OncoHealth

Provenge (sipuleucel-T)

Effective Date: 9/1/2020
Revision Date(s): 9/2020, 10/2021, 10/2022, 10/2023
Review Date: 10/2/2023
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 3 doses per lifetime and cannot be renewed.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

Indication Specific Criteria

Prostate Cancer - Metastastic

- The member has metastatic castrate-resistant (hormone refractory) prostate cancer (CRPC), as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy, **AND**
- The member must be ≥18 years of age, **AND**
- The member exhibits asymptomatic or minimally symptomatic disease with an Eastern Cooperative Oncology Group performance score of 0-1, **AND**
- The member has a life expectancy of at least six months, **AND**
- The member does not have hepatic or other visceral metastases, **AND**
- The member has not received prior treatment with sipuleucel-T, **AND**
- The member will receive sipuleucel-T as monotherapy

Billing

Drug Name	HCPCS Code	Description
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion

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References

1. Provenge [package insert]. Dendreon Pharmaceuticals LLC, Seal Beach, CA. Available at: https://www.provenge.com/Portals/_default/Skins/ProvengeDTC/downloads/PRV.0039.USA.18-%20Provenge%20Prescribing%20Information.pdf
2. Sipuleucel-T. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
11/2023	Policy updated to new format. No changes to criteria.

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