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).
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 for use in patients with metastatic castrate resistant (hormone refractory) prostate cancer and 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

Policy History
**Section:** Prescription Drugs  **Effective Date:** July 1, 2019  
**Subsection:** Antineoplastic Agents  **Original Policy Date:** September 8, 2011  
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<td>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</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.