Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 263.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

I. Policy:
Pluvicto (lutetium Lu 177 vipivotide tetraxetan)

II. Purpose/Objective:
To provide a policy of coverage regarding Pluvicto (lutetium Lu 177 vipivotide tetraxetan).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION: Lutetium Lu 177 (^{177}Lu) vipivotide tetraxetan is a radioligand therapeutic agent. The active moiety of lutetium ^{177}Lu vipivotide tetraxetan is the radionuclide lutetium-177, which is linked to a moiety that binds to prostate-specific membrane antigen (PSMA), a transmembrane protein that is expressed in prostate cancer, including metastatic castration-resistant prostate cancer (mCRPC). Upon binding of lutetium ^{177}Lu vipivotide tetraxetan to PSMA-expressing cells, the beta-minus emission from ^{177}Lu delivers radiation to PSMA-expressing cells, as well as to surrounding cells, and induces DNA damage, which can lead to cell death.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that Pluvicto is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of prior treatment with an androgen-receptor pathway inhibitor and a taxane-based chemotherapy **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently OR member has had bilateral orchiectomy

AUTHORIZATION DURATION: Approval will be for a one-time authorization of 6 visits (15 months) of therapy. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved labeling.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Note:
Examples of androgen-receptor pathway inhibitors include but are not limited to: abiraterone (Zytriga), enzalutamide (Xtandi), apalutamide (Erleada), darolutamide (Nubeqa)

Examples of gonadotropin-releasing hormone (GnRH) analogs include but are not limited to: leuprolide (Lupron Depot, Eligard), goserelin (Zoladex), histrelin (Vantas), triptorelin (Trelstar)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 6/24/22

Revised: 6/6/23 (LOB carve out, Medicaid business segment)

Reviewed: