

# STANDARD MEDICARE PART B MANAGEMENT

## PROVENGE (sipuleucel-T)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

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

B. Compendial Use

Biochemical relapse of nonmetastatic androgen-dependent (castration-naïve) prostate cancer

C. CMS Nationally Covered Uses

The following NCD policy applies to these criteria: Autologous Cellular Immunotherapy Treatment (110.22).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Prostate cancer**

Authorization of 6 months may be granted when Provenge is prescribed for a maximum of 3 doses for either of the following indications:

- A. Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer
- B. Biochemical relapse of nonmetastatic androgen-dependent (castration-naïve) prostate cancer

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Provenge is administered every 2 weeks for a total of 3 doses. Authorization for 3 months to complete the 3-dose treatment may be granted when all of the following criteria are met:

- A. The member is currently receiving treatment with Provenge
- B. Provenge is requested to treat an indication enumerated in Section II
- C. The member has not yet completed treatment with all 3 doses

Reference number(s)
2409-A

#### IV. REFERENCES

1. Provenge [package insert]. Seattle, WA: Dendreon Corporation; July 2017.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 27, 2020.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed July 27, 2020.
4. National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22-Version 1). <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&from2=search.asp&bc=gAAAAAgAAAA&> Accessed July 27, 2020.