Medical Coverage Policy | Cellular Immunotherapy for Prostate Cancer-PREAUTH

EFFECTIVE DATE: 08|17|2010
POLICY LAST UPDATED: 08|20|2013

OVERVIEW

The policy for cellular immunotherapy includes coverage guidelines for the infusion therapy BlueCHiP for Medicare and Commercial products.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare Prior authorization and recommended for Commercial products.

POLICY STATEMENT

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.

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.

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®.

BACKGROUND

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.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable infusion therapy 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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update	Nov 2013
Provider Update	Jun 2012
Provider Update	Aug 2011
Provider Update	Oct 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

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