STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Abecma (idecabtagene vicleucel)
PAM–038

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	10/01/2021
Revision Number:	3	**Last Rev Date:**	10/20/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	10/18/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	10/15/2021

Overview

Medication:[1]	idecabtagene vicleucel
Brand Name:	Abecma®
Pharmacologic Category:	Antineoplastic agent, CAR-T immunotherapy
FDA-Approved Indication(s):	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.
How Supplied:	Supplied in one or more infusion bags (containing 50 mL, 250 mL, or 500 mL of a frozen suspension of genetically modified autologous T cells in 5% DMSO).
Dosage and Administration:	Intravenous (IV) infusion: a single dose of Abecma contains a cell suspension of 300 to 460 x 10^6 CAR-positive T cells in one or more infusion bags.
Benefit Category:	Medical

BOXED WARNING: Cytokine release syndrome, neurologic toxicities, HLH/MAS, and prolonged cytopenia

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with Abecma®. Do not administer to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic toxicities, which may be severe or life-threatening, occurred following treatment with Abecma®, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment. Provide supportive care and/or corticosteroids as needed.
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with Abecma®. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with Abecma®.
- Abecma® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.

Descriptive Narrative

Multiple myeloma (MM) is a malignant hematological disorder characterized by the clonal proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Clinical manifestations of multiple myeloma may include bone pain, increased total serum protein concentration, anemia, hypercalcemia, and acute kidney failure.

MM primarily affects older individuals, the median age at diagnosis is 65 to 74 years. It is slightly more frequent in men than in women (approximately 1.4:1), and while MM occurs in all races and all geographic locations, the incidence varies by ethnicity. The incidence in African Americans and Black populations is two to three times that in White populations in studies from the United States and United Kingdom. In contrast, the risk is lower in the Japanese and Mexican populations.[2]

Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimates 35,730 new cases of MM and 12,590 deaths from MM in the United States in 2023 (representing 1.8% of all new cancer cases and 2.1% of all cancer deaths). This correlates with an annual incidence of 7.1 per 100,000 men and women per year, and a death rate of 3.2 per 100,000 men and women per year.

Most patients with multiple myeloma will have an initial response to treatment. However, conventional therapy is not curative, and MM will ultimately relapse. In addition, a minority will have primary refractory disease that does not respond to initial treatment. Relative survival is an estimate of the percentage of patients who would be expected to survive the effects of their cancer. It excludes the risk of dying from other causes. The introduction of proteasome inhibitors, immunomodulatory agents, monoclonal antibodies, and stem cell transplantation has extended median survival. [3]

Guidelines

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[4]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for Multiple Myeloma (Version 1.2024 – September 22, 2023).[5]

NCCN Guidelines® Recommendation(s) for idecabtagene vicleucel in previously treated multiple myeloma
(1) Relapsed/refractory disease after 3 prior therapies [a,b] A. After at least four prior therapies, including an anti-CD38 monoclonal antibody, a PI, and an IMiD [c] i. Idecabtagene vicleucel: Category 2A, preferred regimen PI = proteosome inhibitor IMiD = immunomodulatory drug [a] Regimens included under 1–3 prior therapies can also be used later in the disease course. Attempt should be made to use drugs/drug classes the patients have not been exposed to or exposed to >1 line prior. [b] Autologous HCT should be considered in patients who are eligible and have not previously received HCT or had a prolonged response to initial HCT. [c] Patients can receive more than one B-cell maturation antigen (BCMA) targeted therapy, but optimal sequencing is unclear.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status[6]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient and determine appropriate treatment and prognosis.

GRADE	ECOG PERFORMANCE STATUS [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Tocilizumab (Actemra®) may be required to manage cytokine release syndrome (CRS) or neurologic toxicities. HCPCS code J3262 suspends for claims review. If tocilizumab therapy is required, may be approved for up to 4 doses of 800 mg each.

Prior authorization is required.

Abecma® is considered medically necessary when **ALL** of the following are met:

1. Member has a diagnosis of multiple myeloma (MM); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has relapsed or refractory disease after four or more prior therapies, which include at least **ONE OF EACH** of the following categories:
   a. An immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide); **AND**
   b. A proteosome inhibitor (e.g., bortezomib, carfilzomib, ixazomib); **AND**
   c. An anti-CD38 monoclonal antibody (e.g., daratumumab, elotuzumab, isatuximab); **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
5. Member does not have active central nervous system involvement with MM; **AND**
6. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
7. Member has **NOT** received any previous treatment with anti-BCMA targeted therapy (e.g., Blenrep®, Tecvayli®); **AND**
8. Member has **NOT** received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Breyanzi®, Carvykti®, Kymriah®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be administered concurrently with Abecma®; **AND**
9. Member is receiving Abecma® as a one-time, single administration treatment; **AND**
10. Member will receive Abecma® at a facility that is certified under the Abecma® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
11. Dose does not exceed 300 to 460 x 10^6 CAR-positive T cells.

Continued therapy will not be authorized, as Abecma is indicated to be dosed one time only.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization
Approval Duration	One course of treatment per lifetime	Not applicable
Quantity Limits	One-time dose, not to exceed 460 x 10^6 CAR-positive T cells	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J3262	Injection, tocilizumab, 1 mg [Actemra®: may be required to manage cytokine release syndrome or neurologic toxicities]
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.

ICD-10	Description
C90.0	Multiple myeloma.
C90.00	Multiple myeloma not having achieved remission.
C90.01	Multiple myeloma in remission.
C90.02	Multiple myeloma in relapse.

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
59572-0515-01	Celgene Corporation	per treatment dose	1	EA	1
59572-0515-02	Celgene Corporation	per treatment dose	1	EA	1
59572-0515-03	Celgene Corporation	per treatment dose	1	EA	1

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Abecma® prescribing information (03/2021). Celgene Corporation, a Bristol-Myers Squibb Company: Summit, NJ. Available online at: www.abecmahcp.com. Accessed October 9, 2023.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed October 10, 2023.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed October 8, 2023.

[4] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

[5] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma (v.1.2024 – September 22, 2023). Accessed October 9, 2023. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[6] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655.

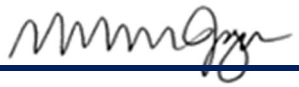
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Annual review. Added boxed warning to Overview section (CRS, neurologic toxicities, and HLH/MAS). Updated Descriptive Narrative with 2023 statistics. Updated reference to NCCN Guidelines®, but no changes in guideline recommendations. Removed criteria containing examples of measurable disease. Added paragraph before prior authorization criteria regarding tocilizumab (Actemra®) to manage CRS or neurological toxicities. Added criterion "Member has not received any previous treatment with B-cell maturation antigen (BCMA)-targeted therapy (e.g., Blenrep®, Tecvayli®)." Put dosing limits into criteria. Added J3262 (Actemra®) to Coding and Product Information.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/21/2022	CAC	Added criteria "The regimen/dosing prescribed is within the FDA-approved labeling." Updated HCPCS code and description. Updated references where applicable.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/15/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee