Drug Therapy Guidelines

Lutathera ® (lutetium Lu 177 dotatate)

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<th>Medical Benefit</th>
<th>Applicable*</th>
<th>Effective: 1/30/20</th>
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<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 12/20</td>
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<td>Pharmacy- Formulary 2</td>
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<td>Pharmacy- Formulary 3/Exclusive</td>
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I. Medication Description

Lutathera (lutetium Lu 177 dotatate) is a radiolabeled somatostatin analog. Lutetium Lu 177 dotatate binds to somatostatin receptors with highest affinity for subtype 2 receptors (SSRT2). Upon binding to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors, the compound is internalized. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Lutathera is available when the following criteria have been met:

- Member is at least 18 years of age AND
- Member is not pregnant or breastfeeding AND
- The medication is prescribed by an oncologist or nuclear medicine specialist AND
- The medication will be used for the treatment of gastroenteropancreatic neuroendocrine tumors (NET), including foregut, midgut, and hindgut neuroendocrine tumors AND
- Member has an inoperable, locally advanced, or metastatic disease AND
- Somatostatin receptor expression of NET has been confirmed by somatostatin receptor-based imaging (e.g. PET/CT scan, somatostatin receptor scintigraphy, etc) AND
- Low or intermediate grade NET (Ki-67 index of 20% or less) has been documented AND
- Member has had a disease progression despite somatostatin analog therapy (octreotide or lanreotide) AND
- The following premedication and concomitant medications will be used in accordance with FDA-approved prescribing information for Lutathera:
  - Somatostatin analogs (long and short acting octreotide agents)
  - Specialized amino acid solution AND
- Provider confirms the following:
  - Member does not have a severe hepatic impairment AND
  - Member does not have a severe renal impairment (creatinine clearance < 30 mL/min by Cockcroft-Gault) or end-stage renal disease AND
• The requested use (including concomitants medications) is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A AND
• The medication will be administered in a facility under the control of physician(s) licensed and authorized to administer radiopharmaceuticals.

IV. Quantity Limitations

Coverage is available for one dose of Lutathera (7.4 GBq [200 mCi]) every 8 weeks for a total of 4 doses per lifetime.

V. Coverage Duration

Coverage is available for total of 8 months and may not be renewed.

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

• Lutathera is available as 370 MBq/mL (10 mCi/mL) of lutetium Lu 177 dotatate for intravenous use supplied in a 30 mL single-dose vial containing 7.4 GBq (200 mCi) ± 10% of lutetium Lu 177 dotatate at the time of injection.
• The solution volume in the vial is adjusted from 20.5 mL to 25 mL to provide a total of 7.4 GBq (200 mCi) of radioactivity.
• A9513 (Lutetium lu 177, dotatate, therapeutic)
  o 1 billable unit = 1mCi
  o 1 package size (1 vial) = 200 billing units (200 mCi)

VIII. Summary of Policy Changes

• 8/15/18: new policy
• 9/11/18: updated billing/coding information
• 1/15/19: updated billing/coding information
• 1/30/20: updated criteria to address hepatic and renal function

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.