Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Provenge (sipuleucel-T)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Provenge (sipuleucel-T).

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

Sipuleucel-T (Provenge) dose: 3 complete doses, given at approximately 2-week intervals

DEFINITIONS

Eastern Cooperative Oncology Group (ECOG) Performance Status – Scale used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patients, and determine the appropriate treatment and prognosis.

Grade	ECOG

0	Fully active, able to carry on all pre-disease performance without restriction
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
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Provenge (sipuleucel-T), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a hematologist/oncologist or urologist
- Must have a diagnosis of castrate resistant (hormone refractory) prostate cancer with documented serum testosterone level of <50ng/dL
    - Testosterone level <50ng/dL not required for members treated with bilateral orchiectomy
- Must have radiologic evidence of metastatic disease to soft tissue AND/OR bone
    - Member must NOT have evidence of any visceral metastases (e.g. lung, liver, brain)
- Must have evidence of disease progression at metastatic sites or by serial Prostate Specific Antigen (PSA) measurements. Chart documentation of progression following treatment with androgen deprivation therapy or orchiectomy is required.

- Must be asymptomatic or minimally symptomatic, as evidenced by NOT currently having any of the following:
    - Moderate to severe prostate cancer-related pain
    - Use of narcotics for cancer-related pain
- Must have an ECOG performance status of one of the following:
    - 0 (Fully active, able to carry on all pre-disease performance without restriction)
    - 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)
- Must NOT be using chemotherapy or immunosuppressive agents concurrently with Provenge

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization (after consultation with medical director)	1 course of therapy (3 doses given at approximately 2 week intervals) per lifetime
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Provenge [package insert]. Seattle, WA: Dendreon Corporation; May 2010
2. Higano CS, Schellhammer PF, Small EJ et al. Integrated data from 2 randomized, double-blind, placebo-controlled phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. *Cancer* 2009;115:3670-9
3. Small EJ, Schellhammer PF, Higano CS et al. Placebo-controlled phase III trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. *J Clin Oncol* 2006;24:3089-3094
4. Kantoff PW, Higano C, Berger ER et al. Updated survival results of the IMPACT trial of sipuleucel-T for metastatic, castration-resistant prostate cancer (CRPC). [poster] Presented at the American Society of Clinical Oncology genitourinary cancers symposium. San Francisco, CA. March 5, 2010.
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. V.2.2010
6. Oken MM, Creech RH, Hoton J et al. Toxicty and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol* 1982;5:649-655

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*