Drug Policy:

Abecma™ (idecabtagene vicleucel)

POLICY NUMBER UM ONC_1429	SUBJECT Abecma™ (idecabtagene vicleucel)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 05/12/21, 11/15/21, 02/09/22, 04/13/22, 05/11/22, 02/08/23, 02/14/24, 05/08/24	APPROVAL DATE May 08. 2024	EFFECTIVE DATE May 31, 2024	COMMITTEE APPROVAL DATES 05/12/21, 11/15/21, 02/09/22, 04/13/22, 05/11/22, 02/08/23, 02/14/24, 05/08/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
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 Abecma (idecabtagene vicleucel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent 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. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Multiple Myeloma

1. Abecma (idecabtagene vicleucel) may be used for adult members with relapsed/refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab).

III. EXCLUSION CRITERIA

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

B. Concurrent use with other anti-myeloma therapy.

C. The member does NOT have measurable disease defined as any of the following :

1. Serum M-protein greater or equal to 1.0 g/dL
2. Urine M-protein greater or equal to 200 mg/24 h
3. Serum free light chain (FLC) assay: involved FLC level greater or equal to 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal.

D. The member has solitary plasmacytomas or non-secretory myeloma without other evidence of measurable disease.

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

F. Dosing exceeds single dose limit of Abecma (idecabtagene vicleucel) 460×10^6 CAR-positive T cells.

G. Investigational use of Abecma (idecabtagene vicleucel) 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 definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering 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

A. Rodriguez-Otero P, et al. Ide-cel or Standard Regimens in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2023 Mar 16;388(11):1002-1014. doi: 10.1056/NEJMoa2213614.

B. Munshi NC, et al. KarMMa Trial. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716.

C. Raje N, et al. CRB-401 Trial. Anti-BCMA CAR T-Cell Therapy bb2121 in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2019 May 2;380(18):1726-1737.

D. Abecma prescribing information. Celgene Corporation, Summit, NJ 2024.

E. 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.

F. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

G. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.