VENTURA COUNTY
HEALTH CARE PLAN

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: 03/29/2023

OVERVIEW

Abecma, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adults with relapsed or refractory **multiple myeloma** 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 3.2023 – December 8, 2022) 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. 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 the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has received four or more lines of systemic therapy, including one therapy from each of the following (i, ii, and iii):
     - **i.** Patient has received an immunomodulatory agent; AND
       Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, Pomalyst (pomalidomide capsules).
     - **ii.** Patient has received a proteasome inhibitor; AND
       Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
     - **iii.** Patient has received an anti-CD38 monoclonal antibody; AND
       Note: Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous 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 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. 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; March 2021.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 20, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 20, 2023. Search term: idecabatgene.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/23/2022
Update	08/26/2022: 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.	NA
Annual Revision	No criteria changes.	03/29/2023