## Prior Authorization Review Panel

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**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 05/01/2022** |
| **Policy Number: PA.CP.PHAR.120** | **Effective Date: 01/2018**<br>**Revision Date: 04/2022** |
| **Policy Name: Sipuleucel-T (Provenge)** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

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.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Venkateswara R. Davuluri, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: PA.CP.PHAR.120
Effective Date: 01/18
Last Review Date: 04/2022

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 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 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 a 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 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 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 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: 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), Vantas® (histrelin), 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)

## 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<br><br>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 25, 2022.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed January 25, 2022.
3. National Comprehensive Cancer Network. Prostate Cancer Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 25, 2022.

**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. | 04/19 | |
| 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 | |