Geisinger

# POLICIES AND PROCEDURE MANUAL

**Policy: MBP 170.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Lutathera (lutetium Lu 177 dotatate)**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| Commercial | X | Medicaid | X |
| Medicare | X | ACA | X |
| CHIP | X | | |

**I. Policy:**
Lutathera (lutetium Lu 177 dotatate)

**II. Purpose/Objective:**
To provide a policy of coverage regarding Lutathera (lutetium Lu 177 dotatate)

**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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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:**
Lutathera (lutetium Lu 177 dotatate) is a beta- and gamma-emitting radionuclide which binds to somatostatin receptors with highest affinity to subtype 2 receptors (SSRT2). Upon binding to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors, the compound is internalized. The beta emission form Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells.

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

Lutathera (lutetium Lu 177 dotatate) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescribed by a hematologist/oncologist **AND**
- Patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET) (including foregut, midgut, and hindgut tumors) **AND**
- Medical record documentation of presence of somatostatin receptors on all lesions (somatostatin receptor positive disease) **AND**
- Medical record documentation that long-acting somatostatin analogs have been (or will be) discontinued/held at least 4 weeks prior to initiation of treatment with Lutathera

Note**:** Tests for somatostatin receptors can include, but are not limited to:
- Gallium (Ga)-68 DOTATATE PET/CT scan [NETSPOT®]
- Copper (Cu)-64 DOTATATE PET/CT scan [DetectnetTM]
- Somatostatin Receptor Scintigraphy (SRS) with indium 111 (111-In) [OctreoScanTM]

**Note:** Per the package labeling, short-acting somatostatin analogs may be used within 4 weeks of treatment with Lutathera but must be discontinued 24 hours prior to Lutathera treatment. Long-acting somatostatin analogs may be given between 4 and 24 hours after each Lutathera dose provided that it is again discontinued 4-weeks prior to retreatment with Lutathera. After completing Lutathera treatment, long-acting somatostatin analogs may be restarted for 18 months.

**AUTHORIZATION DURATION:** Approval will be for a one-time authorization of **4 visits (7 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.

**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.**

**REFERENCES:**
1. Lutathera [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA Inc; January 2018.

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

**Devised:** 3/20/18

**Revised:** 9/16/22, 9/12/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 8/30/24 (tests added, LOB box, taglines), 12/19/24 (added held)

**Reviewed:** 1/30/19, 11/1/19, 9/30/20, 9/16/21

**MA UM Committee approval:** 12/31/23, 12/31/24, 2/26/25

**DHS PARP approval**: 3/4/25