QUICK REFERENCE CODING & BILLING GUIDE
PHYSICIAN OFFICE

CMS National Coverage Determination and Q-Code for PROVENGE

- Simplifies patient coverage criteria
- Clarifies coding requirements
- Expedites electronic billing and payment
- Reduces paperwork for initial claims submission

PROVENGE Has Robust Coverage With Major Commercial and Public Payors

- All Medicare Administrative Contractor regions are required to cover PROVENGE based on the FDA-approved label per the National Coverage Determination
- Plans representing approximately 99% of patients with private insurance cover PROVENGE based on the FDA-approved label

For expert assistance on your coding and billing questions contact Dendreon ON Call at 1-877-336-3736.

Medicare Reimburses Separately for PROVENGE Administration
See inside for coding information

INDICATION
PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

IMPORTANT SAFETY INFORMATION

Acute Infusion Reactions: Acute infusion reactions (reported within 1 day of infusion) may occur and include nausea, vomiting, fatigue, fever, rigor or chills, respiratory events (dyspnea, hypoxia, and bronchospasm), syncope, hypotension, hypertension, and tachycardia.

Thromboembolic Events: Thromboembolic events, including deep venous thrombosis and pulmonary embolism, can occur following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events. PROVENGE should be used with caution in patients with risk factors for thromboembolic events.

Vascular Disorders: Cerebrovascular events (hemorrhagic/ischemic strokes and transient ischemic attacks) and cardiovascular disorders (myocardial infarctions) have been reported following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events.

Handling Precautions: PROVENGE is not tested for transmissible infectious diseases.

Concomitant Chemotherapy or Immunosuppressive Therapy: Chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure or PROVENGE has not been studied. Concurrent use of immune-suppressive agents may alter the efficacy and/or safety of PROVENGE.

Adverse Reactions: The most common adverse reactions reported in clinical trials (≥ 15% of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache.

Please see accompanying full Prescribing Information.
PROVENGE was awarded a National Coverage Determination (NCD) in June 2011. The Centers for Medicare & Medicaid Services (CMS) subsequently released Medicare Transmittal 2254 (July 8, 2011), providing instructions to contractors on implementing the PROVENGE NCD.1,2

The transmittal states that, for Medicare coverage of PROVENGE for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, providers must report at least two ICD-10-CM codes for PROVENGE, one of which must be: C61—Malignant neoplasm of prostate. The secondary ICD-10-CM codes included in the transmittal are listed below. This guidance is effective for claims dated on or after October 1, 2015.

### ICD-10-CM Diagnosis Codes3:

<table>
<thead>
<tr>
<th>Diagnosis Code</th>
<th>Diagnosis Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate (for on-label or off-label indications)</td>
</tr>
</tbody>
</table>

And at least one of the following ICD-10-CM codes, as documented in the medical record:

- C77.1: Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
- C77.2: Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
- C77.4: Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
- C77.5: Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
- C77.8: Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
- C77.9: Secondary and unspecified malignant neoplasm of lymph node, unspecified
- C78.00: Secondary malignant neoplasm of unspecified lung
- C78.01: Secondary malignant neoplasm of right lung
- C78.02: Secondary malignant neoplasm of left lung
- C78.7: Secondary malignant neoplasm of liver
- C79.00: Secondary malignant neoplasm of unspecified kidney and renal pelvis
- C79.01: Secondary malignant neoplasm of right kidney and renal pelvis
- C79.02: Secondary malignant neoplasm of left kidney and renal pelvis
- C79.10: Secondary malignant neoplasm of unspecified urinary organs
- C79.11: Secondary malignant neoplasm of bladder
- C79.19: Secondary malignant neoplasm of other urinary organs
- C79.51: Secondary malignant neoplasm of bone
- C79.52: Secondary malignant neoplasm of bone marrow
- C79.70: Secondary malignant neoplasm of unspecified adrenal gland
- C79.71: Secondary malignant neoplasm of right adrenal gland
- C79.72: Secondary malignant neoplasm of left adrenal gland
- C79.82: Secondary malignant neoplasm of genital organs

Coding systems provide a uniform language for describing medical, surgical, and diagnostic services, as well as patient conditions and certain drugs and supplies. Correct coding of all components of a service is necessary to obtain appropriate payment. Coding requirements will vary by payor and setting of care. The relevant codes and coding systems for PROVENGE are summarized in the tables above and on the next page. Please refer to specific payor guidelines for the appropriate selection of codes.

**NOTE:** While Dendreon has identified these codes as appropriate, coding determinations are at the discretion of the provider and should be made in accordance with applicable regulations and payor guidance.

**IMPORTANT:** The coding information provided is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider’s responsibility to determine the appropriate health care setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payors for specific information on their coding, coverage, and payment policies. Information provided should in no way be considered a guarantee of coverage or reimbursement for any product or service.4
### HCPCS Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2043</td>
<td>Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion</td>
<td>Effective for claims with dates of service on or after July 1, 2011. Medicare requires PROVENGE to be billed with the product-specific Q-code of Q2043.</td>
</tr>
</tbody>
</table>

HCPCS=Healthcare Common Procedure Coding System.

