TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: idecabtagene Vicleucel (Abecma®)	**CRITERIA ID:** TX.CC.PHAR.12
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/18/2021	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 08/10/2022, 08/15/2023, 03/15/2024, 07/17/2024, 09/11/2024,8/6/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

POLICY STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for idecabtagene vicleucel (Abecma®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria, but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code Q2055 (used for Abecma) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management
CPS = Centene Pharmacy Services
SHP = Superior HealthPlan

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of idecabtagene vicleucel (Abecma®); procedure code: Q2055.

Description/Mechanism of Action:
Idecabtagene Vicleucel (Abecma®) is an B-cell maturation antigen (BCMA) directed genetically modified autologous T-cell immunotherapy.

FDA Approved Indications:
Idecabtagene Vicleucel (Abecma®) is indicated for the treatment of adult clients 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.

Formulations:
unit infusion bag: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient.

- 50 mL infusion bag (NDC: 59572-0515-01)
- 250mL infusion bag (NDC: 59572-0515-02)
- 500mL infusion bag (NDC: 59572-0515-03)

Certified healthcare facilities must enroll and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements for this drug. There are only seven centers in Texas authorized to provide this drug due to REMS (Risk Evaluation and Mitigation Strategy) requirements for the drug. Medical Directors should attempt to direct to a participating (PAR) provider. On a case-by-case basis, said Medical Director may make an exception outside of a PAR provider but will require a single case agreement (SCA). The approved centers are:

- Covenant Health Joe Arrington Cancer Research and Treatment Center (Lubbock)
- Baylor Scott & White (Temple)
- St. David's Healthcare (Austin)
- Methodist Hospital (San Antonio)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
- Medical City (Dallas)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (Houston)

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the medical director but will not make the ultimate determination on any case.
3. The client is 18 years of age or older.
4. The client must have a histologically confirmed diagnosis of relapse or refractory multiple myeloma (diagnosis codes: C90.00 and C90.02)
5. The client must have received two or more lines of the following therapies before treatment with (Abecma):
    a. A proteasome inhibitor
    b. An immunomodulatory agent
    c. An anti-CD38 monoclonal antibody
7. The client does not have primary central nervous system lymphoma/disease.
8. The client does not have an active infection or inflammatory disorder.
9. The client has not received prior CAR-T therapy.
10. The health-care facility has enrolled in the Abecma Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities. Currently, there are only 9 facilities which may provide this drug under these parameters and these are:

- Covenant Health Joe Arrington Cancer Research and Treatment Center (Lubbock)
- Baylor Scott & White (Temple)
- St. David's Healthcare (Austin)
- Methodist Hospital (San Antonio)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
- Medical City (Dallas)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (Houston)

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider.

REFERENCES:

Abecma Prescribing Information. Summit, NJ: Celgene Corporation; March 2021. Available at: https/www.abecma.com

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED

Ad Hoc Review	Changed to new P&P template Updated procedure code	8/10/2022
Annual Review	Updated Policy Statement verbiage to align with verbiage in other CAR T-cell therapy policies Adjusted criteria point verbiage to “the client” for consistency throughout document Added TX authorized centers to Policy section and to criteria points I.9 Replaced Superior HealthPlan/SHP with Centene Pharmacy Services/CPS throughout document Added name/titles list under Policy and Procedure Approval section Updated Definitions section Updated Scope to include CPS and Claims team	8/15/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed criteria step: 10. If the facility is non-PAR the medical director will redirect to a PAR provider. On a case by case basis, said medical director may make an exception outside of a PAR provider but will require a single case agreement (SCA). Once the case is determined, the pharmacy team via pharmacy management will work with the SCA team to assist on the SCA. This should be the exception and not the rule as a PAR facility/provider is preferable. The pharmacist supporting the medical director will contact pharmacy management to start the SCA process.	03/15/2024
Ad Hoc Review	The number of systemic therapies has changed from four or more lines to two or more lines in the following criterion: The client must have received two or more lines of the following therapies before treatment with idecabtagene vicleucel (Abecma): • An immunomodulatory agent • A proteasome inhibitor • An anti-CD-38 monoclonal antibody	07/17/2024
Ad Hoc Review	Updated PURPOSE section to include NRB status effective 10/1/2024	09/11/2024
Annual Review	Font and formatting change for 508 remediation Updated treatment facilities obtained from the manufacturer’s website	8/6/2025