

Provenge (sipuleucel-T)

POLICY

A. 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.

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.

Compendial Use

- Appropriate therapy for castration-recurrent metastatic disease for asymptomatic or minimally symptomatic patients with performance status 0-1, life expectancy greater than 6 months, and no hepatic metastases

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Oncology/clinical notes that include the history or previous treatments and any pertinent pathology reports and/or imaging studies
 - Cancer stage
 - Previous hormone therapy

C. PRESCRIBER RESTRICTION

The medication must be recommended by an oncologist or urologist.

D. EXCLUSIONS

- Members who have received Provenge previously
- Members who have hepatic metastases
- Members requesting greater than 3 doses

E. CRITERIA FOR APPROVAL

1. Prostate Cancer

- a. Authorization of 6 months may be granted for members prescribed Provenge for metastatic, castration-resistant prostate cancer who meet the following criteria:
 - Member is asymptomatic or minimally symptomatic
 - Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
 - Member has a life expectancy of greater than, or equal to, 6 months

F. DOSING AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. REFERENCES

1. Provenge [package insert]. Seattle, WA: Dendreon Corporation; October 2014.
2. The NCCN Drugs & Biologics Compendium™. © 2015 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. May 20, 2015.