



MEDICAL COVERAGE POLICY

SERVICE: Idacabtagene Vicleucel (Abecma[®])

Policy Number: 290

Effective Date: 12/01/2022

Last Review: 10/27/2022

Next Review Date: 10/27/2023

Important note:

Unless otherwise indicated, this policy will apply to all lines of business. Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Idacabtagene Vicleucel (Abecma[®])

PRIOR AUTHORIZATION: Required

POLICY:

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination).

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM. Texas Mandate HB1584 is applicable for Medicaid plans.

Idacabtagene Vicleucel (Abecma[®])

BSWHP may consider idacabtagene vicleucel (Abecma[®]) medically necessary for the treatment of multiple myeloma when ALL of the following criteria are met:

1. The member has a diagnosis of multiple myeloma; **AND**
2. Member is ≥ 18 years old; **AND**
3. Member diagnosed by a hematologist or oncologist; **AND**
4. One-time, single administration treatment; **AND**
5. Member will be using idacabtagene vicleucel at a certified treatment center; **AND**
6. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
7. Member has adequate bone marrow, renal, hepatic, and cardiac function; **AND**
8. Member has relapsed or refractory disease and received four or more prior lines of systemic therapy including:
 - a. Immunomodulatory agent
 - b. Proteasome inhibitor
 - c. Anti-CD38 monoclonal antibody**AND**
9. Member has or will receive lymphodepleting chemotherapy (fludarabine 30 mg/m² IV daily and cyclophosphamide 300 mg/m² IV daily) for 3 days before infusion of idacabtagene vicleucel; **AND**
10. Member will NOT be treated with more than 460×10^6 viable CAR-T cells; **AND**
11. Member does NOT have any of the following conditions:

MEDICAL COVERAGE POLICY

SERVICE: Idacabtagene vicleucel (Abecma[®])

Policy Number: 290

Effective Date: 12/01/2022

Last Review: 10/27/2022

Next Review Date: 10/27/2023

- a. Active infection (including hepatitis B, hepatitis C, or HIV infection)
- b. Inflammatory disorder

AND

12. The individual has NOT previously been treated with CD-19 targeted therapy or prior CD-19 targeted CAR-T cell therapy; **AND**
13. Member has been assessed by a hematologist/oncologist to be an appropriate candidate for apheresis.

BSWHP considers repeat administration of idacabtagene vicleucel experimental and investigational because the effectiveness of this strategy has not been established.

BSWHP considers idacabtagene vicleucel to be experimental and investigational for all other indications.

All requests will be reviewed by a clinical pharmacist and medical director.

OVERVIEW:

Chimeric antigen receptor (CAR) T cells and genetically engineered T-cell receptor (TCR T) cells are manufactured by collecting lymphocytes from a patient or donor and modifying them using gene transfer techniques. Viral vectors are introduced that express cell receptors that are highly specific for tumor antigens. CAR T and TCR T cells are then infused back into the patient where they direct a targeted immune response to cancerous tissue. CAR T cells express a hybrid receptor with an extracellular single-chain antibody fragment, a transmembrane domain, and at least 1 intracellular signaling domain. CAR T cells are most often used to treat hematological malignancies, and a common target is B-cell cluster of differentiation antigen 19 (CD19).

Multiple myeloma (MM) is a rare hematologic cancer arising from plasma cells in the bone marrow. Malignant plasma cells produce abnormal monoclonal paraproteins that cause organ damage. According to the American Cancer Society (ACS), an estimated 34,920 new cases of MM will be diagnosed, and 12,410 people will die from the disease in the U.S. in 2021. The median age at diagnosis is 69 years, and almost all cases of MM (95%) are diagnosed after the cancer has metastasized. The treatment landscape for MM has evolved over the past 15 years, delivering many new options for improved management of the disease. Despite these advances, MM remains incurable. Almost all patients eventually relapse and develop relapsed/refractory MM (RRMM). The overall 5-year survival rate for MM is 53.9%.

The U. S. Food and Drug Administration (FDA) granted approval for idacabtagene vicleucel (Abecma[®]) on March 26, 2021 which 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The boxed warning includes the clarification that idacabtagene vicleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS), neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), and prolonged cytopenia.

The FDA approval of idacabtagene vicleucel is based on data from the KarMMA (NCT03361748) open-label, single-arm, multicenter study showing an overall response rate (ORR) of 72%, stringent complete



MEDICAL COVERAGE POLICY

SERVICE: Idacabtagene Vicleucel (Abecma[®])

Policy Number: 290

Effective Date: 12/01/2022

Last Review: 10/27/2022

Next Review Date: 10/27/2023

response rate (sCR) of 28%, median progression-free survival (PFS) of 8.8 months overall, a PFS of 20.2 months among patients with a complete response (CR) or better, and a median overall survival (OS) of 19.4 months out of 100 evaluable patients.

