

POLICY: Oncology – Provenge® (sipuleucel-T intravenous infusion – Dendreon Pharmaceuticals LLC)

APPROVAL DATE: 02/20/2019

OVERVIEW

Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic castrate-resistant (hormone-refractory) prostate cancer (CRPC).¹ Provenge consists of autologous peripheral blood mononuclear cells, including antigen presenting cells, that have been activated during a defined culture period with a recombinant human protein found on prostate cancer tissue, linked to an immune cell activator. Provenge is designed to induce an immune response targeted against an antigen expressed in most prostate cancer cells.

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 4.2018) lists Provenge as a category 1 recommended therapy for metastatic CRPC.^{2,3} It is noted that Provenge has not been studied in patients with visceral metastases. The guidelines note that Provenge can be considered in patients who meet the following: good performance status (Eastern Cooperative Oncology Group [ECOG] performance status) of 0 or 1; estimated life expectancy > 6 months; no hepatic metastases; and no or minimal disease symptoms. If not previously used as therapy, Provenge is also listed as an option (category 2A) after Xtandi® (enzalutamide capsules), Zytiga® (abiraterone acetate tablets), or docetaxel therapy in patients with no visceral metastases.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Provenge. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing (i.e., repeat course of Provenge therapy beyond the three doses) documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Provenge as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Provenge to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Provenge is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Prostate Cancer.** Approve for 3 months if the patient meets the following criteria (A, B, C, D, and E):
 - A) The patient has metastatic castration-resistant (hormone-refractory) prostate cancer; AND
 - B) The patient has minimal or no disease symptoms, according to the prescribing physician; AND
 - C) The patient does not have liver metastasis; AND
 - D) The patient has not been previously treated with a complete course (3 doses) of Provenge for prostate cancer; AND
 - E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to three doses, given at approximately 2-week intervals.

Each dose of Provenge contains a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF).

As noted in the prescribing information, in controlled clinical trials, the median dosing interval between infusions was 2 weeks; however, the dosing interval range could elapse between 1 week to 15 weeks. The maximum dosing interval has not been established.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

REFERENCES

1. Provenge® Intravenous Infusion [prescribing information]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; July 2017.
2. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 15, 2018. Search term: Sipuleucel-T.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4.2018 – August 15, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 11, 2019.

HISTORY

Type of Revision	Summary of Changes*	Approval Date
New policy	--	11/21/2018
Early annual revision	Added criteria for prostate cancer to require minimal or no disease symptoms and no liver metastases as per guidelines. Also added criteria patient has not received Provenge before.	02/20/2019