MEDICAL COVERAGE POLICY	
SERVICE: Sipuleucel-T (Provenge®)	
Policy Number:	**246**
Effective Date:	**07/01/2019**
Last Review:	**04/25/2019**
Next Review Date:	**04/25/2020**

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Sipuleucel-T (Provenge®)

PRIOR AUTHORIZATION: Required. This policy provides guidelines for medical review when that review is NOT performed by vendor Oncology Analytics.

POLICY:

SWHP considers vaccine therapy, e.g., Sipuleucel-T (Provenge®), medically necessary for the treatment of castrate-resistant, metastatic prostate cancer in members who meet the following criteria:

1. The member does not have visceral metastases: AND
2. The member has a life expectancy of at least six months; AND
3. Patient is asymptomatic or minimally symptomatic;
4. The member has an Eastern Cooperative Oncology Group (ECOG) Performance Score of 0-1; AND
5. The member has NOT had disease progression while receiving Provenge®.

SWHP considers Sipuleucel-T (Provenge®) experimental and investigational for all other indications because the clinical evidence is not sufficient to permit conclusions on the health outcome effects of this therapy.

OVERVIEW: Provenge® (sipuleucel-T) is a novel autologous cellular immunotherapy or therapeutic vaccine for the treatment of castration-resistant prostate cancer. It was the first therapeutic cancer vaccine to receive FDA approval. Provenge® is designed to activate a patient's own antigen-presenting cells (APCs), a type of immune cell that expresses co-stimulatory molecules and secretes immune-activating cytokines. The activated and loaded APCs elicit a cellular immune response against a specific protein target found in prostate cancer cells, thereby stimulating the body's immune system against the prostate cancer.

Provenge® is made from autologous peripheral blood mononuclear cells. The final vaccine product is produced by isolating an individual's CD54+ antigen-presenting cells (APCs) via leukapheresis, culturing the exposed cells with PA2024 antigen, and administering the vaccine back into the patient by intravenous infusion. Once administered, Provenge® acts to activate T-cells, which then proliferate to target and kill prostate cancer cells.

Based on available data, Provenge® appears to be a reasonable treatment option for men with castration-resistant metastatic prostate cancer who are asymptomatic or minimally symptomatic and whose tumors are not responsive to hormone therapy.

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
CPT Not Covered:	
HCPCS Covered:	Q2043 Sipuleucel-T
HCPCS Not Covered:	
ICD-10:	C61 - Malignant neoplasm of prostate Z19.2 - Hormone resistant malignancy status BOTH codes required

CMS: There are no NCDs or LCDs related to this coverage.

POLICY HISTORY:

Status	Date	Action
New	03/13/2018	New policy
Reviewed	04/25/2019	Updated criteria to reflect NCCN. Process change noted.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Abdulla A, Kapoor A. Emerging novel therapies in the treatment of castrate-resistant prostate cancer. Can Urol Assoc J. 2011;5(2):120-133.
2. American Cancer Society (ACS). Cancer Facts & Figures 2011. Atlanta, GA: American Cancer Society; 2011. Available at: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-029771.pdf.
3. Beinart G, Rini BI, Weinberg V, Small EJ. Antigen-presenting cells 8015 (Provenge) in patients with androgen-dependent, biochemically relapsed prostate cancer [abstract]. Clin Prostate Cancer. 2005;4(1):55-60.
4. Bracarda S, Logothetis C, Sternberg CN, Oudard S. Current and emerging treatment modalities for metastatic castration-resistant prostate cancer. BJU Int. 2011;107(Suppl 2):13-20.
5. Kantoff PW, Higano CS, Shore ND, et al. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010;363(5):411-422.
6. 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(19):3089-3094.