Provenge® (sipuleucel-T)
(Intravenous)

Document Number: IC-0100

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I. Length of Authorization

Coverage will be provided for 3 doses only.

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 hepatic 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); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage cannot be renewed.

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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 over 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 March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. 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 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 1.2023. 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 2023.
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

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Medicare & Medicaid Services, Inc. Updated on 09/29/2020 with effective date 10/19/2018. Accessed March 2023.

7. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Centers for Medicare & Medicaid Services, Inc. Updated 01/06/2012 with effective date 06/30/2011. Accessed March 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): E	NCD/LCD Document (s): A55719
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a55719&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): F	NCD/LCD Document (s): A52926
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52926&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): ALL	NCD/LCD Document (s): NCD 110.22
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=110.22&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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)

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Jurisdiction	**Applicable State/US Territory**	**Contractor**
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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Phone: 1.800.940.5049 (TTY: 763.847.4013)
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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