Provenge (sipuleucel-T)

Document Number: 047

	Commercial and Qualified Health Plans	MassHealth
Authorization required	X	X
No Prior Authorization		

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.

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:
     A. Absence of hepatic metastases
     B. Testosterone levels <50 ng/dl
     C. Life expectancy greater than 6 months
     D. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1[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.

[1] 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.

References

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Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; October 2014. Available at: http://www.provenge.com/ (Accessed June 6, 2017).

Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed November 11, 2016.

National Cancer Institute (NCI). Surveillance, Epidemiology, and End Results Program (SEER). SEER Stat Fact Sheets: Prostate Cancer. (Accessed June 6, 2017).

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