

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____ Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Metastatic, castrate-resistant (hormone-refractory) prostate cancer	<input type="checkbox"/> Other (please state): _____
Clinical Consideration	Please indicate the nature of the patient's metastatic disease: <input type="checkbox"/> Soft tissue/and or bone metastases <input type="checkbox"/> Visceral (liver, lung, or brain) metastases <input type="checkbox"/> Other (please state): _____	Please indicate which describes the patients current level of cancer-related pain: <input type="checkbox"/> None or minimally symptomatic <input type="checkbox"/> Moderate to severely symptomatic (ie. requires opioids for pain control)
	Please indicate status of current chemotherapy and/or immunosuppressive therapies: <input type="checkbox"/> Patient has discontinued or will discontinue prior to Provenge therapy <input type="checkbox"/> Discontinuation of chemotherapy and/or immunosuppressive therapy IS NOT planned	
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription order below: Provenge® (sipuleucel-T) Strength _____ Sig _____ Qty _____ Refills _____	
We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.		

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 02/13/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Provenge (sipuleucel-T)

CLASSIFICATION

- Antineoplastic, immunological agent

DESCRIPTION

- Provenge (sipuleucel-T) is a treatment vaccine containing a fusion protein that is combined ex vivo with autologous dendritic cells, obtained via leukapheresis, and reinfused into the patient to create an immune response targeted towards prostatic cancer cells. The fusion protein, PA2024, consists of recombinant prostatic acid phosphatase (PAP), an antigen located only in prostate tissue, fused with granulocyte-macrophage-colony stimulating factor (GM-CSF).
- Three days prior to the infusion date, the patient's peripheral blood mononuclear cells are obtained by standard leukapheresis. During ex vivo culture, PAP-GM-CSF binds to the APCs and is processed into smaller protein fragments that are displayed on the surface of the APC.
- Although the exact mechanism of action of sipuleucel-T is unknown, the therapy is thought to induce an immune response against PAP.
- Sipuleucel-T has been evaluated in 3 randomized clinical trials. The largest trial evaluated overall survival as the primary endpoint, and showed an average survival benefit of 4 months (25 months versus 21 months on placebo). The 2 other trials used time to progression as a primary endpoint. This endpoint was not met, but pooled data (with the 1st trial) again showed a survival benefit on about 4 months.
- Patients included in clinical trials had metastatic disease in the soft tissue and/or bone, were either asymptomatic or minimally symptomatic, and did not require narcotics for cancer-related pain. Exclusion criteria included visceral (liver, lung, or brain) metastases, moderate to severe prostate cancer-related pain, and the use of narcotics. Thus, efficacy of Provenge has not been established in these patients.
- Use of Provenge concomitantly with chemotherapy or immunosuppressive therapy has not been studied. This becomes significant due to the mechanism of action of this immunological agent.
- Previous to 2010, docetaxel was the only treatment shown to offer a survival benefit in metastatic, hormone-resistant prostate cancer. In one trial (n=1006) docetaxel increased overall survival by 2.4 months versus palliative therapy.
- Jevtana (cabazitaxel) is a third agent that has also been approved recently. Jevtana is indicated after docetaxel failure. This agent has a high potential for treatment related side effects.
- Treatment with docetaxel is expected to cost less than \$20,000, while the cost of treatment with Provenge is about \$93,000.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T6
Commercial Formulary:	T6
Medicare Part D coverage:	T5 at a pharmacy; Part B if incident to a physician's service

COVERAGE CRITERIA

Provenge (sipuleucel-T) meets the definition of **medical necessity** for the following:

- Hormone refractory (castrate resistant) prostate cancer with the following conditions:
 - Radiographic evidence of metastases (ie. bone and soft tissue) *EXCEPT* visceral metastases (namely liver, lung, or brain metastases)
 - Asymptomatic or minimally symptomatic disease that current does not require opioid use for prostate cancer-related pain
 - Chemotherapy and/or immunosuppressive therapies are not given concurrently

Provenge (sipuleucel-T) is considered **experimental** for the following:

- Androgen dependant, biochemically relapsed prostate cancer
- Any use or indication outside of FDA approval

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing

- One dose (250mL) IV over 60 min given approximately every 2 wk for 3 doses
 - Each dose contains a minimum of 50 million autologous CD54+ cells in 250 mL LR and is activated with prostatic acid phosphatase linked to granulocyte-macrophage stimulating factor
 - Peripheral blood mononuclear cells are obtained via leukapheresis approximately 3 days prior to each infusion
 - Premedicate patients with acetaminophen and an antihistamine (eg, diphenhydramine) 30 min prior to dose

Pediatric dosing

- Safety and efficacy has not been established in pediatric patients

Dosing adjustments

- Temporarily stop or slow the sipuleucel-T infusion if patients develop an acute infusion reaction

PRECAUTIONS:

- Acute infusion reactions (eg, fever, chills, nausea, vomiting, dyspnea, hypoxia, bronchospasm, and hypertension) have been reported, with some cases requiring hospitalization; closely monitor patients with cardiac and pulmonary conditions; decrease the infusion rate or discontinue the infusion if necessary
- Final sterility test results of product may not be available prior to sipuleucel-T infusion; microbial contamination may be reported after infusion
- Health care professionals; risk of exposure to transmissible infectious diseases present in leukapheresis material; use proper precautions when handling the product

Billing/Coding information

Associated HCPCS Codes:

C9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Associated CPT Coding:

36511	Therapeutic apheresis; for white cells

Associated ICD-9 Coding:

185	Malignant neoplasm of the prostate

COST

- AWP (September 2010) – 250mL vial for IV infusion (1): \$37,200
 - Therapy consists of a three dose course

COMMITTEE APPROVAL:

- September 22, 2010

GUIDELINE UPDATE INFORMATION:

Sep 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 09/14/2010
- Product Information: PROVENGE(R) suspension for IV infusion, sipuleucel-T suspension for IV infusion. Dendreon Corporation, Seattle, WA, 2010.