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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 8, 2011
Subject:	Provenge	**Page:**	1 of 4

Last Review Date: September 8, 2023

Provenge

Description

Provenge (sipuleucel-T)

Background
Provenge, an autologous cellular immunotherapy, is intended for men with asymptomatic or minimally symptomatic prostate cancer that has metastasized (spread to other parts of the body) and is resistant to standard hormone treatment. Provenge is designed to stimulate the patient's own immune system to respond against the cancer. Each dose of Provenge is manufactured by first obtaining immune cells from the patient's blood, using a machine process known as leukapheresis. Then the cells are exposed to a protein linked to an immune-stimulating substance that is found in normal prostate tissue and in most prostate cancers. Finally, the cells are infused back into the patient to treat the cancer. Provenge is intended for autologous use only (1).

Provenge is administered intravenously in a three-dose schedule, given at approximately 2-week intervals. In controlled clinical trials, the median dosing interval between infusions was 2 weeks (range 1 to 15 weeks); the maximum dosing interval of 15 weeks has been established by the manufacturer. If, for any reason, the patient is unable to receive a scheduled infusion of Provenge, the patient will need to undergo an additional leukapheresis procedure if the course of treatment is to be continued. According to the manufacturer, in no circumstances should a patient receive more than 3 doses (1).

Regulatory Status

FDA-approved indication: Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer (1).

Provenge is intended solely for autologous use and intravenous use only (1).

Provenge may cause acute infusion reactions (reported within 1 day of infusion). Patients with cardiac or pulmonary conditions should be closely monitored. To minimize potential acute infusion reactions such as chills and/or fever, it is recommended that patients be pre-medicated orally with acetaminophen and an antihistamine such as diphenhydramine approximately 30 minutes prior to administration of Provenge (1).

Use of either chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure or Provenge has not been studied. Provenge is designed to stimulate the immune system, and concurrent use of immunosuppressive agents may alter the efficacy and/or safety of Provenge. Therefore, patients should be carefully evaluated to determine whether it is medically appropriate to reduce or discontinue immunosuppressive agents prior to treatment with Provenge (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Provenge may be considered **medically necessary** if the conditions indicated below are met.

Provenge may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Metastatic castrate resistant (known as hormone refractory) prostate cancer

AND ALL of the following:

a. Histological confirmation of prostate cancer with radiologic evidence of metastases
b. Prostate-specific antigen (PSA) ≥ 2ng/ml
c. PSA measurement is a minimum of 25 percent greater than baseline
d. Testosterone level < 50ng/dl
e. Progressive disease on the basis of imaging studies or PSA measurements

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 3 infusions (1 treatment) within 15 weeks

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Provenge is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. Provenge is intended solely for autologous use and intravenous use only. Provenge may cause acute infusion reactions (reported within 1 day of infusion). Patients with cardiac or pulmonary conditions should be closely monitored. Provenge is administered intravenously in a three-dose schedule, given at approximately 2-week intervals within 15 weeks (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Provenge while maintaining optimal therapeutic outcomes.

References

1. Provenge [package insert]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; July 2017.
2. NCCN Drugs & Biologics Compendium® Sipuleucel-T 2023. National Comprehensive Cancer Network, Inc. Accessed on July 27, 2023.

Policy History

Date	Action
December 2012	Annual editorial review and update
December 2013	Annual editorial review and reference update
March 2014	Annual editorial review and reference update
March 2015	Annual editorial review and reference update
February 2016	Addition of requirements: histological confirmation of prostate cancer with radiologic evidence of metastases, PSA measurement is a minimum of 25 percent greater than baseline and change of PSA from 5 to 2ng/ml per PMPC Policy change from 5.04.09 to 5.21.09
March 2016	Annual review
June 2016	Annual review and reference update
June 2017	Annual editorial review and reference update
December 2017	Annual review
June 2018	Annual editorial review
June 2019	Annual review and reference update
June 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.