of bone marrow transplantation.
6. The member has HUS related to any of the following:
    a. Drug induced HUS
    b. HUS related to bone marrow transplant
    c. HUS related to vitamin B12 deficiency
    d. Infection-related HUS
7. Dosing exceeds single dose limit of Ultomiris (ravulizumab) 3000 mg as a loading dose or 3,600 mg as a maintenance dose.
8. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Ultomiris PI prescribing information. Alexion Pharmaceuticals Inc. Boston, MA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.