Evolent Clinical Guideline 3097 for Abecma™ (idecabtagene vicleucel)

Guideline Number:	Applicable Codes	
Evolent_CG_3097		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
May 2021	May 2026	May 2026

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STATEMENT

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.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

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

Multiple Myeloma (MM)

- 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).

CONTRAINDICATIONS/WARNINGS

- US Boxed Warning
  - Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with idecabtagene vicleucel. Do not administer idecabtagene vicleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
  - Neurologic toxicities, which may be severe or life-threatening, occurred following

treatment with idecabtagene vicleucel, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with idecabtagene vicleucel. Provide supportive care and/or corticosteroids as needed.

- Hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with idecabtagene vicleucel. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with idecabtagene vicleucel.
- T cell malignancies have occurred following treatment of hematologic malignancies with BCMA-and CD19-directed genetically modified autologous T-cell immunotherapies, including idecabtagene vicleucel.

EXCLUSION CRITERIA

- Disease progression while receiving Abecma (idecabtagene vicleucel).
- Concurrent use with other anti-myeloma therapy.
- The member does NOT have measurable disease defined as any of the following :
  - Serum M-protein greater or equal to 1.0 g/dL
  - Urine M-protein greater or equal to 200 mg/24 h
  - 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.
- The member has solitary plasmacytomas or non-secretory myeloma without other evidence of measurable disease.
- Does not exceed duration limit as one time administration.
- Dosing exceeds single dose limit of Abecma (idecabtagene vicleucel) 510 × 10^6 CAR-positive T cells.
- 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:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - 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.

- 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).
- 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.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- 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.

CODING AND STANDARDS

Codes

- Q2055 - Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
May 2026	• Removed REMS requirement under "Contraindications/Warnings" section • Updated maximum dose under exclusion criteria • Updated references
May 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1429 Abecma (idecabtagene vicleucel) • Updated references
May 2024	• Updated indication section • Added new reference

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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