MEDICAL MUTUAL®

Drug Policy

Policy:	**201013**	**Initial Effective Date: 11/03/2010**
Code(s):	**HCPCS Q2043**	**Annual Review Date: 10/18/2018**
SUBJECT:	**Sipuleucel-T (Provenge®)- Prostate Cancer**	**Last Revised Date: 10/18/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Sipuleucel-T (Provenge®, Dendreon Corporation, Seattle, WA) is an autologous cellular immunotherapy (ACI) product that utilizes autologous dendritic cells to manufacture a personalized prostate cancer vaccine. Immune cells harvested via leukapheresis (cytapheresis) are conditioned with a proprietary recombinant fusion protein to recognize prostatic acid phosphatase (PAP) as foreign. Administered intravenously, sipuleucel-T is thought to trigger an antigen-antibody response to prostatic acid phosphatase, a protein found in approximately 95 percent of prostate cancer cells.

The U.S. Food and Drug Administration (FDA) approved (April 29, 2010) sipuleucel-T Biologics License Application (BLA) for treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone-refractory, androgen-independent) prostate cancer (CRPC).

POLICY STATEMENT

This policy involves the use of Provenge. Prior authorization is recommended for medical benefit coverage of Provenge. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Provenge as well as the monitoring required for AEs and long-term efficacy, initial approval requires Provenge be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. Metastatic, castrate-resistant (hormone-refractory) prostate cancer

Criteria. *Patient must meet the following criteria (A, B, C, D, E, F, G, H and I)*

A. Metastatic, castrate-resistant (hormone-refractory) prostate cancer ; and
B. Asymptomatic or minimally symptomatic with Eastern Cooperative Oncology Group (ECOG) performance status 0-1[†]; and
C. Histologically-confirmed prostate adenocarcinoma and ***at least one*** of the following:
    i. Measurably progressive disease as evidenced by changes in lymph node size, parenchymal mass on physical examination or radiographic studies (e.g., computed tomography [CT], magnetic resonance imaging [MRI]); or
    ii. Serial bone scan demonstrates ≥1 new lesion(s) or increased lesion size (excluding "flare" occurring at onset of hormonal treatment or chemotherapy); or
    iii. Elevated and increasing prostate-specific antigen (PSA) level (i.e., prostate-specific antigen progression) after additional elevated prostate specific antigen level: two additional values, obtained on separate days and a minimum of one week after the baseline level, that are **both** determined to be ≥25% **and** ≥5 ng/ml above the baseline prostate-specific antigen level; and
D. Prior surgical castration (bilateral orchiectomy) or ≥3 months of chemical castration (serum testosterone level <50ng/dl) treatment with luteinizing hormone releasing hormone (LHRH) agonists (e.g., leuprolide, goserelin, triptorelin, histrelin) or antagonists (e.g., degarelix); and
E. Not administered concomitantly with chemotherapy, other immunotherapy or radiation therapy; and
F. Administered ***only*** to the individual from whom cells were harvested; and
G. No moderate to severe prostate cancer-related pain and/or use of opioid analgesics for cancer-related pain; and
H. Visceral (e.g., liver, lung, brain) metastases are not present; and
I. Life expectancy ≥6 months.

Frequency limitations: The Company limits the frequency of sipuleucel-T to one treatment cycle. One treatment cycle consists of three doses, given at approximately two-week intervals for a treatment period ≤30 weeks from initial administration. Requests for retreatment with sipuleucel-T will be reviewed on a case-by-case basis. No data were available supporting the benefit of retreatment.

The Company considers sipuleucel-T for ***all*** other indications **not medically necessary** and **not** eligible for reimbursement.

NOTE: Leukapheresis (cytapheresis) is addressed in Corporate Medical Policy 94052: Therapeutic Apheresis.

[†]Eastern Cooperative Oncology Group Performance Status:

Grade 0	Fully active, able to carry on all pre-disease performance without restriction.
Grade 1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.

Grade 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.
Grade 3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
Grade 4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
Grade 5	Dead.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Provenge has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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- National Cancer Institute. (2010, May 04). *Featured Article. FDA approves first therapeutic cancer vaccine.* Retrieved from http://www.cancer.gov/ncicancerbulletin/050410/page2.
- National Comprehensive Cancer Network®. (2015). *NCCN clinical practice guidelines in oncology (NCCN guidelines™). Prostate cancer. Version 4.2018.*

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- Silverman, E. (2010). Provenge approval means sensitive coverage decisions. *Manag Care, 19*(9), 31-34.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPS Code Q2043.

HCPCS Code(s):	
Q2043	Sipuleucel-T-t, minimum of 50 million autologous CD54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion