Medical Coverage Policy

Cellular Immunotherapy for Prostate Cancer-
PREADUTH

☐ Device/Equipment  ☒ Drug  ☐ Medical  ☐ Surgery  ☐ Test  ☐ Other

| Effective Date:    | 08/17/2010 | Policy Last Updated: | 4/3/2012 |

☒ 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.

Medical Criteria:
Sipuleucel-T therapy (Provenge®️) is considered medically necessary for all BCBSRI products in the treatment of asymptomatic or minimally symptomatic, metastatic, androgen-independent (hormone-refractory) prostate cancer when the patient has met all of the following conditions:

- 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** for all BCBSRI products for 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:**
Sipuleucel-T therapy is considered medically necessary for conditions listed in the medical criterial above and not medically necessary for all other indications.

**Prior authorization is required for BlueCHIP for Medicare members and recommended for all other BCBSRI products.**

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:**
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**(therapeutic apheresis; for white cells).

**Related Topics:**
None

**Also Known As:**
Provenge
Sipuleucel-t

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

**References:**
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

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member’s subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.