Medical Policy:
Provenge® (sipuleucel-T) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.101	January 12, 2024	

Length of Authorization

Coverage will be provided for 3 doses only

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

1 billable unit every 14 days x 3 doses only

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

1. <u>Prostate Cancer †</u>

A. Patient has castration-resistant metastatic disease; **AND**

B. Patient has an ECOG Performance status of 0-1; **AND**

C. Patient has no hepatic metastases; **AND**

D. Must not be used in combination with chemotherapy; **AND**

E. Patient's life expectancy is estimated to be greater than 6 months; **AND**

F. Patient is asymptomatic or minimally symptomatic; **AND**

G. Patient has not previously received therapy with sipuleucel-T

† FDA Approved Indication(s)

II. RENEWAL CRITERIA

Coverage cannot be renewed.

Limitations/Exclusions

Provenge is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
Q2043	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion; 1 billable unit = 1 dose (Code Price is per 250 mL)

Applicable NDCs

Code	Description
30237-8900-xx	Provenge suspension for injection

ICD-10 Diagnoses

Code	Description
C61	Malignant neoplasms of prostate

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/12/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	5/18/2023	Annual Revision: Removed code Z85.46
EmblemHealth & ConnectiCare	10/13/2022	Transferred policy to new template

EmblemHealth & ConnectiCare	01/01/2020	Annual review

References

1. Provenge [package insert]. Seattle, WA; Dendreon Corporation; July 2017. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 2.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
4. CGS, Administrators, LLC. Local Coverage Article for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (A52422). Centers for Medicare & Medicaid Services, Inc. Updated on 7/31/2017 with effective date 7/1/2016. Accessed March 2018.
5. Noridian Healthcare Solutions, LLC. Local Coverage Article for SIPULEUCEL-T (Provenge®) - Coverage Criteria for Prostate Cancer – Clarification (A52926; A55719). Centers for Medicare & Medicaid Services, Inc. Updated on 09/09/2017 with effective date 10/1/2015. Accessed March 2018.
6. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Centers for Medicare & Medicaid Services, Inc. Updated 07/2011 with effective date 06/30/2011. Accessed March 2018.