Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 08/08/2024

Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)

HCPCS: A9607

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Must have at least 1 prostate-specific membrane antigen (PSMA)-positive metastatic lesion and no PSMA-negative lesions on ^{68}Ga-PSMA-11 OR F-18 piflufolastat PSMA PET/CT scan. 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
   d. Trial and failure, contraindication, or intolerance to at least 1 androgen-receptor pathway inhibitor
   e. Trial and failure, contraindication, or intolerance to at least 1 taxane-based regimen
   f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 9 months at a time
   c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Pluvicto is a targeted radioligand therapy (RLT) for the treatment of adult patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

- The 2024 National Comprehensive Cancer Network (NCCN) treatment guidelines for prostate cancer state castrate-resistant prostate cancer is defined as prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone of less than 50 ng/dL. Any increase in prostrate specific antigen or the development of or worsening of exisiting bone metastasis while the patient has a testosterone level less than 50 ng/dL would be considered resistant.

- Safety and efficacy were evaluated in the VISION trial, an international, open-label, phase III study of 831 patients with mCRPC exhibiting disease progression after treatment with one or more androgen-receptor pathway inhibitor and one or two taxane regimens. Subjects were randomized to either standard care plus Pluvicto (every 6 weeks for 4-6 cycles) or standard care alone. Patients must have had at least 1 PSMA-positive metastatic lesion and no PSMA-negative lesions as determined using a ^{68}Ga-PSMA-11 PET/CT. PSMA-negative lesions were defined as metastatic disease that lacked PSMA uptake including bone with soft tissue components greater than 1.0 cm, lymph nodes greater than 2.5 cm in short axis, solid organ metastases greater than 1.0 cm in size. Standard care therapies included hormonal treatment (ie, abiraterone and enzalutamide), bisphosphonates, radiation therapy, denosumab or glucocorticoids and excluded chemotherapy, radioisotopes and immunotherapy. Primary endpoints included radiographic progression-free survival (rPFS) and overall survival (OS). At a median follow-up of 20.9 months, rPFS was 8.7 months in the Pluvicto group vs 3.4 months in the control group ($p < 0.001$). Median OS was 15.3 months in the Pluvicto group vs 11.3 months in the control group ($p < 0.001$).

- NCCN guidelines recommend multiple first-line hormonal-ablative therapies for use in prostate cancer. All these therapies are category 1 and none are preferred over the other when making treatment decisions. All of these therapies should be tried to control the spread of prostate cancer and maintain the patient's testosterone level below 50 ng/dL. If patients progress on androgen deprivation therapy, guidelines recommend treatment with docetaxel every 3 weeks for those with mCRCP.

References:

1. Pluvicto [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; October 2022.
2. Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. NEJM. 2021 Sep 16; 385 (12): 1091 - 103.
3. National Comprehensive Cancer Network. Prostate cancer (Version 4.2024). 2024 May 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed on May 30, 2024.

Policy History		
#	Date	Change Description
1.2	Effective Date: 08/08/2024	Annual review of criteria was performed, no changes were made
1.1	Effective Date: 08/10/2023	Annual review of criteria was performed, no changes were made
1.0	Effective Date: 08/04/2022	New Policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*