JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP070
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	Subject **Provenge**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: provenge

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I. POLICY

A. Provenge (sipuleucel-T) 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. Provenge may be approved for patients who meet the following:
   1. Documentation has been provided showing the patient has been diagnosed with one of the following:
      a. Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer
      b. Biochemical relapse of nonmetastatic androgen-dependent (castration-naïve) prostate cancer

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months for a maximum of 3 doses
B. Continuation of therapy: Approval for an additional 3-months may be provided to patients that meet the initial criteria noted above, as well as the following:
   1. Patient is currently receiving treatment with Provenge
   2. Patient has not yet completed treatment with all 3 doses

IV. EXCLUSIONS

A. Provenge will not be covered for the following:
   1. More than 3 doses total
   2. Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

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

VI. CODES

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
Sipuleucel-t, minimum of 50 million tautologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	Q2043

VII. REFERENCES

1. Provenge [prescribing information]. Seattle, WA: Dendreon Corporation; July 2017.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 25, 2022.

VIII. APPROVALS

Signature on file at JHHC

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