**EFFECTIVE DATE:** 06|01|2018
**POLICY LAST UPDATED:** 05|15|2018

## OVERVIEW

This policy for Cellular Immunotherapy for Prostate Cancer includes coverage guidelines for BlueCHiP for Medicare. Sipuleucel-T (Provenge®; Dendreon Corp.) is a class of therapeutic agent used in the treatment of asymptomatic or minimally symptomatic, androgen-independent (castration-resistant), metastatic prostate cancer.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

## MEDICAL CRITERIA

Sipuleucel-T therapy (Provenge) is considered medically necessary in the treatment of asymptomatic or minimally symptomatic, metastatic, castrate-resistant (hormone refractory) prostate cancer.

## PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare members

## POLICY STATEMENT

**BlueCHiP for Medicare**

Sipuleucel-T therapy (Provenge) is covered when the criteria have been met and is limited to one treatment regimen in a patient's lifetime.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the Evidence of Coverage for the applicable infusion therapy coverage.

## BACKGROUND

The goal of immunotherapy is to stimulate the body's natural defenses (such as the white blood cells called dendritic cells, T-lymphocytes and mononuclear cells) in a specific manner so that they attack and destroy, or at least prevent, the proliferation of cancer cells. Specificity is attained by intentionally exposing a patient's white blood cells to a particular protein (called an antigen) associated with the prostate cancer. This exposure "trains" the white blood cells to target and attack the prostate cancer cells. Clinically, this is expected to result in a decrease in the size and/or number of cancer sites, an increase in the time to cancer progression, and/or an increase in survival of the patient.

Sipuleucel-T differs from other infused anti-cancer therapies. Most such anti-cancer therapies are manufactured and sold by a biopharmaceutical company and then purchased by and dispensed from a pharmacy. In contrast, once the decision is made totreat with sipuleucel-T, a multi-step process is used to produce sipuleucel-T. Sipuleucel-T is made individually for each patientwith his own white blood cells. The patient's white blood cells are removed via a procedure called leukapheresis. In a laboratory the white blood cells are exposed to PA2024, which is a molecule created by linking prostatic acid phosphatase(PAP) with granulocyte/macrophage-colony stimulating factor (GM-CSF). PAP is an antigen specifically associated with prostate cancer cells; GM-CSF is a protein that targets a receptor on the surface of white blood cells. Hence, PAP serves toexternally manipulate the immunological functioning of the patient's white blood cells while GM-CSF serves to stimulate the white blood cells into action. As noted in the FDA's clinical review, each

dose of sipuleucel-T contains a minimum of 40 million treated white blood cells, however there is "high inherent variability" in the yield of sipuleucel-T from leukapheresis toleukapheresis in the same patient as well as from patient to patient. The treated white blood cells are then infused back into the same patient.

Coverage for Provenge for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer is limited to one (1) treatment regimen in a patient's lifetime. consisting of three (3) doses with each dose administered approximately two (2) weeks apart for a total treatment period not to exceed 30 weeks from the first administration.

## CODING

**BlueCHiP for Medicare**

The following code is covered when the medical criteria have been met:

**Q2043** Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

## RELATED POLICIES

Prior Authorization of Drugs

## PUBLISHED

Provider Update, June 2018
Provider Update, December 2017
Provider Update, September 2016
Provider Update, November 2015
Provider Update, November 2013
Provider Update, June 2012

## REFERENCES

1. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Autologous CELLULAR IMMUNOTHERAPY Treatment (110.22). Available at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&kq=true&bc=gAAAAAgAAAAA&

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