With respect to safety, the most common grade 3 or higher adverse effects were febrile neutropenia (16%) and infections – pathogen unspecified (15%). Serious adverse reactions occurred in 67% of patients.

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	0540T - Chimeric antigen receptor T cell (CAR-T) therapy; CAR-T cell administration, autologous 96409 - Chemotherapy administration; intravenous, push technique, single or initial substance/drug 96413 - Chemotherapy administration; intravenous infusion technique; up to 1 hour, single or initial substance/drug
CPT Not Covered:	
HCPCS Codes:	Q2055: Idcabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
ICD10 codes:	C90.00 Multiple myeloma not having achieved remission C90.01 Multiple myeloma in relapse Z51.12 Encounter for antineoplastic immunotherapy
ICD10 Not covered:	

CMS: NCD 110.24 - Chimeric Antigen Receptor (CAR) T-cell Therapy: Medicare covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) -i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

Effective date: 08/07/2019. Implementation date: 09/20/2021

POLICY HISTORY:

Status	Date	Action
New	04/22/2021	New policy
Updated	05/27/2021	Removed Oncology Analytics line, added apheresis criteria
Updated	07/22/2021	Added clinician reviewer criteria
Updated	06/23/2022	Added NCD information
Updated	10/27/2022	Removed language with CMS LCD since NCD applies. Updated HCPCS code. Removed Texas Mandate HB1584 language from main policy section as the policy is compliant. Minor formatting update.

MEDICAL COVERAGE POLICY

**SERVICE: Idacabtagene Vicleucel
(Abecma[®])**

Policy Number: 290

Effective Date: 12/01/2022

Last Review: 10/27/2022

Next Review Date: 10/27/2023

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Abecma (idecabtagene vicleucel) [prescribing information]. Summit, NJ: Celgene Corporation; March 2021.
2. Almásbak H, Aarvak T, Vemuri MC. CAR T cell therapy: a game changer in cancer treatment. *J Immunol Res.* 2016;2016:5474602.
3. American Cancer Society. Key Statistics About Multiple Myeloma. Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html>. Accessed April 16, 2021.
4. Brentjens RJ. Are chimeric antigen receptor T cells ready for prime time? *Clin Adv Hematol Oncol.* 2016;14(1):17-19.
5. Children's Hospital of Philadelphia (CHOP). What to Expect: CAR T-cell Therapy Process. 2017. Available at: <http://www.chop.edu/centers-programs/cancer-immunotherapy-program/your-experience>. Accessed August 8, 2017.
6. Fitzgerald JC, Weiss SL, Maude SL, et al. Cytokine release syndrome after chimeric antigen receptor T cell therapy for acute lymphoblastic leukemia. *Crit Care Med.* 2017;45(2):e124-e131.
7. Harris DT, Kranz DM. Adoptive T cell therapies: a comparison of T cell receptors and chimeric antigen receptors. *Trends Pharmacol Sci.* 2016;37(3):220-230.
8. Hettle R, Corbett M, Hinde S, et al. The assessment and appraisal of regenerative medicines and cell therapy products: an exploration of methods for review, economic evaluation and appraisal. *Health Technol Assess.* 2017;21(7):1-204.
9. Ikeda H. T-cell adoptive immunotherapy using tumor-infiltrating T cells and genetically engineered TCR-T cells. *Int Immunol.* 2016;28(7):349-353.
10. Kebriaei P, Singh H, Huls MH, et al. Phase I trials using Sleeping Beauty to generate CD19-specific CAR T cells. *J Clin Invest.* 2016;126(9):3363-3376.
11. Leukemia and Lymphoma Society (LLS). Chimeric Antigen Receptor (CAR) T-Cell Therapy. 2017. Available at: <https://www.lls.org/treatment/types-of-treatment/immunotherapy/chimeric-antigen-receptor-car-t-cell-therapy>. Accessed April 16, 2021.
12. Locke FL, Davila ML. Regulatory challenges and considerations for the clinical application of CAR-T cell anti-cancer therapy. *Expert Opin Biol Ther.* 2017;17(6):659-661.
13. Maus MV, Nikiforow S. The why, what, and how of the new fact standards for immune effector cells. *J Immunother Cancer.* 2017;5:36.
14. NIH National Cancer Institute. Cancer Stat Facts: Myeloma. Available at: <https://seer.cancer.gov/statfacts/html/mulmy.html>. Accessed April 16, 2021.
15. Ye B, Stary CM, Gao Q, et al. Genetically modified T-cell-based adoptive immunotherapy in hematological malignancies. *J Immunol Res.* 2017;2017:5210459.

Note: Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health



MEDICAL COVERAGE POLICY

SERVICE: Idacabtagene Vicleucel (Abecma®)

Policy Number:	290
Effective Date:	12/01/2022
Last Review:	10/27/2022
Next Review Date:	10/27/2023

Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plans.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA's. Individual HMO plans are offered through FirstCare in West Texas.