Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: PA.CP.PHAR.120
Effective Date: 01/2018
Last Review Date: 04/2023

Coding Implications
Revision Log

Description
Sipuleucel-T (Provenge®) is an autologous cellular immunotherapy.

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

Policy/Criteria
It is the policy of PA Health & 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 metastatic CRPC, as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy (*see Appendix D*);
2. Member is asymptomatic or minimally symptomatic;
3. Member does not have visceral disease (e.g., lung, liver, or brain metastases);
4. Member has an estimated life expectancy of > 6 months;
5. Member's Eastern Cooperative Oncology Group (ECOG) performance status is 0 or 1;
6. Prescribed by or in consultation with an oncologist or urologist;
7. Age ≥ 18 years;
8. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
9. Member has not received ≥ 3 doses (infusions) of Provenge.

Approval Duration: 6 months (up to a total of 3 doses)

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & 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 continues to use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
4. Member has not received ≥ 3 doses (infusions) of Provenge.

Approval Duration: 6 months (up to a total of 3 doses)

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
   Approval duration: 8 weeks;
   or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CRPC: castration-resistant prostate cancer

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Examples of androgen deprivation therapy include:
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
    - LHRH agonists: Zoladex® (goserelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
  - LHRH antagonist: Firmagon® (degarelix), Orgovyx™ (relugolix)

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Metastatic CRPC	One dose IV over 60 minutes given approximately every 2 weeks for 3 doses Each dose contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection	1 dose approximately every 2 weeks (max 3 doses)

V. Product Availability

Suspension for injection: minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection

VI. References

1. Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; July 2017. Available at: http://www.provenge.com/. Accessed January 6, 2023.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed January 10, 2023.
3. National Comprehensive Cancer Network. Prostate Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 10, 2023.

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	Suspension of Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2019 annual review: references reviewed and updated.	04/2019	
2Q 2020 annual review: added urologist as prescriber option to criteria; removed dose quantity restriction from approval duration and added it to criteria, and modified approval durations to 6 months; added appendix D; references reviewed and updated.	04/2020	
2Q 2021 annual review: added that member has no or minimal symptoms without visceral metastases with greater than 6 months of life expectancy and an ECOG status of 0 to 1 per NCCN; references reviewed and updated.	04/2021	
2Q 2022 annual review: added requirement that "member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy" per NCCN and alignment with other prostate cancer clinical policies; added clarification on approval duration for up to a total of 3 doses; references reviewed and updated.	04/2022	
2Q 2023 annual review: no significant changes; updated *Appendix D* examples of androgen deprivation therapy per NCCN; clarified *estimated* life expectancy of > 6 months requirement consistent with NCCN; references reviewed and updated.	04/2023	