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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Clinicians who find metastatic disease early in CRPC patients

This Guide provides information to help you identify patients in your practice who are appropriate for PROVENGE® (sipuleucel-T), enroll them for treatment, use PROVENGE with confidence, and educate patients about PROVENGE and their disease. To help your patients with PROVENGE immunotherapy and promote a smooth process, this Guide also provides an overview of patient resources available electronically and by phone.

Dendreon ON Call
A comprehensive support service for office practices using PROVENGE, is your source for patient and product support and reimbursement expertise. Enroll your PROVENGE-eligible patients through Dendreon ON Call to receive the following program benefits:

- Support throughout the entire enrollment and treatment process
- Dedicated staff, including reimbursement coordinators, to answer your questions

IMPORTANT SAFETY INFORMATION (con't)

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
As a clinical champion, you are responsible for ensuring the successful implementation of PROVENGE immunotherapy in your practice

It starts with the Clinical Champion, whose duties include:

- Identifying and confirming patients appropriate for PROVENGE
- Educating patients about the treatment
- Prescribing PROVENGE
- Overseeing the treatment protocol

### Identifying eligible patients

- Progressed on ADT
- Has testosterone <50 ng/dL
- Has confirmed metastatic disease
- Does not require narcotics for cancer pain

### TIPS FOR IDENTIFYING APPROPRIATE PATIENTS

Keep in mind:

- Identify patients early to begin therapy when they have a lower tumor burden
- When screened via imaging, more than 30% of men thought to have nonmetastatic CRPC were found to be metastatic
- PSA tests may not always be a certain indicator for the presence of mCRPC; out of more than 1000 mCRPC patients, 55% had a PSA <11 ng/mL at diagnosis
- More patients may be candidates for PROVENGE than widely recognized
  - Elevates the importance of routinely scanning patients who have a rising PSA – or rapid PSA doubling time – for metastatic disease

*Based on a chart review of 1021 patient charts from treating urologists.

### IMPORTANT SAFETY INFORMATION (con’t)

**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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Managing patient expectations is critical to success. Consider discussing the following topics with PROVENGE-eligible patients to help them understand the therapy and what to expect from it:

<table>
<thead>
<tr>
<th><strong>PROVENGE</strong></th>
<th><strong>is immunotherapy</strong></th>
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<tbody>
<tr>
<td>- Immunotherapy works differently – it activates the immune system and elicits an immune response&lt;sup&gt;6&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>- Immunotherapies such as PROVENGE have demonstrated improved survival without showing an impact on markers of disease progression (eg, PSA) that one may see with cytotoxic therapies. Because immunotherapies work differently from cytotoxic therapies, there are different criteria for measuring their success&lt;sup&gt;7,8&lt;/sup&gt;</td>
<td></td>
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<table>
<thead>
<tr>
<th><strong>How PROVENGE works</strong></th>
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<tr>
<td>- Designed to target and attack prostate cancer cells, allowing a treatment approach that is different from more traditional therapies&lt;sup&gt;1&lt;/sup&gt;</td>
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<table>
<thead>
<tr>
<th><strong>PROVENGE benefits</strong></th>
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<tbody>
<tr>
<td>- Delivered a statistically significant overall survival advantage&lt;sup&gt;1,7&lt;/sup&gt;</td>
</tr>
<tr>
<td>- Median overall survival in clinical trials was 25.8 months with PROVENGE (n=341) vs 21.7 months with control (n=171); P=0.032</td>
</tr>
<tr>
<td>(95% CI: 0.614, 0.979)</td>
</tr>
<tr>
<td>- Sustained* immune response following short duration of treatment&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>- No conclusions could be made regarding the clinical significance of the observed immune responses</td>
</tr>
<tr>
<td>- PROVENGE treatment is completed in about a month</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PROVENGE and PSA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Because PROVENGE is an immunotherapy and works differently, it may not lower PSA. The goal of PROVENGE is not to lower PSA, it is to help patients live longer&lt;sup&gt;7,8&lt;/sup&gt;</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th><strong>PROVENGE side effects</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- The most common side effects reported in clinical trials (≥ 15% of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache. These are not all the side effects. See Important Safety Information throughout</td>
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<table>
<thead>
<tr>
<th><strong>PROVENGE coverage</strong></th>
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<tbody>
<tr>
<td>- 2 out of 3 patients treated with PROVENGE spend less than $50 OOP&lt;sup&gt;†&lt;/sup&gt;</td>
</tr>
<tr>
<td>- More than 90% of Medicare fee-for-service (FFS) patients have NO OOP costs for PROVENGE&lt;sup&gt;†&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PROVENGE support</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- If your patient needs financial assistance with treatment-related costs, a case manager can refer him to independent resources to determine if he is eligible for help with these costs&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>*A sustained immune response was seen out to 26 weeks in the pivotal study (the last time point measured).<sup>1</sup></sup>  
<sup>1Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.<sup>1</sup></sup>  
<sup>2Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.<sup>1</sup></sup>  
<sup>3Co-pay and travel assistance foundations provide assistance regardless of the choice of treatment, and decisions are based on patient financial need and according to criteria established by the individual foundations. Dendreon ON Call can assist patients by referring them to these independent organizations. Dendreon cannot guarantee that patients will be eligible for or receive assistance after referral. Dendreon does not have control or managerial influence over these independent organizations.</sup>
Nurses who help patients understand PROVENCE immunotherapy, assist with their infusion, and help establish a treatment model for their practice

As an Operational Champion, your responsibilities include scheduling, infusion preparation, overseeing the infusion itself, and patient education. Resources to help you complete these responsibilities are included in this Guide, as well as phone and electronic access to these resources.

The role of the Operational Champion is critical to a successful treatment course with PROVENCE:

- Educates patients about disease course, how PROVENCE works, and other topics
- Educates about apheresis and infusion
- Monitors patient charts for mCRPC diagnosis and other criteria to assist with early identification of PROVENCE-eligible patients

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Managing patient expectations is critical to success. Consider discussing the following topics with PROVENGE-eligible patients to help them understand the therapy and what to expect from it:

PROVENGE benefits
- Delivered a statistically significant overall survival advantage\(^1,2\)
  - Median overall survival in clinical trials was 25.8 months with PROVENGE (n=341) vs 21.7 months with control (n=171); \(P=0.032\) (95% CI: 0.614, 0.979)
- Sustained* immune response following short duration of treatment\(^1\)
  - No conclusions could be made regarding the clinical significance of the observed immune responses
  - PROVENGE requires 6 treatment visits and is completed in about a month. See information on the next page regarding treatment visits

PROVENGE and PSA
- Because PROVENGE is an immunotherapy and works differently, it may not lower PSA. The goal of PROVENGE is not to lower PSA, it is to help patients live longer\(^2,3\)

PROVENGE side effects
- The most common side effects reported in clinical trials (≥ 15% of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache.\(^1\) These are not all the side effects. See Important Safety Information throughout

PROVENGE coverage
- 2 out of 3 patients treated with PROVENGE spend less than $50 OOP\(^\dagger\)
- More than 90% of Medicare fee-for-service (FFS) patients have NO OOP costs for PROVENGE\(^\ddagger\)

PROVENGE support
- If your patient needs financial assistance with treatment-related costs, a case manager can refer him to independent resources to determine if he is eligible for help with these costs\(^\S\)

\(^*\)A sustained immune response was seen out to 26 weeks in the pivotal study (the last time point measured).\(^1\)
\(^1\)Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.
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**IMPORTANT SAFETY INFORMATION (con’t)**

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
**PROVENGE treatment process**¹

- PROVENGE requires 6 treatment visits and is completed in about a month
- The first visit is to collect the patient’s immune cells, which are then “personalized” to help the immune system attack cancer cells
- The next visit is to infuse the personalized PROVENGE immunotherapy. This completes 1 treatment cycle
- A total of 3 cycles complete PROVENGE treatment

**Preparing for treatment**

- It is important to make patients aware that a venous assessment, which is a vein check, is required at least a week prior to treatment
- On apheresis days, patients should be reminded to stay hydrated, avoid caffeine, eat a calcium-rich breakfast, and wear loose clothing
- Patients will also need to bring a government-issued ID

**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.
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• Support throughout the enrollment process
• Dedicated staff, including reimbursement coordinators, to answer your questions

Patient enrollment
Patients must be enrolled through Dendreon ON Call. The process, including benefit verification, is completed within 48 hours of receiving the Patient Enrollment Form. (Exclusion of any information may delay turnaround time.)

Patients can be enrolled:
• Hard-copy enrollment form (available at www.DendreonONCall.com) and fax the completed form to 1-877-556-3737
• Online enrollment at the Dendreon ON Call Provider Portal (www.DendreonONCall.com)
  — Your office must be registered prior to enrolling a patient. Visit www.DendreonONCall.com and click on the “Register or Sign In” button
  — Log in to www.DendreonONCall.com to complete and submit the Online Enrollment Form

IMPORTANT SAFETY INFORMATION (con’t)
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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
TIPS FOR COMPLETING THE ENROLLMENT FORM

Page 1
• Provide a primary AND secondary diagnosis code on all enrollment forms
• Include DEA number
• Tax ID number MUST be associated with infusion location
• Physician MUST sign the form
• Include patient’s primary AND secondary insurance information

Page 2

Section 1: Patients insured through government programs (eg, Medicare)*,†
• Check box to initiate eligibility review
• The independent foundation will contact the patient directly; practice is notified if patient is approved

Section 2: Patients insured through commercial health plans‡
• Check box for PROvide™ Commercial Co-pay Program (physicians and patients MUST BOTH sign this form)

Section 4: Uninsured patients‡,§
• Check box only if patient wants to be enrolled (if payment is denied by payor, drug cost may be covered by Dendreon)
• Send patient’s income documentation to Dendreon ON Call at time of enrollment to speed processing

Section 5: Physician and patient certification
• Signatures only required for the Uninsured Patient Program

Section 6: Patient acknowledgement
• Patient MUST sign the form for ALL programs
• eSign, an electronic signature feature, enables patients to electronically sign their enrollment form in 2 convenient ways:
  — In the physician’s office via our secure provider portal
  — Remotely, via email, eliminating a return trip to the office

*Government-funded programs, for example, Medicare, Medicare Part D, Medicaid, or TRICARE. In the event an eligible patient’s claim for coverage of PROVENGE is denied by his payer after all appeals, the cost of the drug may be covered by Dendreon’s patient assistance program.
†Co-pay and travel assistance foundations provide assistance regardless of the choice of medicine, and decisions are based on financial need and according to criteria established by individual foundations. Dendreon can assist patients by referring them to these independent organizations. Dendreon cannot guarantee that patients will be eligible for or receive assistance after referral. Dendreon does not have controlling or managerial influence on these independent organizations.
‡PROvide Commercial Co-pay and Uninsured Patient Program eligibility criteria can be changed or the program can be discontinued at any time at the sole discretion of Dendreon. Patients with government-funded insurance including Medicare, Medicare Part D, Medicaid, or TRICARE are not eligible for the PROvide Program. Additional terms and conditions apply.
§In the event an eligible patient’s claim for coverage for PROVENGE is denied by his payer after all appeals, the cost of the drug may be covered by Dendreon’s patient assistance program.

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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 additional Important Safety Information throughout and accompanying full Prescribing Information.
Coverage and reimbursement

Dendreon ON Call (DOC) case managers are available to help with every step of benefit verification and scheduling infusion sessions. Areas of support include:

- Enrollment, benefit verification, and patient eligibility checks (completed within 48 hours)
- Assistance for uninsured patients
- Patients needing financial aid or treatment-related assistance to travel to their infusion location will be referred to independent foundations by DOC

<table>
<thead>
<tr>
<th>Benefit verification assistance</th>
<th>Payor coverage</th>
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<tbody>
<tr>
<td></td>
<td>• All Medicare Administrative Contractor (MAC) regions cover PROVENGE for on-label use&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• More than 90% of Medicare fee-for-service (FFS) patients have NO OOP costs for PROVENGE&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• Health care plans representing about 99% of patients with private insurance cover PROVENGE for on-label use&lt;sup&gt;5,6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• DOC provides a Benefit Verification Summary for each eligible patient, available within 48 hours of receiving the completed enrollment form</td>
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</table>

<table>
<thead>
<tr>
<th>Prior authorization support</th>
<th>DOC provides:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Researching and collecting information</td>
</tr>
<tr>
<td></td>
<td>• Tracking status with the payor</td>
</tr>
<tr>
<td></td>
<td>• Sample Letter of Medical Necessity (if required), available at <a href="http://www.DendreonONCall.com">www.DendreonONCall.com</a></td>
</tr>
</tbody>
</table>

**TIPS ON MEDICARE COVERAGE**

- It is critical to document in the chart that the patient meets the labeled indication for PROVENGE
- A National Coverage Determination (NCD) for PROVENGE ensures coverage for on-label uses in Medicare beneficiaries.<sup>4</sup> Visit www.DendreonONCall.com
- An online Coverage by State Map for Medicare and commercial plan coverage can be accessed at www.DendreonONCall.com

*Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
**Coverage and reimbursement (con’t)**

| Co-pay assistance | • Refers Medicare patients to the appropriate independent foundation that may provide financial assistance for co-pays, co-insurance, and deductible costs*
| Eligibility is determined by Dendreon | - Eligibility is determined by the individual foundation
| | • Commercially insured patients may be eligible to access PROvide™, which provides coverage of up to $6,000 for PROVENGE treatments† |
| Support for uninsured or rendered uninsured patients‡ | PROVENGE is provided free of cost to eligible uninsured patients and those eligible patients who have become uninsured due to a final payer claim denial.§ |
| Eligibility criteria are determined by Dendreon | Requirements include:
| | • Adjusted gross income of $150K a year or less
| | • Age 18 or older
| | • US resident
| | • On-label prescription
| Travel cost assistance | • If your patient needs financial assistance with treatment-related costs, a case manager can refer him to independent resources to determine if he is eligible for help with these costs* |

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†The PROvide Commercial Co-pay Program provides flexible coverage of up to $6,000 over 3 PROVENGE treatments for co-pays, co-insurance, and deductible costs. Eligibility criteria can be changed or program can be discontinued at any time at the sole discretion of Dendreon. Patients with government-funded insurance including Medicare, Medicare Part D, Medicaid, or TriCare are not eligible for the PROvide Program. Additional terms and conditions apply.

‡Contact Dendreon ON Call at 1-877-336-3736 for eligibility criteria. Uninsured patient assistance program eligibility criteria can be changed or program can be discontinued at any time at the sole discretion of Dendreon.

§In the event an eligible patient’s claim for coverage for PROVENGE is denied by his payer after all appeals, the cost of the drug may be covered by Dendreon’s patient assistance program.

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Coding and billing assistance

DOC-provided assistance includes:

- Dedicated Reimbursement Coordinators with expertise in your specific region
- Coding resources, including a quick reference coding and billing guide and sample claim form
- Claims tracking and appeals support

TIPS FOR COMPLETING THE CLAIM FORM CORRECTLY

Box 19 (RESERVED FOR LOCAL USE) – Enter appropriate product information, if required by payor

Box 21 (DIAGNOSIS OR NATURE OF ILLNESS OR INJURY) – Enter appropriate ICD-10-CM diagnosis code(s) as documented in the medical record

Box 24D – For Medicare claims, enter appropriate HCPCS code

A Sample Claim Form is provided at www.DendreonONCall.com

RESOURCES AVAILABLE at www.PROVENGEHCP.com

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Dendreon will work with your office to manage the key steps in the PROVENGE treatment process:

1. Personalized treatment schedule
2. Venous Assessment and Complete Blood Count (CBC)
3. Apheresis (cell collection process)
4. PROVENGE dose is created and delivered
5. PROVENGE infusion
6. Therapy is complete after 3 cycles

A PROVENGE Treatment Plan tear sheet is available from your Dendreon Clinical Nurse Educator.

