Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)

Effective: November 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Pluvicto (Lutetium Lu 177 vipivotide tetraxetan) was approved by the US Food and Drug Administration for treatment of prostate-specific membrane antigen (PSMA) expressing metastatic castration-resistant prostate cancer (mCRPC) previously treated with androgen-receptor pathway inhibitors (ARPIs) and taxane-based chemotherapy on the basis of improved survival over second-line hormone therapy, but few trials have compared this agent with other survival-prolonging agents in CRPC.

Androgen deprivation therapy (ADT) is a usual first-line option for males with advanced prostate cancer, but the vast majority eventually progress while receiving ADT, and the disease state is referred to as castration-resistant prostate cancer (CRPC). The mechanisms driving progression from androgen-dependent (hormone-sensitive or castration-sensitive) prostate cancer to CRPC are still largely unclear, although continued androgen receptor signaling, despite depletion of circulating androgens and androgen receptor blockade, is thought to be central to the development of CRPC.

Food and Drug Administration (FDA) Approved Indications:

- Pluvicto is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA) – positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

PLUVICTO is available at select treatment centers across the United States. To find the PLUVICTO Treatment Center nearest you, go to Treatment Center Locator I PLUVICTO. Treatment centers may have different patient eligibility criteria. Please contact the treatment center directly for more information.

NOTE: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Pluvicto when all the following clinical criteria are met:

1. The Member has a documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC).

AND

2. The Member is 18 years of age or older.

AND

3. There is documentation that the Member is prostate-specific membrane antigen (PSMA)-positive as confirmed using Locametz or another approved PSMA-11 imaging agent.

AND

4. The Member has failed or did not tolerate prior treatment with androgen receptor (AR) pathway inhibition (e.g., abiraterone) **OR** the treating provider has determined that these therapies are not clinically appropriate for the member**.**

AND

5. The Member has not received Radium-223 in prior 6 months.

AND

6. The Member has not received prior PSMA-targeted radioligand therapy.

AND

7. Pluvicto is being prescribed by an oncologist specializing in urology disorders.

AND

8. The medication will be administered at a Pluvicto Qualified Treatment Center.

Limitations

- Pluvicto will only be authorized for an FDA-approved indication. All other uses are considered experimental or investigational.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie

References:

1. Pluvicto (Lutetium Lu 177 vipivotide tetraxetan) [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; March 2022
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology® Prostate Cancer. (Version 5.2026). January 23, 2026.Accessed July 7, 2026. https://www.nccn.org/guidelines/
3. What's new in Oncology. Lutetium Lu 177 vipivotide tetraxetan in metastatic castration-resistant prostate cancer. UpToDate.com/login [via subscription only]. Published June 1, 2022. Accessed November 7, 2022.
4. Novartis Pluvicto approved by FDA press release 3/23/22. Accessed 11/4/22 @ https://www.novartis.com/news/media-releases/novartis-pluvictotm-approved-fda-first-targeted-radioligand-therapy-treatment-progressive-psma-positive-metastatic-castration-resistant-prostate-cancer.
5. JNM FDA approves Pluvicto/Locametz for Metastic Castration -Resistant Prostate Cancer, May 2022, accessed 11/3/22; FDA Approves Pluvicto/Locametz for Metastatic Castration-Resistant Prostate Cancer | Journal of Nuclear Medicine (snmjournals.org)
6. Morris MJ, Castellano D, Herrmann K, et al. 177Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naïve patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial [published correction appears in Lancet. 2025 Dec 21;404(10471):2542. Doi: 10.1016/S0140-6736(24)02716-8]. Lancet. 2024;404(10459):1227-1239. Doi:10.1016/S0140-6736(24)01653-2
7. Fizazi K, Herrmann K, et. al. Health-related quality of life and pain outcomes with [177Lu]Lu-PSMA-617 plus standard of care versus standard of care in patients with metastatic castration-resistant prostate cancer (VISION): a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2023 Jun;24(6):597-610. doi: 10.1016/S1470-2045(23)00158-4. PMID: 37269841; PMCID: PMC10641914.
8. Jiang Z, Kadeerhan G, Zhang J, Guo W, Guo H, Wang D. Advances in prostate-specific membrane antigen-targeted

theranostics: from radionuclides to near-infrared fluorescence technology. Front Immunol. 2025 Jan 10;15:1533532. doi: 10.3389/fimmu.2024.1533532. PMID: 39867892; PMCID: PMC11757288.

9. Sartor O, de Bono J, Chi KN, Fizazi K, et al. VISION Investigators. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2021 Sep 16;385(12):1091-1103. doi: 10.1056/NEJMoa2107322
10. Zhang AY, et. al. Lutetium 177Lu Vipivotide Tetraxetan Efficacy and Toxicity in Advanced Prostate Cancer. Adv Radiat Oncol. 2025 Oct 10;11(1):101917. doi: 10.1016/j.adro.2025.101917. PMID: 41399484; PMCID: PMC12702008.
11. Bone metastases in advanced prostate cancer: Management. UpToDate.com/login [via subscription only].Published November 4, 2024. Updated June 1, 2026. Accessed July 7, 2026.
12. Saqib M, et. al. FDA expanded approval of Pluvicto (Lutetium-177 vipivotide tetraxetan) in metastatic castration-sensitive prostate cancer. Ann Med Surg (Lond). 2025 Dec 9;88(1):1140-1141. doi: 10.1097/MS9.0000000000004548. PMID: 41496923; PMCID: PMC12768061.
13. Späth MS, Dittmann H, Spallek R, Calderón E, Mück J, Brendlin A, Rausch S, la Fougère C, Trautwein NF. PET-imaging derived prognostic factors for prostate cancer patients with visceral metastases receiving [^{177}Lu]Lu-PSMA radiopharmaceutical therapy (RPT). Eur J Nucl Med Mol Imaging. 2026 May;53(6):3590-3597. doi: 10.1007/s00259-025-07712-2. Epub 2026 Jan 13. PMID: 41528461; PMCID: PMC13121192.
14. Bosbach WA, et. al. Prompt PSA changes as a prognostic marker for response to PSMA-radioligand therapy. Eur J Nucl Med Mol Imaging. 2026 May;53(6):3518-3528. doi: 10.1007/s00259-026-07772-y. Epub 2026 Jan 23. PMID: 41575546.

Approval And Revision History

November 16, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- Originally approved at November 16, 2022 MPAC effective January 1, 2023
- Administrative update: December 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939, and change Unify name to One Care
- November 16, 2023: Reviewed by MPAC, renewed without changes effective January 1, 2024
- August 30, 2024: Reviewed by MPAC, renewed without changes, effective October 1, 2024
- February 19, 2025: Reviewed by MPAC, removed taxane-based chemotherapy requirement. Also added requirements that Member not receive Radium-223, and PSMA-targeted radioligand therapy. Updated references. Effective April 1, 2025.
- August 20, 2025: Reviewed by MPAC for annual review, renewed without changes, effective October 1, 2025. References updated.
- September 17, 2025: Reviewed by the UM Committee, renewed without changes effective October 1, 2025.
- September 18, 2025: Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template
- September 16, 2026: Reviewed by MPAC, renewed without changes effective November 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.