Pluvicto (lutetium Lu 177 vipivotide tetraxetan) 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.

Criteria

1. Criteria for Approval
   Authorization of a single treatment given every six weeks for up to six doses may be granted to patients 18 years of age or older for treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer when ALL of the following criteria are met:
   - The member has metastatic castration-resistant prostate cancer; and
   - The member has been treated with androgen receptor (AR) pathway inhibition (e.g., abiraterone) and taxane-based chemotherapy (e.g., docetaxel); and
   - The member has at least 1 PSMA-positive metastatic lesion and no dominant PSMA-negative lesions on Gallium Ga-68 PSMA-11 OR Pylarify (piflufolastat F18) PSMA PET/CT scan.

2. Dosing and Administration
   - 1,000 MBq/mL (27 mCi/mL) in a single-dose vial for intravenous use. 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity.
   - If a treatment delay due to an adverse reaction persists for > 4 weeks, treatment with Pluvicto must be discontinued.

Medicare Variation

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, no Medicare NCD or LCD was identified for Pluvicto.

Codes

1 PSMA negative lesions are defined as metastatic disease that lacks PSMA uptake including bone with soft tissue components ≥ 1.0 cm, lymph nodes ≥ 2.5 cm in short axis, solid organ metastases ≥ 1.0 cm in size.
Mass General Brigham Health Plan

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<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<td>A9607</td>
<td>Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 mCi</td>
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**Effective**
December 2022: Effective Date.

**References**
