Blue Cross Blue Shield Blue Care Network of Michigan

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Retired
Effective Date: 02/02/2023

Provenge® (sipuleucel-T)

HCPCS: Q2043

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. Diagnosis of metastatic prostate cancer
      i. Histologically confirmed adenocarcinoma of the prostate
      ii. Bone scan or CT scan with evidence of prostate cancer spread to the lymph nodes or bones (but not the lungs, liver, or brain) with evidence of progression at either of these sites
   b. Hormone refractory (castrate resistant)
      i. Baseline testosterone levels < 50 ng/mL
   c. Asymptomatic or minimally symptomatic (such as little or no cancer-related pain, no need for narcotic pain medications for cancer pain, ect)
   d. ECOG performance status of 0 – 1
   e. Life expectancy of greater than 6 months
   f. Should not be used if prior treatment failure has occurred with Provenge

B. Approval Length and Quantity Limits
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the patient has not received the maximum 3 infusions allowed

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer. It involves collection of white blood cell fraction-containing, antigen-presenting cells from each patient; exposure of the cells to prostatic acid phosphatase-granulocyte macrophage colony stimulating factor; and subsequent reinfusion of the cells.

- The pivotal study was a phase III, multicenter, randomized, double-blind trial of 512 patients with minimally symptomatic or asymptomatic castration-resistant prostate cancer (CRCP). The study defined castration resistant as a testosterone level of less than 50 ng/mL. Asymptomatic or minimally symptomatic were defined as little or no cancer-related pain or no need for narcotic pain medications for cancer pain. Patients were randomzed 2:1 to receive Provenge or placebo. Median survival was 25.8 months in the Provenge arm compared to 21.7 months in the placebo arm. Provenge showed a reduction in mortality risk by 22%.

- The 2022 National Comprehensive Cancer Network (NCCN) prostate cancer guidelines recommend Provenge as a category 1 option in metastatic CRPC who are asymptomatic or mininimally symptomatic, have a ECOG performance status of 0 – 1, estimated life expectancy greater than 6 months, and no liver metastases. Provenge has not been studied in patients with visceral metastases and has only been shown to work in patients with metastases to the lymph nodes or bone. NCCN guidelines state Provenge should be used only for adenocarcinoma of the prostate as it has not been shown to be effective for small cell or neuroendocrine tumors of the prostate.

- There are no studies to support use of Provenge following failure of its use. NCCN guidelines also do not recommend use of Provenge following a previous failure.

References:

1. Provenge [prescribing information]. Seatle, WA: Dendreon Corporation; July 2017.
2. Kantoff PW, Hogano CS, Shore ND, et al. Sipuleucel-T immunotherapy for castration-resistent prostate cancer. NEJM. 2010; 363: 411 – 22.
3. National Comprehensive Cancer Network. Prostate cancer (Version 4.2022). 2022 May 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed on August 23, 2022.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.1</td><td>Effective Date: 02/02/2023</td><td>Retiring policy as drug will no longer be part of the prior authorization program</td></tr>
<tr><td>2.0</td><td>Effective Date: 10/06/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.9</td><td>Effective Date: 10/07/2021</td><td>Annual review of criteria was performed, no changes were made.</td></tr>
<tr><td>1.8</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.7</td><td>Effective Date: 10/08/2020</td><td>Updated to allow an authorization period of 6 months and only allow renewal if the patient has not had a total of 3 infusions</td></tr>
<tr><td>1.6</td><td>Effective Date: 01/01/2020</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.5</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.4</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.3</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/10/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/11/2016</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 10/07/2010</td><td>Initial Criteria Write-Up
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*