**Personalized treatment schedule**

PROVENGE is administered in 3 treatment cycles and is typically completed in 1 month¹

- Each cycle consists of an apheresis procedure (at a cell collection center), followed 3 days later by PROVENGE infusion in your office
- Each apheresis/PROVENGE infusion cycle is generally 2 weeks apart

**Venous Assessment and CBC**

| Before starting treatment, ask patients about | • Any serious medical problems  
• Any concurrent medications, including prescription and over-the-counter medicines, vitamins, and supplements |
| Before the first apheresis, every PROVENGE patient must | • Obtain a CBC before the first infusion  
• Obtain a vein check at least 1 week before the first infusion  
  – Required to determine whether placement of an apheresis catheter may be necessary  
  – Prescribing physician or infusion staff initiates the venous assessment and can be coordinated with the local apheresis center as needed |

**TIPS FOR VENOUS ASSESSMENT**

- Peripheral IV lines are preferred, though some patients may require an apheresis catheter
- Use a tourniquet or blood pressure cuff with visualization and palpation
- Verify access in both arms, since apheresis is a dual-arm procedure
- If inadequate access, a central venous catheter (CVC) must be scheduled and placed prior to first apheresis appointment
- The apheresis center can be available for consultation

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**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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
The apheresis procedure
- The cell collection process takes 3 to 4 hours and is scheduled 3 days prior to each infusion.1
- Cells are collected using blood vessels in both arms or through a dialysis-type apheresis catheter.
- The cell collection will take place at a blood center with staff that have been trained to perform the procedure.
- Dendreon's Clinical Nurse Educators can reach out to patients before their first collection appointment to provide preparation tips and education around the apheresis procedure.

APHERESIS TIPS
Before each procedure, advise patients to:
- Drink plenty of water and be well hydrated.
- Avoid caffeinated beverages on days when apheresis is scheduled.
- Eat a calcium-rich breakfast.
- Have a meal prior to the procedure.
- Bring the same photo ID to each procedure (patients must bring a government-issued ID, such as a driver's license, to all appointments).
- Wear loose-fitting clothing with sleeves that can be raised above the elbow.
- Have someone to drive them home since most people feel tired after the procedure.

RESOURCES AVAILABLE at www.PROVENGEHCP.com

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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 additional Important Safety Information throughout and accompanying full Prescribing Information.
Setting up an infusion area in your office

PROVENGE is shipped directly to your office. Dendreon will provide support with:

- Product ordering
- Facilitating product delivery and returns
- Assisting with treatment-related questions
- Infusion protocol for PROVENGE
- Infusion resources
  - “Incorporating PROVENGE into Practice: Preparing for Infusions”

- Infusion Demonstration Kit
- Available Nurse Educator to educate the Infusion RN
- Video series highlighting the infusion process, available at www.PROVENGEHCP.com
- A PROVENGE Infusion Checklist is available from Dendreon

Recommended infusion supplies

<table>
<thead>
<tr>
<th>PROVENGE infusion essentials (basic supplies to have in advance of infusion)</th>
<th>• Peripheral IV Catheter (18-22 gauge)</th>
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<tbody>
<tr>
<td></td>
<td>• IV Start Supplies</td>
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<tr>
<td></td>
<td>• IV Pole</td>
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<tr>
<td></td>
<td>• Macro Drip IV Tubing (10-20 gtts/mL with 1 injection port), no cell filter</td>
</tr>
<tr>
<td></td>
<td>• Normal Saline Solution</td>
</tr>
<tr>
<td></td>
<td>• 10-mL Syringe</td>
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<table>
<thead>
<tr>
<th>Supplies for patients with an apheresis catheter</th>
<th>• Sterile Dressing Change Supplies</th>
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<tbody>
<tr>
<td></td>
<td>• Male Luer Lock Adapters (needleless IV endcap for apheresis/dialysis catheter)</td>
</tr>
<tr>
<td></td>
<td>• Normal Saline Solution</td>
</tr>
<tr>
<td></td>
<td>• 10-mL Syringe</td>
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<tr>
<td></td>
<td>• Anticoagulant Locking Solution (eg, heparin)</td>
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<thead>
<tr>
<th>Supplies you may already have</th>
<th>• Tourniquet(s)</th>
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<tbody>
<tr>
<td></td>
<td>• Tape (transparent and paper)</td>
</tr>
<tr>
<td></td>
<td>• Gauze (2” x 2”), sterile and nonsterile</td>
</tr>
<tr>
<td></td>
<td>• Alcohol Swabs</td>
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<thead>
<tr>
<th>Recommended for premedication and side effect management¹</th>
<th>• Acetaminophen</th>
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<tbody>
<tr>
<td></td>
<td>• Antihistamine (such as oral diphenhydramine)</td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION (con’t)**

