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 can not 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 of 1 billable unit = 1 dose (Code Price is per 250 mL)</td>
</tr>
</tbody>
</table>

Applicable NDCs

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

