

Provenge® (sipuleucel-T)

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I. Length of Authorization

Coverage will be provided for 3 doses only

II. Dosing Limits

A. Max Units (per dose and over time) [Medical Benefit]:

- 1 billable unit every 14 days x 3 doses only

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prostate Cancer †

- Patient has castration-recurrent metastatic disease; **AND**
- ECOG Performance status of 0-1; **AND**
- Patient has no hepatic metastases; **AND**
- Not to be used in combination with chemotherapy; **AND**
- Life expectancy is estimated to be greater than 6 months; **AND**
- Patient is asymptomatic or minimally symptomatic

† FDA Approved Indication(s)

ECOG PERFORMANCE STATUS	
Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction

1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

Indication	Dose
Prostate Cancer	1 pre-made bag (containing at least 50 million autologous CD54+ cells activated with PAP-GM-CSF) every 2 weeks for 3 doses

VI. Billing Code/Availability Information

Jcode:

- Q2043 – Provenge (Dendreon) contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, suspended in 250 mL of Lactated Ringer’s Injection, USP.
 - 1 billable unit = 1 dose

NDC(s):

- Provenge suspension for injection: 30237-8900-xx

VII. References

1. Provenge [package insert]. Seattle, WA; Dendreon Corporation; October 2014. Accessed January 2017.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2017. 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 January 2017.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 1.2017. National Comprehensive Cancer Network, 2016. 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 January 2017.

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 7/25/2016 with effective date 7/1/2016. Accessed January 2017.
5. Noridian Healthcare Solutions, LLC. Local Coverage Article for SIPULEUCEL-T (Provenge®) - Coverage Criteria for Prostate Cancer – Clarification (A52924; A52926). Centers for Medicare & Medicaid Services, Inc. Updated on 3/31/2014 with effective date 10/1/2015. Accessed January 2017.
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 January 2017.

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)

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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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):

Jurisdiction(s): 15	NCD/LCD Document (s): A52422
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52422&ver=5&Date=11%2f02%2f2016&DocID=A52422&bc=hAAAABAAAAAAAAA%3d%3d&	

Jurisdiction(s): F	NCD/LCD Document (s): A52924
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52924&ver=2&DocID=A52924&bc=gAAAABAAAAAAAAA%3d%3d&	

Jurisdiction(s): F	NCD/LCD Document (s): A52926
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52926&ver=2&DocID=A52926&bc=gAAAABAAAAAAAAA%3d%3d&	

Jurisdiction(s): ALL	NCD/LCD Document (s): NCD 110.22
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&articleId=52422&ver=5&bc=gAAAABAAAAAAAAA%3d%3d&	

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 Corporation (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 Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, 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