Carvytki™ (Ciltacabtagene autoleucel)

Policy Number: 061

	Commercial and Qualified Health Plans	MassHealth
Authorization required	X	X
No Prior Authorization		

Carvytki is a chimeric antigen receptor T cell therapy (CAR-T), designed to harness the power of the patient's immune system to recognize and attack their cancer cells. CAR-T is a type of treatment where white blood cells (T cells) are modified in a laboratory to add a gene that helps the patient's own T cells target their cancer.

FDA-Approved Indication

Carvytki is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy for the treatment of:

- Adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including:
  - Immunomodulatory agent;
  - Anti-CD38 monoclonal antibody;
  - Proteasome inhibitor.

Criteria

1. Criteria for Initial Approval

Authorization of a single treatment may be granted to patients 18 years of age or older for treatment of multiple myeloma when ALL of the following criteria are met:

A. The disease is relapsed or refractory to treatment after four or more lines of systemic therapy.
B. The member has not received any prior FDA approved CAR-T cell therapy directed against B-cell maturation antigen (BCMA).
C. The patient will receive lymphodepleting chemotherapy (cyclophosphamide and fludarabine) prior to infusion of Carvykti.
D. The patient has stable and adequate kidney, liver, pulmonary, and cardiac function as determined by the treating oncologist or hematologist.
E. The patient does not have clinically significant active infectious or inflammatory disorders.
F. The patient does not have active graft versus host disease.
G. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Any performance status above 2 can be considered on a case by case basis.
H. The healthcare facility that dispenses and administers Carvytki must be enrolled and comply with the Carvytki Risk Evaluation and Mitigation Strategy known as REMS.
I. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.

2. Required Documentation
    - Documentation of four prior lines of therapy
    - Provider/patient REMS certification/enrollment

3. Duration of Therapy
    - Single treatment course
    - Additional courses of therapy are considered experimental/investigational.

CPT/HCPC Codes

Authorized CPT/HCPCS Codes	Code 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

July 2022: Effective Date.

References

Berdeja JG, Madduri D, Usmani SZ, et al. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): A phase 1b/2 open-label study [published correction appears in Lancet. 2021 Oct 2;398(10307):1216]. Lancet. 2021;398(10297):314-324.

Janssen Biotech, Inc. Carvykti (ciltacabtagene autoleucel) suspension for intravenous infusion. Prescribing Information. Horsham, PA; Janssen Biotech: revised February 2022.