Coverage of any drug intervention discussed in the plan prior authorization guideline is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

---

**LUTATHERA (lutetium Lu 177 dotatate)**

**MB1823**

**Covered Service:** Yes

**Prior Authorization Required:** Yes

**Additional Information:** May only be prescribed by, or in consultation with, an oncology specialist with prior authorization through Navitus

**Medicare Policy:** Prior authorization is dependent on the member’s Medicare coverage. Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

**BadgerCare Plus Policy:** Prescription drug benefits are administered by the Wisconsin Medicaid program. Office administered pharmacy benefits are covered by the plan when covered under the Wisconsin Medicaid fee-for-service program and not paid on a fee-for-service basis by the State of Wisconsin Medicaid program.

**Plan Approved Criteria:**

1.0 *Somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumor (GEP-NET):*
   
   1.1 Member is 18 years of age or older; **and**
   
   1.2 Member has unresectable, locally advanced, or metastatic disease; **and**
   
   1.3 Member has had disease progression despite somatostatin analog therapy OR molecularly targeted therapy (e.g. everolimus); **and**
   
   1.4 Documentation is submitted that the tumor is confirmed to be somatostatin receptor-positive.

2.0 *Diagnosis of NCCN category 1, 2a, or 2b (‘recommended’) for off-label uses or FDA indications*

**Comment(s):**

1.0 The plan considers all other indications and conditions from those listed above as experimental and investigational and are not covered.

2.0 Authorizations are for up to a 12 month period.
Coverage of any drug intervention discussed in the plan prior authorization guideline is subject to the limitations and exclusions outlined in the member’s benefit certificate or policy and to applicable state and/or federal laws.

3.0 Maximum approval is 4 doses per lifetime.
4.0 Dose is within the FDA labeled dose.
5.0 Coding specifications*

*Codes and descriptors listed below are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member’s policy of health coverage with the plan. Inclusion of a code in the table below does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

5.1 NDC and HCPCS codes

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>How Supplied</th>
<th>National Drug Code (NDC)</th>
<th>HCPCS code</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUTATHERA</td>
<td>lutetium Lu 177 dotatate</td>
<td>69488-003-01 69488-003-01 69488-003-70</td>
<td>A9513</td>
</tr>
</tbody>
</table>

6.0 NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.

Committee/Source

<table>
<thead>
<tr>
<th>Document Created</th>
<th>Committee/Source</th>
<th>Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Policy Committee/Quality and Care Management Division/Pharmacy Services</td>
<td></td>
<td>June 20, 2018</td>
</tr>
<tr>
<td>Medical Policy Committee/Health Services Division/Pharmacy Services</td>
<td></td>
<td>December 19, 2018</td>
</tr>
<tr>
<td>Medical Policy Committee/Health Services Division/Pharmacy Services</td>
<td></td>
<td>July 17, 2019</td>
</tr>
<tr>
<td>Medical Policy Committee/Health Services Division/Pharmacy Services</td>
<td></td>
<td>December 19, 2018</td>
</tr>
<tr>
<td>Medical Policy Committee/Health Services Division/Pharmacy Services</td>
<td></td>
<td>July 17, 2019</td>
</tr>
</tbody>
</table>

Published: 08/01/2019
Effective: 08/01/2019