PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/31/2021

OVERVIEW
Abecma, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adult patients 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 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 6.2021 – April 12, 2021) 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.

Automation: None.

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

FDA-Approved Indications

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), 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 intravenous infusion), Darzalex Faspro™ (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa® (isatuximab-irfc intravenous infusion).

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

D) Patient has not been previously treated with chimeric antigen receptor (CAR-T) therapy; AND
Note: CAR-T therapy includes 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).

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 suspension for intravenous infusion [prescribing information]. Summit, NJ: Bristol-Myers Squibb; March 2021.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 6.2021 – April 12, 2021). © 2021 National Comprehensive Cancer Network, Inc, Available at: http://www.nccn.org. Accessed on April 13, 2021.
3. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 13, 2021. Search term: idecabtagene.