CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – CAR-T) – Abecma Utilization Management Medical Policy
- Abecma® (idecabtagene vicleucel intravenous infusion – Bristol-Myers Squibb and bluebird bio)

REVIEW DATE: 03/05/2025

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 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.

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. Because of the specialized skills required for evaluation and diagnosis of patients treated with Abecma as well as the monitoring required for adverse events and long-term efficacy, approval requires Abecma to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Multiple Myeloma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has received two or more lines of systemic therapy, including one therapy from each of the following (a, b, and c):
       - **a)** Patient has received an immunomodulatory agent; AND
         Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, Pomalyst (pomalidomide capsules).
       - **b)** Patient has received a proteasome inhibitor; AND
         Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
       - **c)** Patient has received an anti-CD38 monoclonal antibody; OR
         Note: Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion).
     - **ii.** Patient has received at least three prior lines of therapy; AND
   - **C)** Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Abecma; AND
   - **D)** Patient has not been previously treated with chimeric antigen receptor T-cell (CAR-T) therapy; AND
     Note: Examples of CAR-T therapy includes Abecma, Breyanzi (lisocabtagene maraleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene intravenous infusion).
   - **E)** The medication is prescribed by or in consultation with an oncologist.

   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.

REFERENCES

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/29/2023
Annual Revision	No criteria changes.	03/27/2024
Selected 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".	05/29/2024
Annual Revision	**Multiple Myeloma:** Added patient has received at least three prior lines of therapy as a new option for approval.	03/05/2025