Drug Policy:

Darzalex™ and Darzalex Faspro™ (daratumumab IV/SC)

POLICY NUMBER UM ONC_1280	**SUBJECT** Darzalex™ and Darzalex Faspro™ (daratumumab IV/SC)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 4**
DATES COMMITTEE REVIEWED 03/23/16, 01/05/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 05/13/20, 06/10/20, 08/12/20, 09/09/20, 04/14/21, 09/08/21, 11/15/21, 12/8/21, 01/12/22, 04/13/22	**APPROVAL DATE** April 13, 2022	**EFFECTIVE DATE** April 29, 2022	**COMMITTEE APPROVAL DATES** 03/23/16, 01/05/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 05/13/20, 06/10/20, 08/12/20, 09/09/20, 04/14/21, 09/08/21, 11/15/21, 12/8/21, 01/12/22, 04/13/22	
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

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 applicable, generic alternatives are preferred over brand-name drugs.

B. Multiple Myeloma (MM)

1. NOTE 1: Subcutaneous daratumumab, Darzalex Faspro, may be substituted for IV daratumumab, as part of the preferred NCH pathway regimens, and for all the indications listed in this policy.
2. Daratumumab may be used in members with relapsed/refractory multiple myeloma as a part of the following preferred NCH pathway regimens:
    a. Daratumumab + Carfilzomib +/- Steroid
    b. Daratumumab + Pomalidomide + Steroid (DRd) if the member has failed 2 prior regimens or line of therapies that include one proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib) & one immunomodulatory agent (e.g., lenalidomide, thalidomide) OR
    c. Daratumumab + Lenalidomide +/- Steroid (DRd) OR
    d. Daratumumab + Bortezomib +/- Cyclophosphamide +/- Steroid OR
    e. As a single agent if the member has failed 3 prior lines of therapy or double refractory on a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib) & an immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide).
3. NOTE 2: 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 (as measured by Progression Free Survival and Overall Survival) 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. Please refer to NCH Pathway for the preferred first line regimens recommended for use in multiple myeloma.
4. NOTE 3: Per NCH Pathway & NCH Policy, Daratumumab + Selinexor+/- Dexamethasone is a non-Preferred regimen for the treatment of relapsed/refractory MM. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) demonstrating superiority compared to NCH Preferred regimens. Please refer to NCH Pathway for the preferred treatments recommended for use in relapsed/refractory MM.

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 1,800 mg.

C. Investigational use of Darzalex and Darzalex Faspro (daratumumab IV/SC) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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

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F. Darzalex Faspro prescribing information. Janssen Biotech, Inc. Horsham, PA 2021.

G. Clinical Pharmacology Elsevier Gold Standard 2022.

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I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.

K. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

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