**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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
PROVENGE shipping and handling

PROVENGE is shipped directly to your office in a cardboard shipping box, which contains:

- An insulated polyurethane container that stores the infusion bag
- PROVENGE should remain in the insulated polyurethane container with the lid in place until the patient is ready for infusion
- The Final Product Disposition Notification (FPDN) will be faxed or e-mailed separately on the day of infusion and contains:
  - Patient identifiers
  - Expiration date and time
  - Disposition status ("Approved for Infusion" or "Rejected")
- Infuse PROVENGE only if form indicates "Approved for Infusion"
- If the product is "Rejected," call Dendreon ON Call at 1-877-336-3736

IMPORTANT SAFETY INFORMATION (con't)

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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Preparing to infuse PROVENGE®

Approximately 30 minutes before infusion
- Conduct a patient assessment
- Administer premedications (acetaminophen, antihistamine) to mitigate the risk of acute infusion reactions

Place an IV line for infusion
- Do NOT use a cell filter
- Use primary IV tubing and prime with normal saline solution
- Use a 18-20 gauge needle

Remove the lid from the polyurethane container and confirm that PROVENGE is suitable for administration
- PROVENGE should remain at room temperature no more than 3 hours
- Do NOT place the infusion bag back into the polyurethane container once you remove it
- Ensure the product is not:
  - Expired
  - Leaking
  - Visibly damaged
  - Clumped (initial clumps should dissipate with gentle rocking or manual manipulation of the infusion bag. If not, call Dendreon ON CALL at 1-877-336-3736)

INFUSION LABEL VERIFICATION TIPS
- Confirm patient identity by matching identifiers on the FPDN with the label on the PROVENGE infusion bag
- If your practice decides to add a unique patient label to the bag, the added label must NOT cover any PROVENGE labeling on the infusion bag
- Do NOT remove any PROVENGE labeling provided by Dendreon

IMPORTANT SAFETY INFORMATION (con’t)
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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Infusing PROVENGE®

- Administer the infusion over 60 minutes
- Infuse the entire bag
- If an acute infusion reaction occurs, infusion may be interrupted or slowed:
  - Appropriate medical therapy should be administered
    - In clinical trials, acetaminophen, IV H1 and/or H2 blockers, and low-dose IV meperidine were used for acute infusion reactions
    - If infusion bag is held at room temperature for more than 3 hours, do NOT resume the infusion
- Discard infusion bag and tubing according to institutional procedures for disposing biohazardous waste containing human blood
- Observe patient for a minimum of 30 minutes following infusion
- Reassess and discharge if patient is stable

RESOURCES AVAILABLE at www.PROVENGEHCP.com

IMPORTANT SAFETY INFORMATION (con’t)

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.

ADMINISTRATIVE CHAMPION

Practice staff skilled at successfully integrating the PROVENGE process to establish a treatment model for their practice

Allocation of practice resources, reimbursement, and financial reconciliation are key to a successful PROVENGE treatment experience. The information and resources that can support your role as an Administrative Champion, as well as easy access to those resources, are included in this Guide.

Dendreon ON Call

A comprehensive support service for offices using PROVENGE, is your source for patient and product support and reimbursement expertise. Enroll your PROVENGE-eligible patients through Dendreon ON Call to receive the following program benefits:

- Support throughout the entire enrollment and treatment process
- Dedicated staff, including reimbursement coordinators, to answer your questions

Dendreon ON Call
Phone: 1-877-336-3736
Fax: 1-877-556-3737
Monday through Friday | 8:00 AM to 9:00 PM ET
www.DendreonONCall.com

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
As an Administrative Champion, you have a crucial role in assuring that PROVENGE is integrated into your practice

Resource development
PROVENGE is similar to a medical procedure, so you need to focus on:
• Space needed for administration is minimal
• A comfortable recliner chair and an infusion pole are required
• Equipment/supplies – minimal supplies needed
• Staffing – commitment from current staff or hire additional staff
  – Nurse Navigator or Practice Manager for patient ID and education

