Carvykti (ciltacabtagene autoleucel)
PAM – 048

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2022
Revision Number	4	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	01/20/2023

Overview

Medication: [1]	ciltacabtagene autoleucel
Brand Name:	Carvykti®
Pharmacologic Category:	Antineoplastic agent; autologous T cell immunotherapy, B-cell maturation antigen (BCMA)-directed
FDA-Approved Indication(s):	Treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one (1) prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.
How Supplied:	Provided as a single dose containing a suspension of chimeric antigen receptor (CAR)-positive viable T cells in one infusion bag.
Dosage and Administration:	The recommended dose range is 0.5 – 1.0 $\times 10^6$ CAR-positive viable T cells per kilogram of body weight, with a maximum dose of 1×10^8 CAR-positive viable T cells per single infusion.
Benefit Category:	Medical

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/HMA, PROLONGED & RECURRENT CYTOPENIA, AND SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine Release Syndrome (CRS)**, including fatal or life-threatening reactions, occurred in patients following treatment with Carvykti®. Do not administer to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)**, which may be fatal or life-threatening, occurred following treatment with Carvykti®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with Carvykti®. Provide supportive care and/or corticosteroids as needed.
- **Parkinsonism and Guillain-Barré syndrome and their associated complications** resulting in fatal or life-threatening reactions have occurred following treatment with Carvykti®.
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)**, including fatal and life-threatening reactions, occurred in patients following treatment with Carvykti®. HLH/MAS can occur with CRS or neurologic toxicities.
- **Prolonged and/or recurrent cytopenias** with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with Carvykti®.

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• **Secondary hematological malignancies**, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with Carvykti®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including Carvykti®.

POST-INFUSION MONITORING
• Monitor patients at least daily for seven days following Carvykti® infusion for signs and symptoms of CRS and neurologic toxicities. • Instruct patients to remain within proximity of a healthcare facility for at least two weeks following infusion. • Advise patients to avoid driving for at least 2 weeks following infusion.

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. Most patients with MM present with signs or symptoms related to the infiltration of plasma cells into the bone or other organs or to kidney damage from immunoglobulin deposition. While the clinical presentation is usually subacute, a small percentage of patients present acutely with findings that require rapid attention and intervention (e.g., spinal cord compression, kidney failure, hyperviscosity).

The acronym "CRAB" is sometimes used to remember myeloma-defining events that are used in the diagnosis of MM: **c**alcium elevation; **r**enal insufficiency (kidney impairment); **a**nemia; and **b**one disease. It is important to distinguish MM both from other causes of the clinical presentations above and from other plasma cell dyscrasias for the purposes of prognosis and treatment.

MM primarily affects older individuals; median age at diagnosis is 65 – 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 the 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 36,110 new cases of MM and 12,030 deaths from MM in the United States in 2025 (representing 1.8 percent of all new cancer cases and 1.9 percent of all cancer deaths). This correlates with an annual incidence of 7.3 per 100,000 men and women per year, and an annual death rate of 2.9 per 100,000 men and women per year. [3]

Treatment alleviates symptoms, reverses cytopenias, and decreases end-organ damage, and it aims to achieve a sustained response, improve quality of life, and prolong overall survival (OS). While most patients with multiple myeloma will have an initial response to treatment, 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.[4]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. 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.[5,6]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[7]

- Multiple Myeloma (v.4.2024 – April 26, 2024)

NCCN Guidelines® Recommendation(s)
Therapy for Previously Treated Multiple Myeloma (1) Relapsed/refractory after 1 – 3 prior therapies [a, b, c] a. After 1 prior therapy including an immunomodulatory drug (IMiD) and a proteosome inhibitor (PI), and refractory to lenalidomide. i. Ciltacabtagene autoleucel: Category 1, Preferred Regimen [a] Regimens included under 1–3 prior therapies can also be used later in disease course. Make attempt 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] If relapse occurs > 6 months after stopping treatment, the primary regimen could be considered.

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 Scale [8]

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 themselves, 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 to 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 housework, 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 or neurologic toxicities. If tocilizumab therapy is required, may be approved for up to 4 doses of 800 mg each. HCPCS code J3262 suspends for claims review.

Prior authorization is required.

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

1. Diagnosis of multiple myeloma (MM); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has relapsed or refractory disease after one prior therapy (which may or may not include therapy supported by hematopoietic stem cell transplant) **AND** prior therapy includes 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**
4. Member's disease is refractory to lenalidomide; **AND**
5. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
6. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
7. Member does not have active central nervous system involvement with MM: **AND**
8. Member has not received any previous treatment with B-cell maturation antigen (BCMA)-targeted therapy (e.g., Blenrep®, Tecvayli®); **AND**
9. Member has not received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy, e.g., Abecma®, Breyanzi®, Kymriah®, Tecartus®, or Yescarta®, nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Carvykti®; **AND**
10. Carvykti® is given as a one-time, single administration treatment; **AND**
11. Dose does not exceed 1×10^8 CAR-positive viable T cells.

Continued therapy will not be authorized, as Carvykti® 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 1 x 10^8 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
~~C9098~~	~~Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose *(effective 7/1/2022 – 9/30/2022)*~~
J3262	Injection, tocilizumab, 1 mg [Actemra®: may be required to manage cytokine release syndrome or neurologic toxicities]
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose *(effective 10/1/2022)*

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 (infusion bag volume)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
57894-0111-01 (70 mL)	Janssen Biotech, Inc. (57894)	per treatment dose	1	EA	1
57894-0111-02 (30 mL)	Janssen Biotech, Inc. (57894)	per treatment dose	1	EA	1

Compliance

1. Should conflict exist between the 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] Carvykti prescribing information (06/2025). Janssen Biotech, Inc.: Horsham, PA. Available online: www.carvyktihcp.com. Accessed August 12, 2025.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed June 9, 2025.

[4] Laubach JP. Multiple myeloma: Overview of management. Connor RF, ed. UpToDate. Waltham, MA. UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[7] NCCN Clinical Practice Guidelines in Oncology. 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, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Multiple Myeloma (v.4.2024 – April 26, 2024)

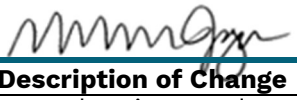
[8] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

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
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. Updated boxed warning to reflect removal of REMS requirement and added post-infusion monitoring requirements in a separate table (Overview section). Updated SEER statistics with 2025 data. Updated criteria to remove requirement that Carvykti® be administered at a REMS facility.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual review. Updated Overview Table with modified indication only requiring 1 prior therapy including an IMiD and a PI (previously was 4 prior therapies). as well as refractory to lenalidomide. Updated boxed warning to include secondary hematological malignancies. Updated Descriptive Narrative, including 2024 statistics. Updated criteria to reflect revised indication. Updated references where applicable.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Annual review. Updated Descriptive Overview with 2023 statistics. Updated NCCN Guidelines. Removed criteria containing examples of measurable disease. Added criterion “Member has not received any previous treatment with B-cell maturation antigen (BCMA)-targeted therapy (e.g., Blenrep®, Tecvayli®).”	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/20/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee