PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/23/2022

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.

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]

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for multiple myeloma (version 5.2022 – March 9, 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. Abecma is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Abecma REMS.[1]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Abecma. All approvals are provided for the duration noted below. 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 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, Carvykti (ciltacabtagene autoleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel 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.

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 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network, Available at: http://www.nccn.org. Accessed on March 15, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 14, 2022. Search term: idecabtagene.