Utilization Review Policy 182

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

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 05/10/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Provenge, an autologous cellular immunotherapy, is indicated for the treatment of asymptomatic or minimally symptomatic metastatic **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. 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.

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 1.2023 – September 16, 2022) lists Provenge as a category 1 recommended therapy under "useful in certain circumstances" for metastatic CRPC for patients who have not received prior docetaxel or prior novel hormone therapy.[2,3] Provenge is also listed as an option (category 2A) for patients who have received either prior docetaxel or prior novel hormone therapy. It is noted that Provenge has not been studied in patients with visceral metastases and is not recommended if visceral metastases are present. Provenge is also not recommended for patients with small cell/neuroendocrine prostate cancer. The guidelines note that Provenge is only recommended for patients who meet the following: Eastern Cooperative Oncology Group performance status of 0 or 1; estimated life expectancy > 6 months; no hepatic metastases; and no or minimal disease symptoms.

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. 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 the following criteria:

FDA-Approved Indication

1. **Prostate Cancer.** Approve for 3 months if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has metastatic castration-resistant (hormone-refractory) prostate cancer; AND
   - **C)** Patient has minimal or no disease symptoms, according to the prescriber; AND
   - **D)** Patient does not have liver metastasis; AND
   - **E)** Patient has not been previously treated with a complete course (3 doses) of Provenge for prostate cancer; AND
   - **F)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to three doses, each dose containing a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF) given at approximately 2-week intervals.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Provenge is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Provenge® intravenous infusion [prescribing information]. Seal Beach, CA: Dendreon Pharmaceuticals; July 2017.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 8, 2023. Search term: Sipuleucel-T.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 8, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Prostate Cancer:** A requirement that the patient is ≥ 18 years of age was added.	05/11/2022
Selected Revision	**Prostate Cancer:** Dosing was reworded to include the dose information "each dose containing a minimum of 50 million autologous CD54-positive cells activated with prostatic acid phosphatase (PAP)-granulocyte-macrophage colony-stimulating factor (GM-CSF)".	07/13/2022
Annual Revision	No criteria changes.	05/10/2023