

## Clinical Policy: Idecabtagene Vicleucel (Abecma)

Reference Number: LA.PHAR.481

Effective Date: 09.29.23

Last Review Date: ~~01.06.26~~04.17.25

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**\*\*Please note: This policy is for medical benefit\*\***

### Description

Idecabtagene vicleucel (Abecma<sup>®</sup>) is an anti-B cell maturation antigen (BCMA) chimeric antigen receptor (CAR) T-cell immunotherapy.

### FDA Approved Indication(s)

Abecma is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.*

All requests reviewed under this policy ~~require medical director review~~**Precision Drug Action Committee (PDAC) Utilization Management Review.**

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It is the policy of Louisiana Healthcare Connections<sup>®</sup> that Abecma is **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

#### A. Multiple Myeloma\* (must meet all):

*\*Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of relapsed or refractory multiple myeloma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. One of the following (a or b):
  - a. Member has measurable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
    - i. Serum M-protein  $\geq$  0.5 g/dL;
    - ii. Urine M-protein  $\geq$  200 mg/24 h;
    - iii. Serum free light chain (FLC) assay: involved FLC level  $\geq$  10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;
  - b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;

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5. Member has received  $\geq 2$  prior lines of therapy (*see Appendix B for examples*) that include all of the following (a, b, and c):
  - a. One immunomodulatory agent (e.g., Revlimid<sup>®</sup>, Pomalyst<sup>®</sup>, Thalomid<sup>®</sup>);
  - b. One proteasome inhibitor (e.g., bortezomib, Kyprolis<sup>®</sup>, Ninlaro<sup>®</sup>);
  - c. One anti-CD38 antibody (e.g., Darzalex<sup>®</sup>/Darzalex Faspro<sup>™</sup>, Sarclisa<sup>®</sup>);*\*Prior authorization may be required. Induction with or without hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen.*
6. Member does not have known central nervous system (CNS) involvement with myeloma, or history or presence of clinically relevant CNS pathology (e.g., epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis);
7. Member has not previously received treatment with anti-BCMA targeted therapy (e.g., Blenrep<sup>™</sup>, Tecvayli<sup>™</sup>);
8. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Breyanzi<sup>™</sup>, Carvykti<sup>™</sup>, Kymriah<sup>™</sup>, Tecartus<sup>™</sup>, Yescarta<sup>™</sup>);
9. Abecma is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta);
10. Dose does not exceed  $510 \times 10^6$  CAR-positive T-cells.

**Approval duration: 3 months (1 dose only, with 4 doses of tocilizumab (Actemra) if requested at up to 800 mg per dose)**

#### **B. Other diagnoses/indications** (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business: LA.PMN.53 for Medicaid.~~

## II. Continued Therapy

### **A. Multiple Myeloma**

1. Continued therapy will not be authorized as Abecma is indicated to be dosed one time only.

**Approval duration: Not applicable**

### **B. Other diagnoses/indications** (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business: LA.PMN.53 for Medicaid.~~



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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
VTD-PACE (dexamethasone/Thalomid® (thalidomide)/cisplatin/doxorubicin/cyclophosphamide/etoposide/bortezomib)	Varies	Varies
Revlimid® (lenalidomide)/low-dose dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/bortezomib/melphan/prednisone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/bortezomib/dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)	Varies	Varies
Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/pomalidomide/dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/bortezomib/dexamethasone	Varies	Varies
Empliciti® (elotuzumab)/pomalidomide/dexamethasone	Varies	Varies
bendamustine/bortezomib/dexamethasone	Varies	Varies
bendamustine/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
panobinostat/bortezomib/dexamethasone	Varies	Varies
panobinostat/Kyprolis® (carfilzomib)	Varies	Varies
panobinostat/Revlimid® (lenalidomide)/ dexamethasone	Varies	Varies
pomalidomide/cyclophosphamide/dexamethasone	Varies	Varies
pomalidomide/dexamethasone	Varies	Varies
pomalidomide/bortezomib/dexamethasone	Varies	Varies
pomalidomide/ Kyprolis® (carfilzomib)/ dexamethasone	Varies	Varies
Sarclisa® (isatuximab-irfc)/pomalidomide/dexamethasone	Varies	Varies
<u>Sarclisa (isatuximab-irfc)/bortezomib/lenalidomide/dexamethasone</u>	<u>Varies</u>	<u>Varies</u>
<u>Sarclisa (isatuximab-irfc)/Kyprolis (carfilzomib)/dexamethasone</u>	<u>Varies</u>	<u>Varies</u>
Xpovio® (selinexor)/bortezomib/dexamethasone	Varies	Varies
Xpovio® (selinexor)/Darzalex® (daratumumab) or Darzalex Faspro™ (daratumumab/hyaluronidase-fihj)/dexamethasone	Varies	Varies
Xpovio® (selinexor)/pomalidomide/dexamethasone	Varies	Varies

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*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome, neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, prolonged cytopenia, and secondary hematological malignancies

*Appendix D: General Information*

- Patients with CNS involvement with their multiple myeloma were excluded from the pivotal KarMMa trial.
- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
  - Increase of 25% from lowest response value in any of the following:
    - Serum M-component (absolute increase must be  $\geq 0.5$  g/dL), and/or
    - Urine M-component (absolute increase must be  $\geq 200$  mg/24 h), and/or
    - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be  $> 10$  mg/dL)
    - Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be  $\geq 10\%$ )
  - Appearance of a new lesion(s),  $\geq 50\%$  increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of  $> 1$  lesion, or  $\geq 50\%$  increase in the longest diameter of a previous lesion  $> 1$  cm in short axis;
  - $\geq 50\%$  increase in circulating plasma cells (minimum of 200 cells per  $\mu\text{L}$ ) if this is the only measure of disease

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Multiple myeloma	Single IV infusion; target dose: 300-510 x 10 <sup>6</sup> CAR-positive T cells	510 x 10 <sup>6</sup> CAR-positive T-cells

**VI. Product Availability**

Single-dose unit infusion bag: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient

**VII. References**

1. Abecma Prescribing Information. Summit, NJ: Celgene Corporation; ~~April~~July 2024. Available at: <https://www.abecma.com>. Accessed ~~April 10, 2024~~January 17, 2025.
2. Efficacy and safety study of bb2121 in subjects with relapsed and refractory multiple myeloma (KarMMa). Available at: <https://clinicaltrials.gov/ct2/show/NCT03361748>. Accessed January 22, 2024.

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3. Munshi NC, Anderson LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. N Engl J Med. 2021; 348(8): 705-716.
4. Raje N, Berdeja J, Lin Y, et al. Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. N Engl J Med. 2019; 380(18): 1726-1737.
5. National Comprehensive Cancer Network. Multiple Myeloma Version ~~3.2024~~1.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed ~~April 10, 2024~~February 11, 2025.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed ~~January 22, 2024~~February 11, 2025.
7. Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or Standard Regimens in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2023 Mar 16; 388(11): 1002-1014.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
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

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	08.28.23
Annual Review; updated criteria to reflect indication expansion for earlier use after two or more prior lines of therapy; added secondary hematological malignancies to boxed warnings. References reviewed and updated.	03.24.24 and 05.21.24	07.10.24
Revised HCPCS code description [Q2055] from 460 to 510 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells. References reviewed and updated.	08.14.24	11.14.24
No significant changes; references reviewed and updated.	04.17.25	<u>07.14.25</u>
<u>Annual review: Updated language under Policy/Criteria to effectively redirect prior authorization reviews to Precision Drug Action Committee (PDAC) Utilization Management Review; references reviewed and updated.</u>	<u>01.06.26</u>	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted



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standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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