

Provenge (sipuleucel-T)

Policy Number: 048

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	X
No Prior Authorization			

FDA-Approved Indication

Provenge is classified as an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Criteria

1. Criteria for Initial Approval

- Patient has a diagnosis of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer and has met **all** of the following criteria:
 - A. Absence of hepatic metastases
 - B. Testosterone levels <50 ng/dl
 - C. Life expectancy greater than 6 months
 - D. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1¹
- Provenge is not to be used in combination with chemotherapy and immunosuppressive medications

2. Prescribing

- Prescribed by an oncologist or urologist

3. Duration of Therapy

- 3 complete doses/infusions

4. Approval Duration

- The total treatment course is 3 complete doses/infusions. Additional courses of therapy are considered investigational. Administer doses at approximately two week intervals for a total of 3 doses.

Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.

At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare has NCD: Autologous Cellular Immunotherapy Treatment (110.22).

¹ 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 housework, office work.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized Code	Code Description
Q2043	Sipuleucel-T, minimum of 50 million autologous cd54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion

Effective

February 2023: Annual review. Medicare Advantage added to table. Variation language added.

References updated.

February 2022: Annual review. References updated.

February 2021: Annual review. Removed Dosing and Administration information. References Updated.

February 2020: Annual review. References Updated.

February 2019: Annual review.

February 2018: Annual review.

September 2017: Effective date.

References

Anassi E, Ndefo, UA. Sipuleucel-T (Provenge) Injection. The First Immunotherapy Agent (Vaccine) for Hormone-Refractory Prostate Cancer. *Pharmacy and Therapeutics*. 2011;36(4):197-202.

Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Autologous CELLULAR IMMUNOTHERAPY Treatment (110.22).

Centers for Medicare and Medicaid Services National Coverage Analysis (NCA) for Autologous CELLULAR IMMUNOTHERAPY Treatment of Metastatic Prostate Cancer (CAG-00422N): Technology Assessment - Outcomes of Sipuleucel-T Therapy.

Higano, C., Armstrong, A., Sartor, A. et al. Real-world outcomes of sipuleucel-T treatment in PROCEED, a prospective registry of men with metastatic castration-resistant prostate cancer. *Cancer*. 2019 125(23), 4172-4180. doi: 10.1002/cncr.32445

Marshall CH, Fu W, Wang H, et al. Randomized Phase II Trial of Sipuleucel-T with or without Radium-223 in Men with Bone-metastatic Castration-resistant Prostate Cancer. *Clin Cancer Res*. 2021 Mar 15;27(6):1623-1630. doi: 10.1158/1078-0432.CCR-20-4476. Epub 2021 Jan 15. PMID: 33451978; PMCID: PMC8121020.

McKay RR, Hafron JM, Ferro C, et al. A Retrospective Observational Analysis of Overall Survival with Sipuleucel-T in Medicare Beneficiaries Treated for Advanced Prostate Cancer. *Adv Ther*. 2020 Dec;37(12):4910-4929. doi: 10.1007/s12325-020-01509-5. Epub 2020 Oct 7. PMID: 33029725; PMCID: PMC7596004.

Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; October 2014. Available at: <http://www.provenge.com/> (Accessed June 6, 2017).

Sheikh, N. Cham, J. Zhang, L et al. Clonotypic Diversification of Intratumoral T Cells Following Sipuleucel-T Treatment in Prostate Cancer Subjects. *Cancer Res*. 2016, 76, 3711–3718.

Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed November 11, 2016.



Twardowski P, Wong JYC, Pal SK, et al. Randomized phase II trial of sipuleucel-T immunotherapy preceded by sensitizing radiation therapy and sipuleucel-T alone in patients with metastatic castrate resistant prostate cancer. *Cancer Treat Res Commun.*2019;19:100116.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf Accessed January 17, 2023.

National Cancer Institute, Surveillance Epidemiology and End Results Program. Cancer Stat Fact: Prostate Cancer. n.d.; <https://seer.cancer.gov/statfacts/html/prost.html>. Accessed January 6, 2021 MICROMEDEX Healthcare Series. Drugdex Drug Evaluations (2016, November). Sipuleucel-T. Retrieved June 6, 2017 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2010, April). Center for Biologics Evaluation and Research. *Provenge® (sipuleucel-T) suspension for intravenous infusion.*

Zhang L, Kandadi H, Yang H, et al. Long-term Sculpting of the B-cell Repertoire following Cancer Immunotherapy in Patients Treated with Sipuleucel-T. *Cancer Immunol Res.* 2020 Dec;8(12):1496-1507. doi: 10.1158/2326-6066.CIR-20-0252. Epub 2020 Sep 23. PMID: 32967912; PMCID: PMC7903967.

