PHARMACY POLICY STATEMENT  
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Provenge (sipuleucel-T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Q2043</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient Hospital</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Preferred Product)</td>
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<tr>
<td>QUANTITY LIMIT</td>
<td>1 doses per 2 weeks, up to 3 doses total</td>
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</tbody>
</table>

LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY: Click Here

Provenge (sipuleucel-T) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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**PROSTATE CANCER**

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by an oncologist, a hematologist, or a urologist; AND
3. Member must have a diagnosis of metastatic castrate resistant prostate cancer (CRPC) and is asymptomatic or minimally symptomatic (Gleason score of 7 or less documented in chart notes); AND
4. Member has level of testosterone (< 50 ng/dL) achieved via medical or surgical castration; AND
5. Members had **not** received ANY of the following treatments within the previous 28 days:
   a) External beam radiation therapy or major surgery requiring general anesthetic;
   b) Systemic corticosteroids;
   c) Non-steroidal anti-androgens (e.g., bicalutamide, flutamide, or nilutamide);
   d) Any other systemic therapy for prostate cancer including secondary hormonal therapies, such as megestrol acetate (Megace®), diethylstilbestrol (DES), and ketoconazole; AND
6. Member must have a life expectancy of 3 months or greater; AND
7. Member does **not** have any of the following:
   a) Visceral metastases (liver, lung, or brain);
   b) Moderate to severe prostate cancer-related pain;
   c) Use of narcotics for cancer-related pain.
8. **Dosage allowed:** 3 doses, 1 dose every 2 weeks.

*If member meets all the requirements listed above, the medication will be approved for 3 months.*

For **reauthorization**:

1. Provenge will not be reauthorized for continued therapy.

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CareSource considers Provenge (sipuleucel-T) not medically necessary for the treatment of the diseases that are not listed in this document.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>11/29/2017</td>
<td>New policy for Provenge created.</td>
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</table>
References:


Effective date: 11/29/2017
Revised date: 11/15/2017