I. PURPOSE

To define and describe the accepted indications for Darzalex and Darzalex Faspro (daratumumab IV/SC) 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. NOTE 1: The preferred anti-CD38 agent for Multiple Myeloma, per NCH policy and NCH pathway, are Darzalex and Darzalex Faspro (daratumumab IV/SC) over Sarclisa (isatuximab). This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) that shows superior outcomes with Sarclissa (isatuximab)-based regimens over Darzalex (daratumumab)-based regimens.

2. NOTE 2: Subcutaneous daratumumab, Darzalex Faspro, may be substituted for IV daratumumab, for all the indications listed in this policy.

3. NOTE 3: First line daratumumab based regimens are non-preferred per NCH Policy and NCH Pathway, for both transplant eligible and transplant ineligible multiple myeloma. This position is based on the lack of Level 1 evidence (randomized trial) showing the superiority of daratumumab-based first line regimens compared to standard RVd- Revlimid Velcade Dexamethasone and long term follow up of the RVd regimen showing excellent long term outcomes.

4. Daratumumab may be used in members with relapsed/refractory multiple myeloma as a part of the following regimens:
   - Daratumumab + Lenalidomide + Steroid (DRd) OR
   - Daratumumab + Bortezomib + Steroid (DVd)
   - As a single agent.

   All of the above regimens are the preferred regimens per NCH Pathway & NCH Policy for relapsed/refractory myeloma.

III. EXCLUSION CRITERIA

A. Disease progression while on a Darzalex and Darzalex Faspro (daratumumab IV/SC) containing regimen, or disease progression on Sarclisa (isatuximab) or Sarclisa (isatuximab) containing regimen.

B. Dosing exceeds single dose limit of Darzalex IV 16 mg/kg or Darzalex Faspro SC 1800 mg.

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