ECOG score of 2 or greater, a creatinine clearance of less than or equal to 45 mL/minute, alanine aminotransfe greater than 2.5 times upper limit of normal, and left ventricular ejection fraction less than 45%. Also, Pat excluded if absolute neutrophil count less than 1000 cells/mm³ and platelet count less than 50,000/mm³. Patients were required to have measurable disease. The primary endpoints included overall response rate (ORR), comp response (CR), and duration of response (DOR). The ORR was 72% (95% CI: 62% to 81%) with 28% of patients achieving a stringent complete response (sCR; 95% CI: 19% to 38%). Responses were rapid and durable with a median time to response of 30 days (range: 15 to 88 days) and a median duration of response of 11 months (95% CI: 10.3 11.4) for all responders and 19 months (95% CI: 11.1 not reached) for those who achieved a sCR. Of the 28 patients who achieved sCR, an estimated 65% (95% CI: 31% to 82%) had remission lasting at least 12 months.

- Disease should be measured/staged with CT or PET. Focal uptake in nodal and extranodal sites is considered involvement with lymphoma, including spleen, liver, bone, thyroid, and so on. A measurable node must have a longest diameter (LDi) greater than 1.5 cm. A measurable extranodal lesion should have an LDi greater than 1.0 cm All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured dis (eg, cutaneous, GI, bone, spleen, liver, kidneys, lung, pericardial effusions, ascites).

- While use of Abecma has not been established in patients with creatinine clearance of less than 45 mL/minute, other CAR-T therapies have been studied in subjects with a creatinine clearance of 30 mL/minute. The National Institute of Health/National Cancer Institute Common Terminology Criteria of Adverse Events (CTCAE) classify 2 chronic kidney disease as a creatinine clearance of 50 to 30 mL/minute. As the classification system uses 30 mL/minute as a cutoff for grade 2 disease and data from other CAR-T therapies support their use in these patients, Abecma should be able to be tolerated in this population. As there is no data to support administration of CAR-T at levels lower than 30 ml/minute, therapy should not be given in patients not meeting the 30 mL/minute threshold.

- While use of Abecma has not been established in patients with an alanine aminotransferase of greater than 2.5 the upper limit of normal (ULN), other CAR-T therapies have been studied in subjects with an alanine aminotransferase of up to 5 times the ULN and the CTCAE recommendations have set 5 times the ULN as the for grade 2 adverse reactions. As the classification system uses 5 times the ULN and other CAR-T therapies have data supporting use in this patient population, Abecma should be tolerated in these patients as well. As there is data to support administration of CAR-T at levels higher than 5 times the ULN, therapy should not be given to patients not meeting that threshold.

- The CTCAE recommendations set the grade 2 cutoff for left ventricular ejection fraction (LVEF) at 40%. While Abecma has only been studied in patients with a LVEF greater than or equal to 45%, there is data from other CAR-T therapies to support use in those with a LVEF of 40% of greater. Therefore, Abecma should be tolerated in these patients as well. There is no data supporting use at LVEF levels less than 40%.

References:

1. Abecma [prescribing information]. Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; March 2021.
2. National Comprehensive Cancer Network. Multiple myeloma. Version 2.2022. March 9, 2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed July 6, 2022.
3. Munshi NC, Anderson Jr LD, Shah N, et al. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. NEJM. 2021 Feb 25; 384 (8): 705-16.
4. U.S. Department of Health and Human Services. Common terminology criteria for adverse events (Version 5.0). 2017 Nov 27. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf Accessed on July 6, 2022.

Policy/UM Medical Management System Update History		
#	Date	Change Description
1.1	Effective Date: 08/04/2022	Updated to align criteria across all CAR-T policies
1.0	Effective Date: 03/07/2022	Medical policy established

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*