



Drug Coverage Policy

Effective Date8/1/2024
Coverage Policy Number..... IP0168
Policy Title.....Abecma

Oncology (Injectable – CAR-T) – Abecma

- Abecma® (idecabtagene vicleucel intravenous infusion – Bristol-Myers Squibb and bluebird bio)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Abecma, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of relapsed or refractory **multiple myeloma** in adults after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.¹ Abecma is a chimeric antigen receptor T-cell (CAR-T) therapy.

Abecma is supplied in one or more frozen infusion bags contain a suspension of genetically modified autologous chimeric antigen receptor (CAR)-positive T-cells in 5% dimethyl sulfoxide.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for multiple myeloma (version 3.2024 – March 8, 2024) recommend Abecma for the treatment of previously treated multiple myeloma after at least four prior treatment regimens.^{2,3} Patients should receive a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody before receiving Abecma.

Safety

Abecma has a Boxed Warning for cytokine release syndrome, neurologic toxicity, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and prolonged cytopenias.¹ Abecma is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Abecma REMS.

Medical Necessity Criteria

Abecma is considered medically necessary when the following are met:

FDA-Approved Indication

- 1. Multiple Myeloma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has received two or more lines of systemic therapy, including one from each of the following (i, ii, and iii):
 - i.** Patient has received an immunomodulatory agent; AND
Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, Pomalyst (pomalidomide capsules).
 - ii.** Patient has received a proteasome inhibitor; AND
Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
 - iii.** Patient has received an anti-CD38 monoclonal antibody; AND
Note: Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion).
 - C)** Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Abecma; AND
 - D)** Patient has not been previously treated with chimeric antigen receptor T-cell (CAR-T) therapy; AND
Note: Examples of CAR-T therapy includes Abecma, Carvykti (ciltacabtagene autoleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene intravenous infusion).
 - E)** The medication is prescribed by or in consultation with an oncologist.

Dosing. The dose of Abecma is up to 460×10^6 CAR-positive T-cells administered intravenous as a single dose.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

HCPCS Codes	Description
Q2055	Idecabtagene 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

References

1. Abecma intravenous infusion [prescribing information]. Summit, NJ: Bristol-Myers Squibb; January 2024.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network, Available at: <http://www.nccn.org>. Accessed on March 20, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 20, 2024. Search term: idecabtagene.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Multiple Myeloma.	7/1/2024

	<p>Removed (1) 'Documentation of an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1', (2) 'Does not have central nervous system involvement with myeloma', (3) Does not have presence or history of plasma cell leukemia, (4) Removed Hematologist from specialist, (5) Documented diagnosis of multiple myeloma</p> <p>Conditions Not Covered. Removed 'Repeat administration of Idecabtagene vicleucel (Abecma)', note that it was added to approve as a single dose in the criteria</p>	
Selected Revision	<p>Multiple Myeloma: Requirement that the patient has received four or more lines of systemic therapy was revised to patient has received two or more lines of systemic therapy.</p>	8/1/2024

The policy effective date is in force until updated or retired.

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