

## Corporate Medical Policy

### Cellular Immunotherapy for Prostate Cancer

<b>File Name:</b>	cellular_immunotherapy_for_prostate_cancers
<b>Origination:</b>	6/2010
<b>Last CAP Review:</b>	8/2011
<b>Next CAP Review:</b>	8/2012
<b>Last Review:</b>	8/2011

#### Description of Procedure or Service

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Sipuleucel-T (Provenge®, Dendreon Corp.) is a new class of therapeutic agent used in the treatment of asymptomatic or minimally symptomatic, androgen-independent (hormone-refractory), metastatic prostate cancer. It consists of specially treated dendritic cells obtained from the patient with leukapheresis. The cells are then exposed in vitro to proteins that contain prostate antigens and immunologic stimulating factors, and then reinfused back into the patient. The cells are administered as 3 intravenous (IV) infusions, each infusion given approximately 2 weeks apart. The proposed mechanism of action is that the treatment stimulates the patient's own immune system to resist spread of the cancer.

#### Background

Prostate cancer is the second leading cause of cancer-related deaths among American men with an estimated incidence of 218,890 cases and an estimated number of 27,050 deaths in 2007. The majority of cases are diagnosed at a localized stage and are treated with prostatectomy or radiation therapy. However, some patients are diagnosed with metastatic disease or recurrent disease after treatment of localized disease. Androgen ablation is the standard treatment for metastatic or recurrent disease. However, most patients who survive long enough eventually develop androgen-independent prostate cancer. At this stage of metastatic disease docetaxel, a chemotherapeutic agent, has been demonstrated to confer a survival benefit of 1.9 to 2.4 months in randomized clinical trials. Chemotherapy with docetaxel causes adverse effects in large proportions of patients, including alopecia, fatigue, neutropenia, neuropathy, and other symptoms. The trials evaluating docetaxel included both asymptomatic and symptomatic patients, and results suggested a survival benefit for both symptomatic and asymptomatic patients. Because of the burden of treatment and its side effects, most patients therefore defer docetaxel treatment until the cancer recurrence is symptomatic.

Cancer immunotherapy has been investigated as a treatment which might be instituted at the point of detection of androgen-independent metastatic disease before significant symptomatic manifestations have occurred. The quantity of cancer cells in the patient during this time interval is thought to be relatively low, and it is thought that an effective immune response against the cancer during this time period could effectively delay or prevent progression. Such a delay could allow effective chemotherapy such as docetaxel to be deferred or delayed until necessary, thus providing an overall survival benefit.

#### Regulatory Status

On April 29, 2010, the U.S. Food and Drug Administration (FDA) approved Provenge® (sipuleucel-T, Dendreon Corp.) via a Biologics Licensing Application (BLA) for "the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate

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cancer (for autologous use only)." Approval was contingent on agreement of the manufacturer to conduct a postmarketing study, based on a registry design, to assess the risk of cerebrovascular events in 1,500 patients with prostate cancer who receive sipuleucel-T.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will cover cellular immunotherapy for prostate cancer when determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Cellular Immunotherapy for Prostate Cancer is covered

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Sipuleucel-T therapy may be considered medically necessary in the treatment of asymptomatic or minimally symptomatic, metastatic, androgen-independent (hormone-refractory) prostate cancer.

## When Cellular Immunotherapy for Prostate Cancer is not covered

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Sipuleucel-T therapy is considered investigational in all other situations, including but not limited to treatment of hormone-responsive prostate cancer, treatment of those with moderate to severe symptomatic metastatic prostate cancer, and those with visceral (liver, lung or brain) metastases.

## Policy Guidelines

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The results of 3 randomized, controlled trials of sipuleucel-T given in the setting of asymptomatic or mildly symptomatic androgen-independent metastatic prostate cancer show an improvement in median survival of 4 months. The 2 early studies of sipuleucel-T were not specifically designed to demonstrate a difference in overall mortality, but showed survival effects consistent with the third study which was designed to demonstrate a mortality difference. All 3 studies are also consistent in demonstrating that sipuleucel-T treatment does not delay time to measurable progression of disease. In all studies, many patients had further chemotherapy treatment at the discretion of their physician; thus, the survival benefit accrues in the context of additional treatment as needed for symptomatic recurrence.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcsnc.com](http://www.bcsnc.com). They are listed in

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the Category Search on the Medical Policy search page.

*Applicable codes: Q2043*

The following codes may be submitted for reimbursement of this service: C9399, J9999, J3590, J3490, 36511, 96413, 96415, and 96365.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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U.S. Food and Drug Administration. Press release: FDA Approves a Cellular Immunotherapy for Men with Advanced Prostate Cancer. Available online at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210174.htm>. Last accessed May 2010.

Dendreon Corporation. Provenge® (sipuleucel-T) prescribing information. Seattle, WA; April 2010. Available online at <http://www.provenge.com/pdf/prescribing-information.pdf>. Last accessed May 2010.

Senior Medical Director – 5/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.53, 5/13/2010

Specialty Matched Consultant Advisory Panel – 8/2011

## Policy Implementation/Update Information

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6/22/10 New policy. Reviewed by Senior Medical Director 5/26/10. “Sipuleucel-T therapy may be considered medically necessary in the treatment of asymptomatic or minimally symptomatic, metastatic, androgen-independent (hormone-refractory) prostate cancer.” “Sipuleucel-T therapy is considered investigational in all other situations, including but not limited to treatment of hormone-responsive prostate cancer, treatment of those with moderate to severe symptomatic metastatic prostate cancer, and those with visceral (liver, lung or brain) metastases.” (btw)

2/1/10 Added HCPCS code “C9273” to “Billing/Coding” section. (btw)

7/1/11 Added new HCPCS code, “Q2043” to Billing/Coding” section and removed deleted code “C9273”. (btw)

9/30/11 Specialty Matched Consultant Advisory Panel review August 31, 2011. No change to policy statement. References added. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.