Provenge (Sipuleucel-T)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

Criteria for Initial Approval

Metastatic Castration-Resistant Prostate Cancer
Authorization of 3 months may be granted for a one-time treatment consisting of 3 doses administered at approximately 2-week intervals for metastatic castrate-resistant (hormone-refractory) prostate cancer in members 18 years of age and older when all of the following criteria are met:

A. Evidence of disease progression documented by one of the following:
    1. Progressively rising prostate specific antigen (PSA) defined as a PSA rise by 2ng/mL or more above the nadir PSA (lowest level that the PSA drops after treatment); **OR**

2. Progressive measurable disease as evidenced by changes in size of lymph nodes, or parenchymal masses on physical examination or imaging studies; **OR**
3. Bone metasteses on imaging with evidence of progression regardless of PSA levels

B. The member is asymptomatic or minimally symptomatic
C. The member has an ECOG performance status of 0 to 1
D. The member has a life expectancy of greater than 6 months
E. The member has no visceral metastases of liver, lung, or brain
F. The member will not be using other immunosuppressive agents (such as systemic corticosteroids) or any of the following chemotherapy and/or systemic therapies within 28 days prior to treatment with Provenge: Abiraterone (Yonsa/Zytiga), Apalutamide (Erleada), Cabazitaxel (Jeytana), Docetaxel (Taxotere), Enzalutamide (Xtandi), Ipilimumab (Yervoy), Mitoxantrone (Novantrone), Olaparib (Lynparza), Pembrolizumab (Keytruda), Rucaparib (Rubraca)
G. The member has not received previous treatment with the requested medication

Continuation of Therapy

Repeat treatment of Provenge for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Provenge approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2043 – Sipuleucel-T, minimum of 50 million autologuous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

REFERENCES

- Provenge [package insert]. Seal Beach, CA: Dendreon Pharmaceuticals, LLC; July 2017.
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- Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized, double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. Cancer. 2009;115(16):3670-3679. https://pubmed.ncbi.nlm.nih.gov/19536890/
- Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. J Clin Oncol. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757. https://pubmed.ncbi.nlm.nih.gov/32716741/
- Small EJ, Schellhammer PF, Higano CS, et al. Placebo-Controlled Phase III Trial of Immunologic Therapy With Sipuleucel-T (APC8015) in Patients With Metastatic, Asymptomatic Hormone Refractory Prostate Cancer. J Clin Oncol. 2006;24(19):3089-3094. https://pubmed.ncbi.nlm.nih.gov/16809734/

POLICY HISTORY

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Revised:
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