**Provenge® (sipuleucel-T)**
(Intravenous)

**Last Review Date:** January 1, 2020  
**Number:** MG.MM.PH.101

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**Medical Guideline Disclaimer**

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**LENGTH OF AUTHORIZATION**

Coverage will be provided for 3 doses only

**DOSING LIMITS**

A. **Max Units (per dose and over time) [Medical Benefit]:**

- 1 billable unit every 14 days x 3 doses only

**Guideline**

I. **INITIAL APPROVAL CRITERIA**

Coverage is provided in the following conditions:

**Prostate Cancer †**

- Patient has castration-resistant metastatic disease; **AND**
- Patient has an ECOG Performance status of 0-1; **AND**
- Patient has no hepatic metastases; **AND**
- Must not be used in combination with chemotherapy; **AND**
- Patient’s life expectancy is estimated to be greater than 6 months; **AND**
- Patient is asymptomatic or minimally symptomatic; **AND**
- Patient has not previously received therapy with sipuleucel-T

† FDA Approved Indication(s)

II. **RENEWAL CRITERIA**

Coverage cannot be renewed.

**Limitations/Exclusions**

Provenge is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

**Applicable Procedure Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</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>
</tr>
</tbody>
</table>

1 billable unit = 1 dose (Code Price is per 250 mL)

**Applicable NDCs**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30237-8900-xx</td>
<td>Provenge suspension for injection</td>
</tr>
</tbody>
</table>

**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasms of prostate</td>
</tr>
<tr>
<td>Z85.46</td>
<td>Personal history of malignant neoplasm of prostate</td>
</tr>
</tbody>
</table>

**Revision History**

N/A

**References**


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Sipuleucel-T. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium”) for Prostate Cancer 2.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium” is a derivative work of the NCCN Guidelines”. NATIONAL COMPREHENSIVE CANCER NETWORK”, NCCN’, and NCCN GUIDELINES’ are trademarks owned by the National
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