Clinical Policy: Idecabtagene Vicleucel (Abecma)

Reference Number: LA.PHAR.481
Effective Date: 09.29.23
Last Review Date: 01.06.26
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®) 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 Precision Drug Action Committee (PDAC) Utilization Management Review**.

It is the policy of Louisiana Healthcare Connections® 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 ≥ 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 ≥ 0.5 g/dL;
      ii. Urine M-protein ≥ 200 mg/24 h;
      iii. Serum free light chain (FLC) assay: involved FLC level ≥ 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;

5. Member has received ≥ 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®, Pomalyst®, Thalomid®);
   b. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);
   c. One anti-CD38 antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);
   **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™, Tecvayli™);
8. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Breyanzi™, Carvykti™, Kymriah™, Tecartus™, Yescarta™);
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 x 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 LA.PMN.53.

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 LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policyLA.PMN.53

B. Known 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).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCMA: B-cell maturation antigen
CAR: chimeric antigen receptor
CNS: central nervous system
FDA: Food and Drug Administration
FLC: free light chain
IMWG: International Myeloma Working Group

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bortezomib/Revlimid® (lenalidomide) /dexamethasone	Varies	Varies
bortezomib/cyclophosphamide/dexamethasone	Varies	Varies
bortezomib/doxorubicin (or liposomal doxorubicin)/ dexamethasone	Varies	Varies
Kyprolis® (carfilzomib)/Revlimid® (lenalidomide) /dexamethasone	Varies	Varies
Kyprolis® (carfilzomib)/cyclophosphamide/ dexamethasone	Varies	Varies
Kyprolis® (carfilzomib – weekly or twice weekly)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/dexamethasone	Varies	Varies
Ninlaro® (ixazomib)/pomalidomide/dexamethasone	Varies	Varies
bortezomib/dexamethasone	Varies	Varies
bortezomib/Thalomid® (thalidomide)/dexamethasone	Varies	Varies
cyclophosphamide/Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
Revlimid® (lenalidomide)/dexamethasone	Varies	Varies
VTD-PACE (dexamethasone/Thalomid® (thalidomide)/cisplatin/doxorubicin/ cyclophosphamide/etoposide/bortezomib)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Sarclisa (isatuximab-irfc)/bortezomib/lenalidomide/dexamethasone	Varies	Varies
Sarclisa (isatuximab-irfc)/Kyprolis (carfilzomib)/ dexamethasone	Varies	Varies
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

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 ≥ 0.5 g/dL), and/or
    - Urine M-component (absolute increase must be ≥ 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 ≥ 10%)
  - Appearance of a new lesion(s), ≥ 50% increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or ≥ 50% increase in the longest diameter of a previous lesion >1 cm in short axis;
  - ≥ 50% increase in circulating plasma cells (minimum of 200 cells per μL) 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 10^6 CAR-positive T cells	510 x 10^6 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; July 2024. Available at: https://www.abecma.com. Accessed 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.
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 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed February 11, 2025.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed 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	07.14.25
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.	01.06.26	

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 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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.