Access and reimbursement support
PROVENGE has excellent coverage across Medicare and major commercial payors per the FDA-approved label:
• 100% of Medicare administrative contractors\(^1\)
• Plans representing about 99% of patients with private insurance\(^2,3\)

Average time to payment is about 30 days across commercial and government payors

IMPORTANT SAFETY INFORMATION (con’t)
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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
**Coding is established for PROVENGE**

<table>
<thead>
<tr>
<th>HCPCS</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. This will help streamline the processing of claims for PROVENGE.</td>
</tr>
</tbody>
</table>

**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 payers 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.

- 2 out of 3 patients treated with PROVENGE spend less than $50 out-of-pocket*
- More than 90% of Medicare fee-for-service (FFS) patients have NO out-of-pocket costs for PROVENGE†

**IMPORTANT SAFETY INFORMATION (con’t)**

**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.

*Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.

†Data from Dendreon ON Call benefit verifications from Q1 2013 to Q4 2013. These data represent the distribution of patient out-of-pocket costs, per infusion, and do not include patient assistance funding.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
Patient Assistance Programs for patients who have no coverage or need help covering costs

<table>
<thead>
<tr>
<th>PROvide co-pay program</th>
<th>Financial help for patients with commercial insurance*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent resources</td>
<td>Co-pay assistance for patients with government programs (eg, Medicare)†</td>
</tr>
<tr>
<td></td>
<td>Treatment-related costs</td>
</tr>
<tr>
<td>Free drug for eligible patients with no coverage</td>
<td>No insurance</td>
</tr>
<tr>
<td></td>
<td>Rendered uninsured after denied appeals</td>
</tr>
<tr>
<td>Dendreon ON Call (DOC)</td>
<td>Available via:</td>
</tr>
<tr>
<td></td>
<td>• 1-877-336-3736</td>
</tr>
<tr>
<td></td>
<td>• Fax: 1-877-556-3737</td>
</tr>
<tr>
<td></td>
<td>• <a href="http://www.DendreonONCall.com">www.DendreonONCall.com</a></td>
</tr>
</tbody>
</table>

**Access Dendreon ON Call for assistance**

- Dedicated Dendreon ON Call reimbursement coordinators can provide:
  - Coding and billing resources to support claims submission, including sample forms and letters
  - Forms tailored to both hospital outpatient departments and physician practices
  - Claim form reviews, prior to submission
    - Real-time tracking status on submitted claims

*The PROvide Commercial Co-pay Program provides flexible coverage of up to $6,000 over 3 PROVENGE treatments for co-pays, co-insurance, and deductible costs. Eligibility criteria can be changed or program can be discontinued at any time at the sole discretion of Dendreon. Additional terms and conditions apply.

†Co-pay and travel assistance foundations provide assistance regardless of the choice of medicine, and decisions are based on financial need and according to criteria established by the individual foundations. Dendreon ON Call can assist patients by referring them to these independent organizations. Dendreon cannot guarantee that patients will be eligible for or receive assistance after referral. Dendreon does not have control or managerial influence over these independent organizations.

**IMPORTANT SAFETY INFORMATION (con’t)**

**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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.
PROVENGE Acquisition Pricing Program (PAPP)

Provides opportunities for value

- **Average sales price (ASP)-based pricing** – reduces acquisition cost for PAPP member accounts
- **Volume rebates** – performance-based rebate opportunity for accounts reaching target infusion volumes
- **Growth rebates** – performance-based rebate opportunity for accounts that drive quarter-to-quarter infusion growth
- **6-month True Up payment** – rebate based on average of total infusions over a 6-month period

### Volume Rebate

Based on the number of infusions of PROVENGE per quarter (see table).

