



Medicare Advantage Medical Utilization Review Policy

Policy:	Oncology (Injectable) – Provenge Utilization Management Medical Policy <ul style="list-style-type: none"> • Provenge® (sipuleucel-T intravenous infusion – Dendreon)
Date:	05/10/2023
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	NCD 110.22 - All States

OVERVIEW

Provenge, an autologous cellular immunotherapy, is indicated for the treatment of asymptomatic or minimally symptomatic metastatic **castrate-resistant (hormone-refractory) prostate cancer (CRPC)**.¹

Provenge consists of autologous peripheral blood mononuclear cells, including antigen presenting cells, that have been activated during a defined culture period with a recombinant human protein found on prostate cancer tissue, linked to an immune cell activator. Provenge is designed to induce an immune response targeted against an antigen expressed in most prostate cancer cells. Each dose of Provenge contains a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF). As noted in the prescribing information, in controlled clinical trials, the median dosing interval between infusions was 2 weeks; however, the dosing interval range could elapse between 1 week to 15 weeks. The maximum dosing interval has not been established.

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 3.2022 – January 10, 2022) lists Provenge as a category 1 recommended therapy for metastatic CRPC for patients who have not received prior docetaxel or prior novel hormone therapy.^{2,3} Provenge is also listed as an option (category 2A) for patients who have received either prior docetaxel or prior novel hormone therapy. It is noted that Provenge has not been studied in patients with visceral metastases and is not recommended if visceral metastases are present. Provenge is also not recommended for patients with small cell/neuroendocrine prostate cancer. The guidelines note that Provenge is only recommended for patients who meet the following: Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; estimated life expectancy > 6 months; no hepatic metastases; and no or minimal disease symptoms.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Provenge. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to

approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Provenge is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Prostate Cancer.

Criteria. Approve for 3 months if the patient meets the following criteria (A, B, C, D and E):

- A) Patient is ≥ 18 years of age; AND
- B) The patient has metastatic castration-resistant (hormone-refractory) prostate cancer; AND
- C) The patient has minimal or no disease symptoms, according to the prescriber; AND
- D) The patient does not have liver metastasis; AND
- E) The patient has not been previously treated with a complete course (3 doses) of Provenge for prostate cancer.

Dosing. Approve up to three doses, each dose containing a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF) given at approximately 2-week intervals.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Provenge is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Provenge® Intravenous Infusion [prescribing information]. Seal Beach, CA: Dendreon Pharmaceuticals; July 2017.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 5, 2022. Search term: Sipuleucel-T.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 5, 2022.
4. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). [Version Number 1, Effective date of version: 6/30/2011. Accessed December 13, 2023].



EmblemHealth®

ConnectiCare

05/10/2023

© 2023. All Rights Reserved.

5. Centers for Medicare and Medicaid Services. Noridian Healthcare Solutions, LLC. Local Coverage Article (LCA): Sipuleucel-T (PROVENGE®) - Coverage Criteria for Prostate Cancer – Clarification (A52926). [Original effective date 10/01/2015; Revision effective date 10/19/2018]. Accessed on December 13, 2023.
6. Centers for Medicare and Medicaid Services. Noridian Healthcare Solutions, LLC. Local Coverage Article (LCA): Sipuleucel-T (PROVENGE®) - Coverage Criteria for Prostate Cancer – Clarification (A55719). [Original effective date 10/01/2015; Revision effective date 10/19/2018]. Accessed on December 13, 2023.

HISTORY

Type of Revision	Summary of Changes*	Date
Policy created	New Medicare Advantage Medical Policy	02/20/2019
Policy revision	Non-clinical update to policy to add the statement “This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does <u>not</u> necessarily mean that the applicable condition or diagnosis is excluded from coverage.”	1/30/2020
Policy revision	Changed “prescribing physician” to “prescriber”.	02/26/2020
Policy revision	Added the following to the Policy Statement “ Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.”	04/03/2020
Policy revision	Prostate Cancer: A requirement that the patient is ≥ 18 years of age was added.	06/23/2022
Policy revision	Prostate Cancer: Dosing was reworded to include the dose information “each dose containing a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF)”.	08/01/2022
Policy review	No criteria changes	05/10/2023

