## Drug Therapy Guidelines

### Provenge® (sipuleucel-T)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective: 10/1/16</th>
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<tbody>
<tr>
<td>Pharmacy-Formulary 1</td>
<td>Next Review: 9/17</td>
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<tr>
<td>Pharmacy-Formulary 2</td>
<td>Date of Origin: 12/10</td>
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<tr>
<td>Pharmacy-Formulary 3/Exclusive</td>
<td>Review Dates: 12/10, 12/11, 12/12, 12/13, 12/14, 9/15, 9/16</td>
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<tr>
<td>Pharmacy-Formulary 4/AON</td>
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### I. Medication Description

Sipuleucel-T is an autologous cellular immunotherapy used in the treatment of asymptomatic or minimally symptomatic, metastatic castrate resistant (hormone-refractory), prostate cancer. The agent consists of specially treated dendritic cells obtained from the patient with leukapheresis. The cells are then exposed in vitro to proteins that contain prostate antigens and immunologic-stimulating factors, and are then reinfused back into the patient. The proposed mechanism of action is that the treatment stimulates the patient’s own immune system to resist spread of the cancer.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

### III. Policy

Provenge® therapy may be considered medically necessary in the treatment of metastatic, castrate resistant (hormone-refractory) prostate cancer where the following apply:

- Prescribed by an oncologist **AND**
- Good performance status (ECOG 0-1) **AND**
- Estimated life expectancy > 6 months **AND**
- No hepatic metastases **AND**
- Disease is asymptomatic or minimally symptomatic

### IV. Quantity Limitations

Up to three doses will be covered per patient.

### V. Coverage Duration

Coverage is provided for 3 months and may not be renewed once doses are administered.

### VI. Coverage Renewal Criteria

n/a
VII. Billing/Coding Information

- Pertinent indications: C61, Z85.46
- Q2043: sipuleucel-T, minimum 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion – 250ml

VIII. Summary of Policy Changes

- 3/1/11: New policy
- 6/15/12: Q code added
- 3/15/13:
  - Clarification of hepatic metastases vs. visceral metastases
  - Addition of criteria to clarify asymptomatic and minimally symptomatic disease
- 3/15/14: no policy changes
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 9/15/16: requirement of oncologist prescriber added to policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.