### CPT Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>96413</td>
<td>Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
<td>The Centers for Medicare &amp; Medicaid Services (CMS) allows separate payment under Medicare for the administration of PROVENGE. <strong>Providers will need to contact their regional Medicare Administrative Contractor (MAC) to obtain the code they should use to bill for the infusion.</strong> Only one of these code sets, 96413-96415 or 96365-96366, should be used. Select appropriate codes based on the length of the infusion. Each additional hour beyond the first hour of diagnostic infusion services can be reported only after more than 30 minutes has passed from the end of a previously billed hour.* Providers should check with the patient’s insurance plan to confirm CPT coding requirements. <strong>Dendreon ON Call</strong> can contact payors to determine the preferred CPT code(s) for PROVENGE.</td>
</tr>
<tr>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional hour</td>
<td></td>
</tr>
<tr>
<td>96365</td>
<td>Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour</td>
<td></td>
</tr>
<tr>
<td>96366</td>
<td>Intravenous infusion for therapy, prophylaxis, or diagnosis; each additional hour</td>
<td></td>
</tr>
</tbody>
</table>

CPT=Current Procedural Terminology. CPT Copyright 2012 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

*Infusion time does not include premedication and the 30 minutes of observation postinfusion.

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For more information, please contact **Dendreon ON Call** at 1-877-336-3736.

**Hours of Operation:** Monday through Friday, 8:00 AM to 9:00 PM ET.

**REFERENCES:**


**Please see Important Safety Information on back cover, and accompanying full Prescribing Information.**

**NOTE:** While Dendreon has identified these codes as appropriate, coding determinations are at the discretion of the provider and should be made in accordance with applicable regulations and payor guidance.

**IMPORTANT:** The coding information provided is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider’s responsibility to determine the appropriate health care setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payors for specific information on their coding, coverage, and payment policies. Information provided should in no way be considered a guarantee of coverage or reimbursement for any product or service.
National Drug Codes (NDCs) are codes that describe the drug by the manufacturer, product, and package size. Many NDCs, including the PROVENGE NDC, are displayed in a 10-digit format. Electronic billing requires the NDC to be submitted in an 11-digit format. The relevant codes for PROVENGE are summarized in the table below. Please refer to specific payor guidelines for the appropriate selection of codes.

<table>
<thead>
<tr>
<th>NDC1: Universal 10- or 11-digit product identifier for human drugs; each NDC identifies the labeler, product, and trade package size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
</tr>
<tr>
<td>30237-8900-6</td>
</tr>
<tr>
<td>30237-8900-06</td>
</tr>
<tr>
<td>30237890006</td>
</tr>
</tbody>
</table>

CMS=Centers for Medicare & Medicaid Services; HCPCS=Healthcare Common Procedure Coding System.

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**PHYSICIAN OFFICE (MEDICARE AND NON-MEDICARE PAYORS) SAMPLE CMS-1500 CLAIM FORM**

**BOX 19:** Enter appropriate product information, if required by the payor:
- For Medicare Claims: Leave blank
- For Medicaid Claims: Enter NDC 30237890006
- For Medicare-Medicaid Crossover Claims: Enter NDC 30237890006
- For Medicare-Secondary Claims: Enter NDC 30237890006 if Q2043 is not accepted
- **Note:** Coding requirements will vary for non-Medicare payors; check with payor to confirm.

**BOX 21:** Enter appropriate ICD-10-CM diagnosis code(s) as documented in the medical record:
- For Medicare Claims for patients with asymptomatic or minimally symptomatic castrate-resistant (hormone refractory) prostate cancer: You must report:
  - C61 — Malignant neoplasm of prostate AND
  - At least one of the following ICD-10-CM codes: C77.1, C77.2, C77.4, C77.5, C77.8, C77.9, C78.00, C78.01, C78.02, C78.7, C79.00, C79.01, C79.02, C79.10, C79.11, C79.19, C79.51, C79.52, C79.70, C79.71, C79.72, or C79.82
- For Non-Medicare Claims: Enter appropriate diagnosis code according to payor-specific coding guidance

**BOX 24G:** Enter appropriate number of service units per payor-specific guidance; eg, "1" unit for Q2043 for Medicare patients in physician office setting.

**BOX 24D:**
- **For Medicare Claims:** Enter appropriate HCPCS code; eg:
  - Q2043 PROVENGE, per dose

  The Centers for Medicare & Medicaid Services allows separate payments for the administration of PROVENGE. Providers will need to contact their regional Medicare Administrative Contractor (MAC) to obtain the code they should use to bill for the infusion.

  Q2043 is all inclusive and represents all routine costs except for the cost of administration.

Dendreon ON Call is available to assist with determining coding requirements for PROVENGE infusions.

For more information, please contact Dendreon ON Call at 1-877-336-3736.

- **For Non-Medicare Claims:** Enter appropriate HCPCS and CPT codes for PROVENGE and its administration:
  - **Note:** Coding requirements will vary; check with payor to confirm.

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www.DendreonONCall.com
Checklist for clean claim submission

Complete, Timely, and Accurate Claim Will Facilitate Prompt Payment

- **Correct and complete patient information**
  - Patient’s and/or subscriber’s name, date of birth, and member ID number

- **PROVENGE information (as required by the payor)**
  - Correct code(s), unit(s), drug name, drug description, dose, route of administration, NDC

- **Diagnosis code(s) (as required by the payor)**
  - Primary diagnosis code and secondary code required for Medicare
  - (as applicable for other payors)

- **Supplemental documentation (as required by the payor)**
  - With the NCD and Q-code, most Medicare carriers do not require additional documentation upon initial claim submission. However, upon processing, additional documents may be requested

- **Prior authorization (as required by the payor)**
  - Failure to obtain a prior authorization before initiating treatment or failure to include the prior authorization approval number on the form may result in a denied claim

- **Punctuation (in the submitted claim, as required by the payor)**
  - Requirement to omit or include punctuation in submitted claims

- **Number of characters (in electronic claim fields) within limits (as required by the payor)**

- **Claim submitted within the required time frame (as required by the payor)**

NDC=National Drug Code; NCD=National Coverage Determination.

If you would like your claim form reviewed prior to submission, please contact Dendreon ON Call at 1-877-336-3736.

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