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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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

2. 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
3. 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 AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. Paroxysmal Nocturnal Hemoglobinuria (PNH)
   1. The member has hemolytic paroxysmal nocturnal hemoglobinuria (PNH) and Ultomiris (ravulizumab) is being used to decrease hemolysis.

C. Atypical Hemolytic Uremic Syndrome (aHUS)
   1. The member has aHUS and Ultomiris (ravulizumab) is being used in members with evidence of hemolysis (LDH above normal/Haptoglobin below normal/Schistocytes on peripheral blood smear) with or without evidence of impaired renal function (serum creatinine above normal).

III. EXCLUSION CRITERIA
   A. Ultomiris (ravulizumab) is being used after disease progression with the same regimen or other anti-complement therapies (e.g. eculizumab).
   B. Ultomiris (ravulizumab) is not indicated for the treatment of members with Shiga toxin E. coli-related hemolytic-uremic syndrome (STEC-HUS).
   C. Dosing exceeds single dose limit of Ultomiris (ravulizumab) 3000 mg as a loading dose or 3,600 mg as a maintenance dose.
   D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT
   A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY
   A. Review – Utilization Management Department
   B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS
   A. None

VII. REFERENCES