

Pharmacy Prior Authorization Form

For Prior Authorization please fax to: (877)974-4411 toll free, or (616)942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Provenge (sipuleucel-T)

Urgent Non-urgent

Member Name:	Member #:
DOB:	Gender:
Provider Name:	Provider Phone:
Provider Office Address:	
Provider Office Contact Name:	Provider Fax:
Provider Signature:	Provider NPI:
Date:	Member's PCP:

Product:

Provenge intravenous suspension 250mL

Dose: _____ Start date: _____

Place of administration:

Self-administered

Provider's Office

Outpatient Infusion Center

Home Infusion

Name of center: _____

Name of agency: _____

Billing options:

Physician buy and bill

Preferred Specialty Vendor

Other: _____

CMS Precertification Requirements:

Per local coverage determination L 28576, authorization of Provenge requires:

- Diagnosis of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer
- Evidence of metastases to soft tissue or bone
- Testosterone levels < 50ug or below lowest level of normal
- Two sequential rising PSA levels obtained 2–3 weeks apart or other evidence of disease progression

Please Complete the Following Information:

Diagnosis:

Asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer
-ICD code: _____

Other: _____ ICD code: _____

Please provide rationale for use:

- Sipuleucel-T (Provenge[®]) is covered only for the treatment of asymptomatic or minimally symptomatic prostate adenocarcinoma in patients with metastatic prostate cancer (to bone or soft tissue) who are castrate resistant (hormone-resistant).
- Minimally symptomatic disease will be considered to be patients with Eastern Cooperative Oncology Group (ECOG) Performance Status of <2.
- Patients should have a life expectancy of greater than six (6) months.
- The product may be administered intravenously through either a peripheral vein or through a centrally inserted intravenous catheter, over a period of sixty (60) minutes.

Limitations:

- Sipuleucel-T (Provenge[®]) is not covered for any condition other than castrate-resistant (hormone-resistant) metastatic prostate adenocarcinoma in asymptomatic or minimally symptomatic men.
- Treatment with sipuleucel-T of patients with visceral metastases and spinal cord compression will not be covered as such patients were not included in the study demonstrating efficacy.
- Sipuleucel-T (Provenge[®]) is covered only for autologous administration into the same patient from whom the mononuclear white blood cells were originally harvested by the treating physician (e.g., in an office) or facility (in an inpatient or outpatient hospital setting).
- Sipuleucel-T (Provenge[®]) is not covered for treatment of prostate cancer in any patient concomitantly receiving chemotherapy, radiation therapy or other immunotherapy as the product has not been studied under these conditions.
- If the prepared dose of Sipuleucel-T (Provenge[®]) is not administered to the designated patient, from whom the cells were retrieved, within the required 72-hour time frame and is therefore discarded, for any reason, the preparation of the product will be considered not reasonable or medically necessary for that patient and that dose of the product and all associated costs will not be reimbursed. No charges resulting from the failure to administer the product to the beneficiary may be billed to the Medicare Program or, in the absence of a properly executed Advance Beneficiary Notice (ABN), to the beneficiary.
- If the processing of the retrieved blood cells is not completed, for any reason, then all related procedures (e.g., the leukapheresis, blood cell processing, re-packaging, transports, etc) are deemed to be not reasonable or medically necessary for the treatment of the specific patient and not reimbursable by Medicare. These services may not be separately billed to Medicare or, in the absence of a properly executed Advance Beneficiary Notice (ABN), to the beneficiary.
- If the Sipuleucel-T (Provenge[®]) is administered using a cell filter, then the preparation of the product will be considered not reasonable or medically necessary for that patient and that dose of the product and all associated costs will not be reimbursed. These services may not be separately billed to Medicare or to the beneficiary.
- All costs of the leukapheresis, transport of the blood products, treatment of the cells, packing and transport of the treated cells back to the specific recipient are included in the cost of the product and are not separately billable by the administering physician or facility, or any other physician, non-physician provider, facility, hospital, clinic, or manufacturer.
- Administration of the Sipuleucel-T (Provenge[®]) is a facility service when performed in the inpatient or

outpatient hospital and may not be separately billed by a physician or non-physician provider.

- Preparation of the product for infusion, insertion of a peripheral intravenous catheter along with all supplies and medications (e.g., a local anesthetic) required to insert an intravenous catheter are included in the administration service and are not separately billable.

