JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP099
		Effective Date	07/17/2024
		Approval Date	07/17/2024
	Subject **Carvykti**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Carvykti

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I. POLICY

A. Carvykti (ciltacabtagene autoleucel) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Carvykti may be approved for patients who meet the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing a diagnosis of relapsed or refractory multiple myeloma
   3. Documentation has been submitted showing all of the following:
      a. Patient has received prior treatment with at least one line of therapy, including at least one drug from each of the following categories:
         I. Immunomodulatory agent
         II. Proteasome inhibitor
      b. The disease is lenalidomide-refractory
      c. Patient has not received previous treatment with the requested medication or another CAR-T therapy directed at any target
      d. Patient has an ECOG performance status of 0 to 2
      e. Patient has adequate and stable kidney, liver, pulmonary and cardiac function
      f. Patient does not have known active or prior history of central nervous system (CNS) involvement, including CNS multiple myeloma
      g. Patient does not have clinically significant active infection
      h. Patient does not have active graft versus host disease
      i. Patient does not have an active inflammatory disorder

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval will be limited to 3 months of therapy

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IV. EXCLUSIONS

A. Carvykti will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
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	Q2056

VII. REFERENCES

1. Carvykti [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; April 2024.
2. 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. Lancet. 2021 Jul 24;398(10297):314-324.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma. Version 2.2024. Accessed July 8, 2024
4. Patel U, Oluwole OO, Kassim A, et al. Sequencing bispecific antibodies and CAR T cell therapy in multiple myeloma with prior exposure to BCMA-targeted therapies. J Clin Oncol. 2023;41(16):e20049

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation

Review Date: 07/17/2024

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