**Provenge**
(sipuleucel-T)

**Document Number:** 047

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<tr>
<th>Authorization required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
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**FDA-Approved Indication**

Provenge is classified as an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

**Criteria**

1. **Criteria for Initial Approval**
   - Patient has a diagnosis of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer and has met all of the following criteria:
     - A. Absence of hepatic metastases
     - B. Testosterone levels <50 ng/dl
     - C. Life expectancy greater than 6 months
     - D. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
   - Provenge is not to be used in combination with chemotherapy and immunosuppressive medications

2. **Prescribing**
   - Prescribed by an oncologist or urologist

3. **Duration of Therapy**
   - 3 complete doses/infusions

4. **Approval Duration**
   - The total treatment course is 3 complete doses/infusions. Additional courses of therapy are considered investigational. Administer doses at approximately two week intervals for a total of 3 doses.

**CPT/HCPC Codes**

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<th>Code Description</th>
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<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>
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1 Eastern Cooperative Oncology Group (ECOG) 0: Fully active, able to carry on all pre-disease performance without restriction.
ECOG 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
Effective
February 2020: Annual review. References Updated.
February 2019: Annual review.
February 2018: Annual review.
September 2017: Effective date.

References

Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Autologous CELLULAR IMMUNOTHERAPY Treatment (110.22).

Centers for Medicare and Medicaid Services National Coverage Analysis (NCA) for Autologous CELLULAR IMMUNOTHERAPY Treatment of Metastatic Prostate Cancer (CAG-00422N): Technology Assessment - Outcomes of Sipuleucel-T Therapy.


