Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: PA.CP.PHAR.120
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for sipuleucel-T (Provenge®).

FDA Approved Indication(s)
Provenge is indicated for treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Provenge is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Metastatic and castrate-resistant (hormone-refractory) disease.

Approval Duration:
3 complete doses/infusions (total treatment course)

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has not received ≥ 3 doses (infusions) of Provenge.

Approval Duration:
Up to maximum of 3 complete doses (complete course of therapy)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
   Approval duration: Duration of request or up to maximum of 3 complete doses (whichever is less); or

2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:
Sipuleucel-T is classified as an autologous cellular immunotherapy. While the precise mechanism of action is unknown, Sipuleucel-T is designed to induce an immune response targeted against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers.

Formulations:
Each dose of Provenge contains a minimum of 50 million autologous CD54+ cells activated with PAP linked to granulocyte-macrophage colony-stimulating factor (GM-CSF), or PAP-GM-CSF, suspended in 250 mL of Lactated Ringer's Injection, USP.

Appendices
Appendix A: Abbreviation Key
ECOG: Eastern Cooperative Oncology Group
GM-CSF: granulocyte-macrophage colony-stimulating factor
PAP: prostatic acid phosphatase

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q2043	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

Reviews, Revisions, and Approvals	Date	Approval Date

References
1. Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; October 2014. Available at: http://www.provenge.com/. Accessed January 2018.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 2018.
3.
4. National Comprehensive Cancer Network. Prostate Cancer Version 2.2017. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed January 2018.