

## Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: CP.PHAR.120

Effective Date: 07.01.15

Last Review Date: 05.20

Line of Business: Commercial, HIM, 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. Prescribed by or in consultation with an oncologist or urologist;
3. Age  $\geq$  18 years;
4. Member has not received  $\geq$  3 doses (infusions) of Provenge.

**Approval duration: 6 months**

##### 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, HIM.PHAR.21 for health insurance marketplace 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 has not received  $\geq$  3 doses (infusions) of Provenge.

**Approval duration: 6 months**

**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, HIM.PHAR.21 for health insurance marketplace 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, HIM.PHAR.21 for health insurance marketplace 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*

- Examples of androgen deprivation therapy include:
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
    - LHRH agonists: Zoladex<sup>®</sup> (goserelin), Vantas<sup>®</sup> (histrelin), leuprolide (Lupron Depot<sup>®</sup>, Eligard<sup>®</sup>), and Trelstar<sup>®</sup> (triptorelin)
    - Anti-androgens: bicalutamide (Casodex<sup>®</sup>), flutamide (Eulexin<sup>®</sup>), nilutamide (Nilandron<sup>®</sup>), Xtandi<sup>®</sup> (enzalutamide), Erleada<sup>®</sup> (apalutamide), Nubeqa<sup>®</sup> (darolutamide)
  - LHRH antagonist: Firmagon<sup>®</sup> (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 February 6, 2020.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [www.nccn.org](http://www.nccn.org). Accessed February 6, 2020.
3. National Comprehensive Cancer Network. Prostate Cancer Version 4.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed February 6, 2020.

**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	P&T Approval Date
Policy created	06.15	06.15
Policy converted to new template. Removed hypersensitivity to Provenge or any of its components as it is not listed as a contraindication per PI. Removed NCCN guidance for use of Provenge requirements (i.e., ECOG 0-1, no hepatic metastases, estimated life expectancy > 6 months) as they are not included per labeled indication. Removed requirement relating to concomitant chemotherapy or immunosuppressive therapy use as those drug interactions are not included as contraindications per PI.	04.16	06.16
Reinserted the above-referenced NCCN criteria to support appropriate use (i.e., ECOG 0-1, no hepatic metastases, estimated life expectancy > 6 months).	11.16	12.16
References reviewed and updated. Added continued approval duration of up to 3 doses for “other diagnoses.”	06.17	06.17
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 clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated	02.13.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

**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.

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**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.

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