FDA-Approved Indication

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

NHP Criteria

1. Criteria for Initial Approval
   - Patient has a diagnosis of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer and has met all of the following criteria:
     - Absence of hepatic metastases
     - Testosterone levels <50 ng/dl
     - Life expectancy greater than 6 months
     - The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1*
   - Provenge is not to be used in combination with chemotherapy and immunosuppressive medications

2. Prescribing
   - Prescribed by an oncologist or urologist

3. Dosing and Administration (For autologous use only. For intravenous use only.)

4. Duration of Therapy
   - 3 complete doses/infusions

5. Approval Duration:
   - The total treatment course is 3 complete doses/infusions. Additional courses of therapy are considered investigational. Administer doses at approximately two week intervals for a total of 3 doses.

Effective

February 2018: Annual review.
September 2017: Effective date.

References


2. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Autologous CELLULAR IMMUNOTHERAPY Treatment (110.22).

*Eastern Cooperative Oncology Group (ECOG) 0: Fully active, able to carry on all pre-disease performance without restriction. ECOG 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.


