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Medicare Advantage Medical Utilization Review Policy

Policy:	**Oncology (Injectable – CAR-T) – Abecma Utilization Management Medical Policy** • Abecma® (idecabtagene vicleucel intravenous infusion – Bristol-Myers Squibb and bluebird bio)
Date:	03/25/2025
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	All States
Applicable NCDs, LCDs, and/or LCAs	NCD 110.24

SUMMARY OF EVIDENCE

Abecma, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of relapsed or refractory **multiple myeloma** in adults after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.[1] Abecma is a chimeric antigen receptor T-cell (CAR-T) therapy.

Dosing Information

Abecma is supplied in one or more frozen infusion bags contain a suspension of genetically modified autologous chimeric antigen receptor (CAR)-positive T-cells in 5% dimethyl sulfoxide.[1] The bags are stored in the vapor phase of liquid nitrogen (less than or equal to minus 130°C). The recommended dose range of Abecma is 300 to 510 x 10^6 CAR-positive T-cells. Abecma is for autologous use only.

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for multiple myeloma (version 1.2025 – September 17, 2024) recommend Abecma as a "Preferred Regimen" for the treatment of previously treated multiple myeloma after two prior treatment regimens including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (category 1) and after at least three prior treatment regimens (category 2A).[2,3]

Safety

Abecma has a Boxed Warning for cytokine release syndrome, neurologic toxicity, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, prolonged cytopenias, and T-cell malignancies.[1] Abecma is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Abecma REMS.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Abecma. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Abecma is recommended in those who meet the following criteria:

FDA-Approved Indications

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1. Multiple Myeloma. ^

Criteria. Approve a single dose if the patient meets the following criteria (A, B, C, and D):

A) Patient is ≥ 18 years of age; [IC-COMP] AND

B) Patient meets ONE of the following (i or ii):

- **i.** Patient has received two or more lines of systemic therapy, including one from each of the following (a, b, and c): [IC-COMP]
  - **a)** Patient has received an immunomodulatory agent; [IC-COMP] AND
    Note: Immunomodulatory agents include Thalomid® (thalidomide capsules), Revlimid® (lenalidomide capsules), Pomalyst® (pomalidomide capsules).
  - **b)** Patient has received a proteasome inhibitor; [IC-COMP] AND
    Note: Proteasome inhibitors include Velcade® (bortezomib injection), Kyprolis® (carfilzomib injection), Ninlaro® (ixazomib capsules).
  - **c)** Patient has received an anti-CD38 monoclonal antibody; [IC-COMP] OR
    Note: Anti-CD38 monoclonal antibodies include Darzalex® (daratumumab IV infusion), Darzalex Faspro™ (daratumumab and hyaluronidase-fihj for subcutaneous injection), Sarclisa® (isatuximab-irfc IV infusion).
- **ii.** Patient has received at least three prior lines of therapy; [IC-COMP] AND

C) Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Abecma; [IC-COMP] AND

D) Patient has not been previously treated with CAR-T therapy. [IC-COMP]
Note: Examples of CAR-T therapy include Abecma, Breyanzi® (lisocabtagene maraleucel suspension for intravenous infusion), Kymriah® (tisagenlecleucel suspension for intravenous infusion), Tecartus™ (brexucabtagene suspension for intravenous infusion), and Yescarta® (axicabtagene suspension for intravenous infusion).

Dosing. Approve up to 510 x 10^6 CAR-positive T-cells administered intravenous as a single dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Abecma is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SOURCES OF INFORMATION

1. Abecma intravenous infusion [prescribing information]. Summit, NJ: Bristol-Myers Squibb; July 2024.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025. Search term: idecabatgene.
4. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Original effective date 8/7/2019. Implementation date 2/16/2021. Revision date: 10/2024. Accessed March 25, 2025.

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HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/21/2021
Policy revision	**Multiple Myeloma:** Added "or plan to receive" to the requirement that the patient has received lymphodepleting chemotherapy prior to infusion of Abcema.	01/14/2022
Policy revision	Added "The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy." to the Policy Statement.	07/26/2023
Policy review	No criteria changes. Review based on commercial policy annual review.	04/19/2024
Policy revision	**Multiple Myeloma:** Requirement that the patient has received four or more lines of systemic therapy was revised to patient has received two or more lines of systemic therapy. Revised Abecma dose from "up to 460 x 10^6 CAR-positive T-cells" to "up to 510 x 10^6 CAR-positive T-cells". Revision based on review of commercial policy updates	06/05/2024
Policy review	No criteria changes. Review based on NCD surveillance review.	01/06/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/10/2025
Policy revision	**Multiple Myeloma:** Added patient has received at least three prior lines of therapy as a new option for approval. Revised based on commercial policy update	03/25/2025