

Policy: MBP 79.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Provenge (sipuleucel-T)

I. Policy:

Provenge (sipuleucel-T)

II. Purpose/Objective:

To provide a policy of coverage regarding Provenge (sipuleucel-T)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:

Provenge (sipuleucel-T) is an immunotherapy product consisting of autologous dendritic cells loaded ex vivo with a recombinant fusion protein. The goal of therapy is to induce therapeutic immunity against prostate cancer cells by targeting the PAP tumor antigen, which is expressed on greater than 95% of prostate cancer cells

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Provenge (sipuleucel-T) will be considered medically necessary when all of the following criteria are met:

1. Metastatic castrate resistant (hormone refractory) prostate cancer
Medical record documentation of:
 - a diagnosis of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer **AND**
 - prescribed by an oncologist **AND**
 - disease that currently does not require opioid use for cancer-related pain **AND**
 - metastatic disease with bone and/or lymph node involvement **AND**
 - testosterone level less than 50 ng/dl **AND**
 - an abdominal CT scan to rule out visceral involvement **AND**
 - a life expectancy greater than 6 months **AND**
 - negative serology for Human Immunodeficiency Virus (HIV) 1&2, Human T-Cell Leukemia Virus (HTLV-1), and Hepatitis B and C **AND**
 - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 **AND**
 - no chemotherapy concurrently or within the past 3 months of Provenge being administered **AND**
 - no immunosuppressives (including systemic corticosteroids) used concurrently and within 1 month of Provenge being administered

AUTHORIZATION DURATION: Authorization for Provenge® (sipuleucel-T) will be limited to three (3) complete doses.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/8/10

Revised: 10/11; 1/14 (add limitation); 1/20/15 (criteria, references, formatting), 3/28/19 (grandfather)

Reviewed: 3/16, 3/30/17, 3/29/18, 1/1/20, 1/1/21, 12/21/21