Mass General Brigham
Health Plan

Medical Policy
Provenge (sipuleucel-T)

Policy Number: 048

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization required	X	X	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 1[1]
   - 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 Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity 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 medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies

[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.

are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had:**

- **NCD - Autologous Cellular Immunotherapy Treatment (110.22)**
- **Medicare Benefit Policy Manual Chapter 15 - Covered Medical and Other Health Services**

MassHealth Variation
Mass General Brigham Health Plan uses the MassHealth Drug List for medical necessity determinations for members of the Mass General Brigham ACO. Criteria for Provenge are found in Table 57: Oncology Agents.

OneCare and SCO Variation
Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

Codes

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

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
January 2026: Ad hoc update. Updated prior authorization table and added variation for OneCare and SCO members. Fixed code disclaimer.
March 2025: Annual review. References updated.
September 2024: Ad hoc update. MassHealth variation added.
February 2024: Annual review.
March 2023: Annual review.
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
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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.

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