Medical Coverage Policy | Cellular Immunotherapy for Prostate Cancer

EFFECTIVE DATE: 08|17|2010
POLICY LAST UPDATED: 10|03|2017

OVERVIEW

This policy for Cellular Immunotherapy for Prostate Cancer includes coverage guidelines for BlueCHiP for Medicare and Commercial products. Sipuleucel-T (Provenge®; Dendreon Corp.) is a new class of therapeutic agent used in the treatment of asymptomatic or minimally symptomatic, androgen-independent (castration-resistant), metastatic prostate cancer.

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 (castration-resistant) 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.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare members 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, androgen-independent (castration-resistant), metastatic 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 hormone-responsive prostate cancer, treatment of moderate to severe symptomatic metastatic prostate cancer, and treatment of visceral (liver, lung or brain) metastases.

COVERAGE

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

BACKGROUND

Cancer immunotherapy has been investigated as a treatment that 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 to the cancer during this time period could effectively delay or prevent progression. Such a delay could allow a course of 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 class of therapeutic agent used in the treatment of asymptomatic or minimally symptomatic, androgen-independent (castration-resistant), metastatic prostate cancer. The agent comprises 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 reinfused into the patient. The cells are administered as 3 intravenous infusions given approximately 2 weeks apart. The proposed mechanism of action is that the treatment stimulates the patient's own immune system to resist cancer spread.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is medically necessary with preauthorization when the criteria have been met:

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

None

PUBLISHED

Provider Update, December 2017
Provider Update, September 2016
Provider Update, November 2015
Provider Update, November 2013
Provider Update, June 2012
Provider Update, August 2011
Provider Update, October 2010

REFERENCES

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