Clinical Policy: Sipuleucel-T (Provenge)

Reference Number: CP.PHAR.120
Effective Date: 06/15
Last Review Date: 04/16

Coding Implications
Revision Log

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

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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 castrate-resistant (hormone-refractory) prostate cancer;
2. Disease is asymptomatic or minimally symptomatic;
3. Performance status of 0-1*;
4. Life expectancy > 6 months;
5. No hepatic metastases.

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** Eastern Cooperative Oncology Group (ECOG) 0: Fully active, able to carry on all pre-disease performance without restriction. ECOG 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.*

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

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

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. 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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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.

FDA Approved Indication(s):
Provenge is an autologous cellular immunotherapy/suspension for intravenous infusion indicated for:

- Treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

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
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

1. Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; October 2014. Available at: http://www.provenge.com/. Accessed April 20, 2016.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed November 11, 2016.

3. Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol.* 1982: 5:649-655.

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.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.