

Sipuleucel-T (Provenge®)**Criteria for Use****March 2012**

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vaww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive Sipuleucel-T.*

- Patient is unable to comply with a minimum of 3 leukapheresis appointments; each appointment to be scheduled every 2 weeks for 3 visits (may be more depending on cell collection)
- Patient has a contraindication to apheresis, such as an active infection, unstable heart or lung condition
- Eastern Cooperative Oncology Group (ECOG) performance status of 2 or more*
- Visceral metastases
- Pathologic bone fractures
- Spinal cord compression
- Previous treatment with chemotherapy or secondary hormonal therapy for prostate cancer within the past 90 days
- Requires opioid therapy for cancer-related pain due to lack of efficacy of prior non-opiate pain regimens, not intolerance
- Requires concomitant immunosuppressive therapy
- Average weekly prostate cancer-related pain score of 4 or more on a 10 point visual analog scale

Inclusion Criteria *The answers to ALL of the following must be fulfilled in order to meet criteria.*

- Patient has been offered a referral for concurrent Palliative Care to assess the goals of care
- Metastatic castrate resistant prostate cancer with progressive disease based on soft tissue and/or bony metastases on serial radiographs **or** PSA progression based on two consecutive PSA values at least 14 days apart, each ≥ 5.0 ng/mL and $\geq 50\%$ above the minimum PSA obtained during castration therapy
- Asymptomatic or minimally symptomatic metastatic disease
- Alternative therapies have been discussed with patient
- Concomitant medical or surgical castration (serum testosterone ≤ 50 ng/dL) started at least 3 months prior to sipuleucel-T

Dosage and Administration

- The recommended course of sipuleucel-T therapy is 3 complete doses given at approximately 2 week intervals. If the patient is unable to receive a scheduled dose, the patient will need another apheresis procedure if the course is to be continued.
- Approximately 3 days prior to each dose, the patient will undergo a leukapheresis procedure to collect cells which are then sent to Dendreon Corporation for incubation with an antigen.
- Sipuleucel-T is sent directly to the provider
- Upon receipt of the patient-specific sipuleucel-T product a number of labels and forms must be checked prior to infusing the product.
- The infusion bag should be inspected for signs of leaks and for clumps and clots.
- Patients should be pre-medicated about 30 minutes prior to the infusion with acetaminophen and diphenhydramine to minimize infusion reactions.
- The infusion must begin prior to the expiration date and time on the Cell Product Disposition Form and Product Label. Sipuleucel-T is administered over 60 minutes. Do Not Use a Cell Filter.
- Observe the patient for at least 30 minutes after each infusion.

Issues for Consideration

- An exception to concomitant immunosuppressive therapy is replacement doses of steroids (< 30 mg /day Hydrocortisone or < 7.5 mg/day Prednisone or equivalent).
- Prior to starting therapy, provider should register with Dendreon and provide an estimate as to the number of patients expected to be treated each year. Phone Dendreon ON Call at: 877-336-3736 and provide contact information and interest in using the

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Updated versions may be found at <http://www.pbm.va.gov> or <http://vaww.pbm.va.gov>

vaccine.

- Patients must be enrolled using the Enrollment Form for Dendreon ON Call Provenge (sipuleucel-T)
- Dendreon will set up a face to face training meeting prior to the first patient for your site.
- If certification of a new apheresis center is required, it may take up to 6 months.

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ECOG PERFORMANCE STATUS	
Grade	ECOG
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

As published in Am. J. Clin. Oncol.:

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.

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