Drug Policy:
Soliris™ (eculizumab)

I. PURPOSE
To define and describe the accepted indications for Soliris (eculizumab) 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 Soliris (eculizumab) is being used to reduce hemolysis. Unless contraindications or intolerance exist, the member has had failure to/contraindication to prior treatment with Ultomiris (ravulizumab). Please refer to UM ONC_1386 Ultomiris (ravulizumab) policy.

C. **Atypical Hemolytic Uremic Syndrome (aHUS)**
   1. The member has aHUS and Soliris (eculizumab) is being for a confirmed diagnosis of atypical HUS with evidence of hemolysis (LDH above normal/Haptoglobin below normal/Schistocytes on peripheral smear) impaired renal function (serum creatinine above normal).

III. EXCLUSION CRITERIA
   A. Soliris (eculizumab) is not indicated for the treatment of patients with Shiga toxin E. coli-related hemolytic-uremic syndrome (STEC-HUS) or thrombotic thrombocytopenia purpura (TTP), defined as ADAMTS-13 activity <5%.
   B. Dosing exceeds single dose limit of Soliris (eculizumab) 900 mg for PNH and 1,200 mg for aHUS.
   C. 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