MEDICAL COVERAGE POLICY	
SERVICE: Idacabtagene Vicleucel (Abecma®)	
Policy Number:	**290**
Effective Date:	**07/01/2021**
Last Review:	**05/27/2021**
Next Review Date:	**05/27/2022**

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.

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PRIOR AUTHORIZATION: Required.

POLICY:

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination) or NDC (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®)

SWHP/FirstCare 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
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 Onology Group (ECOG) performance status of 0 or 1; **AND**
7. Member has adequate bone marrow, renal, hepatic, and cardiac function
8. Member has relapsed or refractory disease; **AND EITHER:**
    a. For members of Plans subject to Texas Mandate HB1584: the member has stage 4 advanced metastatic disease; **OR**
    b. Received four or more prior lines of systemic therapy including:
        a. Immunomodulatory agent
        b. Proteasome inhibitor
        c. Anti-CD38 monoclonal antibody
9. Member has or will receive lymphodepleting chemotherapy (fludarabine 30 mg/m^2 IV daily and cyclophosphamide 300 mg/m^2 IV daily) for 3 days before infusion of idacabtagene vicleucel.

10. Member will NOT be treated with more than 460 x 10^6 viable CAR-T cells.
11. Member does NOT have any of the following conditions:
    a. Active infection (including hepatitis B, hepatitis C, or HIV infection)
    b. Inflammatory disorder
12. The individual has NOT previously been treated with CD-19 targeted therapy or prior CD-19 targeted CAR-T cell therapy
13. Member has been assessed by a hematologist/oncologist to be an appropriate candidate for apheresis.

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

SWHP/FirstCare considers idacabtagene vicleucel to be experimental and investigational for all other indications.

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 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 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:	C9399 Unclassified drugs or biologicals J9999 Not otherwise classified, antineoplastic drugs
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:

POLICY HISTORY:

Status	Date	Action
New	04/22/2021	New policy
Updated	05/27/2021	Removed Oncology Analytics line, added apheresis criteria

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. The health plan 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 the health plan 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.

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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.

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