Documentation Requirements:

The patient's medical record should contain documentation that fully supports the medical necessity for the administration of the Sipuleucel-T (Provenge®). Such documentation should include, but is not limited to:

1. Pathologic diagnosis of prostate cancer (or markedly elevated PSA (e.g., > 100-200)) with radiographic evidence of progressive metastatic disease.
2. Clinical documentation that the patient has been treated with castration or hormone therapy, to which he is no longer responding or in spite of which he has progressed, or has a testosterone level less than 50ng/dl.
3. The patient will not be receiving chemotherapy, other immunotherapy, or radiation therapy concomitantly with the Sipuleucel-T (Provenge®).
4. Clinical documentation that the patient is asymptomatic or only minimally symptomatic from the metastatic disease, and has a life expectancy of at least six (6) months.
5. Dates of all previous treatments with Sipuleucel-T (Provenge®) and planned dates (approximate) of future leukapheresis, and reinfusion of the Sipuleucel-T (Provenge®).
6. Examination and decision-making, as appropriate, while monitoring the patient post-infusion, if performed face-to-face by the physician. Include the actual time spent by the physician with the patient.
7. Identity of the physician or qualified non-physician provider ordering the treatment.
8. Identity of the physician or qualified non-physician provider supervising the treatment.
9. This documentation must be submitted upon request, and not with the claim. Claims for which requested additional documentation is not received will be denied as not medically necessary.

Utilization:

More than three doses of Sipuleucel-T (Provenge®) administered in a patient's lifetime is not supported by medical studies, and will be considered not medically necessary. In addition, all costs associated with more than three (3) doses of Sipuleucel-T (Provenge®) will be deemed to be not reasonable or medically necessary for the treatment of the specific patient and therefore not reimbursable by Medicare. These associated services may not be separately billed to Medicare or, in the absence of a properly executed Advance Beneficiary Notice (ABN), to the beneficiary.

Coding Guidelines:

General Guidelines for claims submitted to Carriers or Intermediaries or Part A or Part B MAC:

1. For claims submitted to the Carrier or Part B MAC, Sipuleucel-T (Provenge®) should be billed using HCPCS code J3590, *Unclassified biologics*. Include the name of the product and the dosage administered in item 19

of the CMS-1500 form or the electronic equivalent. **For Part B, the product will be reimbursed at 106% WAC until CMS establishes the fee on the ASP drug fee schedule.**

2. For claims submitted to the FI or Part A MAC, Sipuleucel-T (Provenge®) should be coded using HCPCS code C9399.
3. Sipuleucel-T (Provenge®) is an autologous cellular immunotherapy and therefore the administration of this product may not be billed using a chemotherapy administration code. The administration of the product should be billed using CPT code 96365, (*Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour*).
4. The insertion of a peripheral intravenous catheter and all associated supplies and medications (e.g., local anesthetic) is included in the practice expense of the administration service and is not separately billable.
5. Any *significant and separately identifiable* E&M service billed should accurately reflect the level of the components documented. Observation of the patient by the physician post-infusion may be included in the E&M service. Only face-to-face time with the physician may be considered. Observation and treatment time by the office or hospital staff may not be billed separately or counted towards a physician E&M service.
6. For claims submitted to the Carrier or Part B MAC, the Sipuleucel-T (Provenge®) is reimbursable in the following places of service: office (11) and independent clinic (49).

Coding Information

Bill Type Codes: [back to top](#)

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)

013x Hospital Outpatient

085x Critical Access Hospital

CPT/HCPCS Codes [back to top](#)

96365 INTRAVENOUS INFUSION, FOR THERAPY, PROPHYLAXIS, OR DIAGNOSIS (SPECIFY SUBSTANCE OR DRUG); INITIAL, UP TO 1 HOUR

C9399 UNCLASSIFIED DRUGS OR BIOLOGICALS

J3590 UNCLASSIFIED BIOLOGICS

ICD-9 Codes that are Covered [back to top](#)

ICD-9-CM Codes that Support Medical Necessity:

Both a primary and secondary diagnosis must be reported.

Coding Information**PRIMARY DIAGNOSES**

196.2 SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF INTRA-ABDOMINAL LYMPH NODES

196.5 SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES OF INGUINAL REGION AND LOWER LIMB

196.6 SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF INTRAPELVIC LYMPH NODES

196.8 SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES OF MULTIPLE SITES

198.5 SECONDARY MALIGNANT NEOPLASM OF BONE AND BONE MARROW

SECONDARY DIAGNOSES

185 MALIGNANT NEOPLASM OF PROSTATE

V10.46 PERSONAL HISTORY OF MALIGNANT NEOPLASM OF PROSTATE

***** All fields must be complete and legible for Prior Authorization Review*****
Please fax this request to: (877)974-4411 toll free or (616)942-8206
YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX