

## Medical Policy: Provenge® (sipuleucel-T) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.101	February 25, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

### Length of Authorization

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

### Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

1 billable unit every 14 days x 3 doses only

### Guideline

**\*\*For Medicare members: Provenge- please refer to our separate LCD/NCD Medicare criteria**

**I. INITIAL APPROVAL CRITERIA**

Coverage is provided in the following conditions:

**1. Prostate Cancer †**

- 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
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z19.2	Hormone resistant malignancy status
Z85.46	Personal history of malignant neoplasm of prostate

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/25/2025	Annual Review: added: R97.21, Z19.2, Z85.46. No criteria changes
EmblemHealth & ConnectiCare	4/8/2024	Added Statement: **For Medicare members: Provenge- please refer to our separate LCD/NCD Medicare criteria
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.