Sipuleucel-T (Provenge®)

NDC CODE(S) 30237-8900-XX - PROVENGE Suspension (DENDREON CORPORATION)

DESCRIPTION

Sipuleucel-T is the first autologous cellular immunotherapy approved for use in the United States. It is designed to induce an immune response targeted against the protein prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers.

Sipuleucel-T is administered by infusion, generally in three doses. Approximately three days prior to each infusion, the individual undergoes a standard leukapheresis procedure in which peripheral blood mononuclear cells, including antigen presenting cells (APCs) are harvested. During a defined culture period, the APCs are activated with recombinant human protein PAP linked with granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune cell activator. During culture, the recombinant PAP and GM-CSF can bind to and be processed by APCs into smaller protein fragments which are then infused into the individual along with other cells retrieved by the leukapheresis, including T cells, B cells, natural killer (NK) cells and other cells suspended in 250 mL of Lactated Ringer's Injection, USP.

POLICY

- Sipuleucel-T for the treatment of prostate cancer is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Sipuleucel-T for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

Prostate Cancer

- Patient has castration-resistant metastatic disease; **AND**
- Patient has an ECOG Performance status of 0-1; **AND**
- Patient has no 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

RENEWAL CRITERIA

Coverage cannot be renewed.

DOSAGE/ADMINISTRATION

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

LENGTH OF AUTHORIZATION

Coverage will be provided for 3 doses only

DOSING LIMITS

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

- 1 billable unit every 14 days x 3 doses only

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Provenge [package insert]. Seal Beach, CA; Dendreon Pharmaceuticals LLC; July 2017. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2021. 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 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 2.2021. National Comprehensive Cancer Network, 2021. 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 2021.
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. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2019, November). *Sipuleucel-T.* Retrieved March 1, 2019 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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