Draft

Medical Coverage Policy

Cellular Immunotherapy for Prostate Cancer

Email comments on this draft Medical Policy are accepted for 30 days after posting

Posting Date:	7/30/2013	Comment by:	8/30/2013

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description:

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.

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.

~~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 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.~~

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Medical Criteria:
BlueCHiP for Medicare and Commercial products:

Sipuleucel-T therapy (Provenge®) is considered **medically necessary** in the treatment of asymptomatic or minimally symptomatic, metastatic, androgen-independent (hormone-refractory) prostate cancer when the patient meets all of the following:

- A failed hormone manipulation; and
- A limited metastatic disease with low volume cancer load (i.e., no visceral organ involvement); and
- A stable pain management without the escalating use of narcotics; and
- A multidisciplinary evaluation has been performed by a multidisciplinary team with expertise in urologic malignancies and the use of Provenge®.

Sipuleucel-T therapy (Provenge®) is considered **not medically necessary** 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:
Prior authorization is required for BlueCHiP for Medicare members and recommended for Commercial products.

BlueCHiP for Medicare and Commercial products
Sipuleucel-T therapy (Provenge®) is considered **medically necessary** in the treatment of asymptomatic or minimally symptomatic, metastatic, androgen-independent (hormone-refractory) prostate cancer when the conditions above are met.

~~To request preauthorization, contact the Health Services Management Department at (401) 272-5670, extension 3012, or fax your request to (401) 272-8885.~~

Coverage:
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable prescription drug benefits/coverage.

Coding:
The following code is medically necessary with preauthorization for BlueCHiP for Medicare and Commercial products:
Q2043 sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion

The leukapheresis procedure to obtain the patient's dendritic cells would most likely be reported with CPT code **36511.**

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Related Topics:
None

Also Known As:
Provenge
Sipuleucel-t

Publications:
Provider Update, 2013
Provider Update, June 2012
Provider Update, August 2011
Provider Update, October 2010

References:

Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Autologous CELLULAR IMMUNOTHERAPY Treatment (110.22). Available at http://www.cms.gov/medicare-coverage-database

Centers for Medicare and Medicaid Services National Coverage Analysis (NCA) for Autologous CELLULAR IMMUNOTHERAPY Treatment of Metastatic Prostate Cancer (CAG-00422N): Technology Assessment - Outcomes of Sipuleucel-T Therapy.

Blue Cross Blue Shield Association Medical Policy Reference Manual (MPRM). 8.01.53 Cellular Immunotherapy for Prostate Cancer

Review History:

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