<table>
<thead>
<tr>
<th>Tier</th>
<th>Threshold (Infusions/Quarter)</th>
<th>Rebate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>0-7</td>
<td>0.0%</td>
</tr>
<tr>
<td>Tier 2</td>
<td>8-20</td>
<td>1.5%</td>
</tr>
<tr>
<td>Tier 3</td>
<td>21-30</td>
<td>2.25%</td>
</tr>
<tr>
<td>Tier 4</td>
<td>31-40</td>
<td>2.75%</td>
</tr>
<tr>
<td>Tier 5</td>
<td>41-50</td>
<td>3.25%</td>
</tr>
<tr>
<td>Tier 6</td>
<td>51-70</td>
<td>3.75%</td>
</tr>
<tr>
<td>Tier 7</td>
<td>71-90</td>
<td>4.75%</td>
</tr>
<tr>
<td>Tier 8</td>
<td>91-110</td>
<td>5.25%</td>
</tr>
<tr>
<td>Tier 9</td>
<td>111+</td>
<td>6.25%</td>
</tr>
</tbody>
</table>

### Growth Rebate

Based on the quarter-over-quarter percent increase in volume (see table).

<table>
<thead>
<tr>
<th>Quarterly Infusions</th>
<th>Quarter-Over-Quarter Growth</th>
<th>Rebate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–7 infusions</td>
<td></td>
<td>0%</td>
</tr>
<tr>
<td>8+ infusions</td>
<td>7.5%–14.9%</td>
<td>0.50%</td>
</tr>
<tr>
<td></td>
<td>15%–24.9%</td>
<td>0.75%</td>
</tr>
<tr>
<td></td>
<td>25+%</td>
<td>1.00%</td>
</tr>
</tbody>
</table>

Please contact your local Dendreon reimbursement specialist to assist you with the details of the contract and for any updates you may need along the way.

**IMPORTANT SAFETY INFORMATION (con’t)**

**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.

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Please see accompanying full Prescribing Information.

www.PROVENGEHCP.com
PROVENGE® (sipuleucel-T)  

PATIENT INFORMATION

This leaflet is designed to help you understand treatment with PROVENGE (pronounced PRO-VEN-gee). If you understand your treatment, the better you will be able to participate in your care. This leaflet does not take the place of talking with your doctor or healthcare professional about your medical condition or your treatment. If you have any questions, speak with your doctor.

What is PROVENGE?

PROVENGE is a prescription medicine that is used to treat certain patients with advanced prostate cancer. PROVENGE is made from your own immune cells.

What should I tell my doctor before getting PROVENGE?

Tell your doctor about all your medical problems, including:

- heart problems
- lung problems
- history of stroke

Tell your doctor about all the medicines you take, including prescription and nonprescription drugs, vitamins, and dietary supplements.

How will I get PROVENGE?

Since PROVENGE is made from your own immune cells, your cells will be collected approximately 3 days before each scheduled infusion of PROVENGE. Your doctor will go to a cell collection center for this collection. The collection is called "leukapheresis" (pronounced loo-kuh-fuh-REE-sis). Your collected cells are sent to a manufacturing center where they are mixed with a protein to make them ready for your infusion.

You will get PROVENGE in 3 intravenous infusions (put into your veins), about 2 weeks apart. Each infusion takes about 60 minutes. Following each infusion, you will be monitored for at least 30 minutes.

Your doctor will give you a schedule for your cell collection and infusion appointments. It is very important that you arrive on time for your appointments. If you miss an appointment and cannot be infused, your PROVENGE dose will not be applicable. Your doctor will work with you to schedule a new appointment at the cell collection center. You may also get a new infusion appointment.

(CONTINUED ON OTHER SIDE)
PROVENGE infusion can cause serious reactions. Tell your doctor right away if:

- you have breathing problems, chest pains, racing heart or irregular heartbeats, high or low blood pressure, dizziness, fainting, nausea, or vomiting after getting PROVENGE. Any of these may be signs of heart or lung problems.

- you develop numbness or weakness on one side of the body, dizziness, or difficulty speaking. Any of these may be signs of a stroke.

- you develop symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain that worsens on deep breathing.

- you get a fever over 100°F, or redness or pain at the infusion or collection sites. Any of these may be signs of infection.

Tell your doctor about any side effect that concerns you or does not go away.

There are not all the possible side effects of PROVENGE treatment. For more information, talk with your doctor.

What are the ingredients in PROVENGE?

The active ingredients of PROVENGE are your own immune cells mixed with the active component to be injected. PROVENGE is a cellular immunotherapy, which produces an immune response to prostate cancer. The product is suspended in an infusion solution called Lactated Ringer's Injection, USP, an inactive ingredient.