I. PURPOSE

To define and describe the accepted indications for Abecma™ (idecabtagene vicleucel) 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. Multiple Myeloma

1. Abecma (idecabtagene vicleucel) may be used as monotherapy for adult members with relapsed/refractory multiple myeloma that have progressed on 4 or more lines of therapy AND

2. Members must have triple refractory disease as defined in the KaMMA trial: refractory to an immunomodulatory agent (e.g. lenalidomide, thalidomide, pomalidomide), a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an anti-CD38 antibody (e.g. daratumumab, isatuximab).

III. EXCLUSION CRITERIA

A. Disease progression while taking Abecma (idecabtagene vicleucel).

B. Concurrent use with other anti-myeloma therapy.

C. The member does NOT have adequate bone marrow reserve defined by ALL of the following:
   1. Absolute neutrophil count (ANC) ≥ 1000/uL
   2. Absolute lymphocyte count (ALC) ≥ 100/uL
   3. Platelet Count ≥ 75,000/uL.

D. The member does NOT have adequate renal, hepatic, cardiac and pulmonary function defined as:
   1. Creatinine clearance > 45 mL/min
   2. AST and/or ALT ≤ 2.5 x ULN and total bilirubin ≤ 1.5 x ULN
   3. Cardiac ejection fraction ≥ 45%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant pleural effusion
   4. Baseline oxygen saturation ≥ 92% on room air.

E. History or presence of CNS disorder.

F. Prior allogeneic hematopoietic stem cell transplant (HSCT).

G. Does not exceed duration limit as one time administration.

H. 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