Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: CP.PHAR.120
Effective Date: 07.01.15
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Provenge is **medically necessary** when 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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Provenge for prostate cancer and has received this medication for at least 30 days;
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: 8 weeks; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. 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

- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL). Per the NCCN, androgen deprivation therapy should be continued in the setting of CRPC while additional therapies are applied.
- Examples of androgen deprivation therapy include:
  - Bilateral orchiectomy (surgical castration)
  - 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)

V. 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)

VI. 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

VII. 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	P&T Approval Date
2Q 2018 annual review: no significant changes; policies combined for Commercial and Medicaid; HIM line of business added; age and dose added; summarized NCCN and FDA approved uses for improved	02.13.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated		
2Q 2019 annual review: no significant changes; changed HIM to HIM-Medical Benefit line of business; references reviewed and updated.	02.26.19	05.19
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; revised HIM-Medical Benefit to HIM line of business; references reviewed and updated.	02.06.20	05.20
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; removed HIM line of business per formulary status as alternatives exist for CRPC indication; references reviewed and updated.	02.20.21	05.21
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.	01.25.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.