POLICY: Oncology (Injectable – CAR-T) – Abecma Utilization Management Medical Policy

- Abecma® (idecabtagene vicleucel injection – Bristol-Myers Squibb and bluebird bio)

EFFECTIVE DATE: 07/01/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

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 four 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 460 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 3.2024 – March 8, 2024) recommend Abecma for the treatment of previously treated multiple myeloma after at least four prior treatment regimens.[2,3] Patients should receive a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody before receiving Abecma.

Safety

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

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

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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 References 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 Reference 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 also covered (and, if applicable, further detailed/referenced) in the corresponding Commercial Care Continuum (CC) Policy. Note: Additional criteria requirements for coverage of the same indication as outlined in the Commercial CC Policy and this Medicare Advantage CC Policy may NOT be the same.

Indications noted with eviCore are managed by eviCore healthcare for those clients who use eviCore for oncology and/or oncology-related reviews. For these indications, a prior authorization should be initiated through eviCore at www.eviCore.com.

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. ^ *eviCore*

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

A) Patient is ≥ 18 years of age; AND

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B) Patient has received four or more lines of systemic therapy, including one from each of the following (i, ii, and iii):

i. Patient has received an immunomodulatory agent; AND
Note: Immunomodulatory agents include Thalomid® (thalidomide capsules), Revlimid® (lenalidomide capsules), Pomalyst® (pomalidomide capsules).

ii. Patient has received a proteasome inhibitor; AND
Note: Proteasome inhibitors include Velcade® (bortezomib injection), Kyprolis® (carfilzomib injection), Ninlaro® (ixazomib capsules).

iii. Patient has received an anti-CD38 monoclonal antibody; AND
Note: Anti-CD38 monoclonal antibodies include Darzalex® (daratumumab IV infusion), Darzalex Faspro™ (daratumumab and hyaluronidase-fihj for subcutaneous injection), Sarclisa® (isatuximab-irfc IV infusion).

C) Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Abecma; AND

D) Patient has not been previously treated with CAR-T therapy.
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. The dose of Abecma is up to 460 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.

REFERENCES

1. Abecma intravenous infusion [prescribing information]. Summit, NJ: Bristol-Myers Squibb; January 2024.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 20, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 20, 2024. 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. Accessed April 19, 2024.

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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
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024

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