ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Provenge® (sipuleucel-T)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Provenge® (sipuleucel-T)

Diagnosis (documentation supportive of diagnosis is required)

☐ Metastatic, castrate-resistant (hormone-refractory) prostate cancer
☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

Please indicate the nature of the patient's metastatic disease:

☐ Soft tissue and/or bone metastases
☐ Visceral (liver, lung, or brain) metastases
☐ Other (please state): _____

Please indicate which describes the patient's current level of cancer-related pain:

☐ None or minimally symptomatic
☐ Moderate to severely symptomatic (i.e. requires opioids for pain control)

Please indicate status of current chemotherapy and/or immunosuppressive therapies:

☐ Patient has discontinued or will discontinue prior to Provenge therapy
☐ Discontinuation of chemotherapy and/or immunosuppressive therapy ***IS NOT*** planned

Physician Specialty (diagnosis made by):
☐ Oncology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

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 phophatase 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

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.