Mass General Brigham
Health Plan

Medical Necessity Guidelines
Provenge (sipuleucel-T)

Policy Number: 048

Contents

Overview

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

Medicare Advantage

Prior Authorization Required	Yes ☒ No ☐

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 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)**

Off-label indications beyond those described in the NCD are not covered.

Mass General Brigham ACO

Prior Authorization Required	Yes ☒ No ☐

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.

One Care and Senior Care Options (SCO)

Prior Authorization Required	Yes ☒ No ☐

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care 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, or the member does not meet all of the medical necessity criteria for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. **See Medicare Advantage criteria and exclusions, above. If Medicare Advantage criteria are not met, then MassHealth criteria are applied.**

Commercial and Qualified Health Plans

Prior Authorization Required	Yes ☒ No ☐

Prior authorization for Provenge for Commercial and Qualified Health Plan members is managed by Prime Therapeutics. See the Prime Therapeutics policy for Provenge for more information.

Codes

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

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 Dates

June 2026: Annual review. Reformatted policy. Clarified hierarchy of criteria in One Care and SCO variation. Updated PA information for Commercial and QHP members.
January 2026: Ad hoc update. Updated prior authorization table and added variation for One Care 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.

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