

## Medical Affairs Policy & Procedure

**Title/Service:** Provence (sipuleucel-T)

<b>Revised</b>	
<b>Reviewed</b>	
<b>Developed</b>	08/31/2011
<b>Policy Committee Approval</b>	09/16/2011

### **Description:**

Provence is an immunotherapy made from the individual's own immune cells for the treatment of asymptomatic or minimally symptomatic metastatic prostate cancer that has not responded to other treatments. Certain blood cells are collected from the individual, activated to respond to the cancer cells, and reinfused.

### **Indications of Coverage:**

Provence is considered medically necessary when **all** of the following criteria are met:

- A. A pathology-confirmed diagnosis of prostate cancer
- B. Imaging evidence of metastatic lesions in soft tissue and/or bone
- C. ECOG (Eastern Cooperative Oncology Group) performance status of 0 or 1 (see table at the end of this guideline)
- D. Testosterone level less than 50 ng/mL
- E. Disease progression documented by **one** of the following:
  - 1) Progression of the size of the metastatic lesions on sequential imaging reports
  - 2) Two sequential rising PSA levels performed at least two weeks apart
- F. The individual has a life expectancy of greater than six months

### **Limitations of Coverage:**

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The use of Provenge is considered investigational in any of the following situations:
- 1) When there is documentation of metastatic lesions of the liver, lung, or brain
  - 2) When there is no documentation of cancer outside of the prostate gland
  - 3) When used in conjunction with chemotherapy
  - 4) In an individual using prescription analgesics for symptom management of metastatic prostate cancer

**Documentation Required:**

- Office notes
- Laboratory reports
- Imaging report

**Rationale:**

The Food and Drug Administration (FDA) approved the use of Provenge for the treatment of prostate cancer that has spread to other locations in the body (metastasis), is not causing significant symptoms (asymptomatic), and has not responded to hormone therapy. The approval was based on a study of individuals whose cancer had spread to soft tissue (for example, fascia, fat, muscles) or bone that was not responding to treatment. The National Comprehensive Cancer Network (NCCN) recommends that the use of Provenge be limited to individuals who are not significantly disabled from the cancer and who are expected to live for at least six months. This guideline is based on the FDA and NCCN recommendations for the use of Provenge.

**References:**

1. NCCN clinical practice guidelines in oncology (NCCN guidelines). National Comprehensive Cancer Network. Prostate Cancer. Version 4.2011. Available at: [www.nccn.org](http://www.nccn.org). Accessed: 31 Aug 11.
2. Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982. 5:649-655.
3. Provenge (sipuleucel-T) suspension for intravenous infusion. Seattle, WA: Dendreon Corporation. Issue date: June 2011. Available at: [www.provenge.com/pdf/prescribing-information.pdf](http://www.provenge.com/pdf/prescribing-information.pdf). Accessed: 31 Aug 11.

ECOG Performance Status

Grade	Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

From Oken, et al.

*Approved by the Medical Director*