STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Alex J. Mayer
Cabinet Secretary

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Commissioner

Office of Pharmacy Services
Prior Authorization Criteria

ABECMA® (idecabtagene vicleucel)
Billed under: Q2055

ABECMA is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Limitations of Use: Abecma is not indicated for the treatment of patients with primary central nervous system lymphoma.

Abecma is considered experimental/investigational and therefore non-covered for any other indications than those listed above. There is insufficient evidence regarding its effectiveness and safety for any other indications.

Initial authorization requires review by the Medical Director and Abecma may be considered medically necessary only when being used for one of the approved indications and when all of the following criteria is met:

1. Must be prescribed by an Oncologist; **AND**
2. Supporting diagnostic documentation, identity of all prior treatments and response MUST be supplied; **AND**
3. Patient is ≥ 18 years of age with diagnosis of multiple myeloma, relapsed or refractory, who has received at least two prior lines of therapy which must include an immunomodulatory agent (e.g. lenalidomide, pomalidomide), a proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib), and an anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab); **AND**
4. No active or latent hepatitis B or active hepatitis C, human immunodeficiency virus (HIV) positive or any uncontrolled infection; **AND**
5. No presence of grade 2-4 acute or extensive chronic graft-versus-host disease (GVHD); **AND**
6. No active central nervous system involvement by malignancy; **AND**
7. No prior Chimeric Antigen Receptor T-cell (CAR-T) or BCMA-targeted therapy; **AND**
8. Karnofsky/Lansky score ≥ 50 or an Eastern Cooperative Oncology Group (ECOG) score of 0-1; **AND**
9. No live vaccination within six weeks prior to initiation of lymphodepleting chemotherapy, during Abecma treatment, and until immune recovery following treatment with Abecma.

Additional Requirements: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, Abecma is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. The required components of the ABECMA REMS are:

- Healthcare facilities that dispense and administer Abecma must be enrolled and comply with the REMS requirements. REMS certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available on-site for each patient for immediate administration within two hours after Abecma infusion, if needed for treatment of CRS.

Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer Abecma are trained in the management of CRS and neurological toxicities.

Monitor patients at least daily for seven days at the REMS certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. The product labeling gives specific treatment recommendations for the different grades of CRS and neurologic toxicity. Instruct patients to remain within proximity of the REMS certified healthcare facility for at least four weeks following infusion. Patients should be advised to refrain from driving or operating heavy machines until at least eight weeks after Abecma administration.

Authorization approval will be for 60 days to allow for a one-time infusion of therapy.

As additional indications may be approved by the FDA, expansion of the covered indications will be considered.

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. Abecma [package insert]. Summit, NJ: Bristol-Myers Squibb Company; 2024. https://packageinserts.bms.com/pi/pi_abecma.pdf (Accessed 12/18/2024)
2. REMS: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=406 (Accessed 12/2/2024)
3. UpToDate Clinical Article "Multiple Myeloma: Initial Treatment" (Accessed 2/27/2024)
4. National Comprehensive Cancer Network (NCCN) Guidelines – Treatment by Cancer Type https://www.nccn.org/guidelines/category_1: (Multiple Myeloma) NCCN Guidelines Version 2.2024 Updated Nov 1, 2023.
5. "Chimeric Antigen Receptor T-Cell Therapy." Optum Clinical Guidelines, Optum, 2024. www.uhcprovider.com/content/dam/provider/docs/public/policies/clinical-guidelines/chimeric-antigen-receptor-tcell-therapy.pdf. (Accessed 12/5/24)
6. Beinfeld MT, Rucker JA, Jenkins NB, de Breed LA, Chambers JD. Variation in Medicaid and commercial coverage of cell and gene therapies. Health Policy Open. 2023 Oct 13;5:100103. doi: 10.1016/j.hpopen.2023.100103. PMID: 38023441; PMCID: PMC10660088. (Accessed 12/17/24)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.