

Provenge® (sipuleucel-T) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 3 doses only and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Provenge suspension for injection: 1 pre-made bag every 14 days for 3 doses only

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit every 14 days x 3 doses only

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prostate Cancer † ‡¹⁻⁵

- Patient has castration-resistant metastatic disease; **AND**
- Patient has an ECOG Performance status of 0-1; **AND**
- Patient does not have liver metastases; **AND**
- Must not be used in combination with chemotherapy; **AND**
- Patient's life expectancy is estimated to be greater than 6 months; **AND**
- Patient is asymptomatic or minimally symptomatic; **AND**
- Patient has not previously received therapy with sipuleucel-T

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
Prostate Cancer	Infuse the contents of 1 pre-made bag (containing at least 50 million autologous CD54 ⁺ cells activated with PAP-GM-CSF) over 60 minutes. Administer 3 doses at approximately 2-week intervals.

VI. Billing Code/Availability Information

HCPCS Code:

- 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)

NDC(s):

- Provenge suspension for injection: 30237-8900-xx

VII. References

1. Provenge [package insert]. Seal Beach, CA; Dendreon Pharmaceuticals LLC; July 2017. Accessed February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2024. 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 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 3.2024. National Comprehensive Cancer Network, 2023. 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 2024.
4. Kantoff PW, Higano CS, Shore ND, et al; IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010 Jul 29;363(5):411-22. doi: 10.1056/NEJMoa1001294.
5. Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. J Clin Oncol. 2006 Jul 1;24(19):3089-94. doi: 10.1200/JCO.2005.04.5252.
6. Noridian Healthcare Solutions, LLC. Local Coverage Article: Sipuleucel-T (Provenge®) – Coverage Criteria for Prostate Cancer – Clarification (A52926; A55719). Centers for Medicare &

Medicaid Services, Inc. Updated on 11/16/2023 with effective date 10/19/2018. Accessed February 2024.

7. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Centers for Medicare & Medicaid Services, Inc. Updated on 01/06/2012 with effective date 06/30/2011. Accessed February 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor
All	110.22	All
F	A52926	Noridian Healthcare Solutions, LLC
E	A55719	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC