

Provenge (sipuleucel-T)

Effective Date: 9/1/2020

Revision Date(s): 9/2020, 10/2021, 10/2022, 10/2023, 6/10/2024

Review Date: 6/10/2024

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are for 3 doses per lifetime.

Universal Criteria:

- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature.

Indication Specific Approval Criteria:

Prostate Cancer, Metastatic

- Member is at least 18 years of age, **AND**
- Member's prostate cancer is castrate resistant (hormone refractory), **AND**
- Member is asymptomatic or minimally symptomatic, **AND**
- Member has an Eastern Cooperative Oncology Group (ECOG) of 0-1¹, **AND**
- Member has a life expectancy of at least six months, **AND**
- Member does not have hepatic or other visceral metastases, **AND**
- Used as a single agent²

Universal Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
 - Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
 - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
 - Clinical Pharmacology (Strong For)
 - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
 - Thompson Micromedex DrugDex® (Class I and IIa)
 - Wolters Kluwer Lexi-Drugs® (Level A)
 - Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals

¹ ECOG score of greater than 1 will be considered on a case-by-case basis

² Members may continue androgen deprivation therapy (ADT) to maintain castrate levels of serum testosterone (<50 ng/dL).

- American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
- **Meeting abstracts and case reports are excluded from consideration.**
 - Non-standard protocols may be approved based on unique clinical circumstances.

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

References

1. Provenge [package insert]. Dendreon Pharmaceuticals LLC, Seal Beach, CA. July 2017. Available at: https://provenge.com/hcp/wp-content/uploads/sites/3/2023/07/Provenge_Prescribing_Information.pdf
2. Provenge. National Comprehensive Cancer Network® (NCCN). NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed June 4, 2024. Updated periodically.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 28th, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
4. Kantoff PW, Higano CS, Shore ND, Berger ER, Small EJ, Penson DF, Redfern CH, Ferrari AC, Dreicer R, Sims RB, Xu Y, Frohlich MW, Schellhammer PF; IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010 Jul 29;363(5):411-22. doi: 10.1056/NEJMoa1001294. PMID: 20818862.

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.
6/10/2024	Annual Review