LUTATHERA® (lutetium Lu 177 dotatate) Reimbursement Guide

Updated August 2018

AAA PatientCONNECT™
www.aaapatientconnect.com
Phone: 1-844-NETS-AAA (1-844-638-7222)
FAX: 1-844-NETS-FAX (1-844-638-7329)

Please see additional Important Safety Information on page 18. Please see full Prescribing Information included in this brochure.
Advanced Accelerator Applications (AAA), a Novartis Company

AAA is committed to providing you and your facility with information to assist with billing, coding, and reimbursement for LUTATHERA® (lutetium Lu 177 dotatate).

This reimbursement guide has been developed to provide you with information regarding:

• LUTATHERA Protocol
• Billing and Coding
• Completing Claims Forms
• Submitting a Prior Authorization Request
• AAA PatientCONNECT™

Information and support for reimbursement of LUTATHERA is available for both health care providers and patients through the AAA PatientCONNECT™ program.

To speak with a AAA PatientCONNECT™ Patient Navigator, call: 1-844-NETS-AAA (1-844-638-7222)

Disclaimer

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice.

• Laws, regulations, and policies concerning reimbursement are complex and are updated frequently:
  – While AAA has made every effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it.
  – Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by AAA about coverage, levels of reimbursement, payment, or charge.
• Please consult your payer organization(s) for local or actual coverage and reimbursement policies and determination processes.
• Please consult with your counsel or internal reimbursement specialist for any reimbursement or billing questions specific to your institution. Copyright in CPT® codes and descriptions are owned by the 2018 American Medical Association.® CPT® is a registered trademark of the American Medical Association (AMA).
Dosing Regimen

The recommended treatment regimen consists of 4 administrations of 7.4 GBq (200 mCi); the LUTATHERA® (lutetium Lu 177 dotatate) dosing regimen is not weight based. The recommended interval between each administration is 8 weeks, which may be extended up to 16 weeks in the case of a dose modification due to an adverse reaction.

Somatostatin analogs bind to the same receptors as LUTATHERA and may affect the efficacy of LUTATHERA. Patients should avoid using long-acting somatostatin analogs for at least 4 weeks prior to the LUTATHERA administration. Short-acting somatostatin analogs may be given for symptomatic management prior to the LUTATHERA administration but must be withheld for at least 24 hours before each LUTATHERA dose.

Long-acting octreotide 30 mg must be administered between 4 to 24 hours after each LUTATHERA dose. Long-acting octreotide 30 mg must be continued every 4 weeks after completing LUTATHERA until disease progression or for up to 18 months following treatment initiation.

INDICATION

LUTATHERA is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors in adults.

IMPORTANT SAFETY INFORMATION

Radiation Exposure: Treatment with LUTATHERA contributes to a patient’s overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices and patient management procedures.

Please see additional Important Safety Information on page 18. Please see full Prescribing Information included in this brochure.
Administration Procedure

1 **Antiemetic**: To help address treatment-related nausea and vomiting, an antiemetic drug should be given 30 minutes before the amino acid solution infusion.

2 **Concomitant Amino Acid Infusion**: Concomitant infusion of an amino acid solution containing sufficient amounts of Lysine HCl and Arginine HCL is required for renal protection. This intravenous amino acid infusion must be initiated 30 minutes before administering LUTATHERA and must be continued during and for at least 3 hours after the LUTATHERA infusion. The amino acid infusion should not be reduced if the dose of LUTATHERA is reduced.

3 **LUTATHERA**: LUTATHERA must be administered by intravenous infusion over approximately 30 to 40 minutes. LUTATHERA must not be injected as a bolus. Please see LUTATHERA Prescribing Information for LUTATHERA administration instructions.

**IMPORTANT SAFETY INFORMATION**

**Adverse Reactions**

The most common Grade 3-4 adverse reactions observed in LUTATHERA clinical trials were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), elevated AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%).

The following serious adverse reactions have been observed with a median follow-up time of more than 4 years after treatment with LUTATHERA: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

Please see additional Important Safety Information on page 18. Please see full Prescribing Information included in this brochure.
Transitional Pass-Through Status

The Centers for Medicare & Medicaid Services (CMS) has granted LUTATHERA Transitional Pass-Through status effective July 1st, 2018.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>NDC</th>
<th>Description</th>
<th>Status Indicator</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9031</td>
<td>69488-0003-01</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 mCi</td>
<td>G</td>
<td>9067</td>
</tr>
</tbody>
</table>

According to the CMS July 2018 Addendum B, 1 mCi is the lowest billable unit for LUTATHERA with a Medicare reimbursement rate of $251.75 per 1 mCi.

Medicare Example

To bill for a LUTATHERA dose of 200 mCi, 200 billable units must be entered on a submitted medical claim form.

<table>
<thead>
<tr>
<th>Ordered Dose (units)</th>
<th>Reimbursement Rate (per unit)</th>
<th>Medicare Maximum Allowable</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>$251.75</td>
<td>$50,350.00</td>
</tr>
</tbody>
</table>

Unclassified/Miscellaneous HCPCS Codes

Unclassified or miscellaneous HCPCS codes are used to allow suppliers to begin billing immediately for an item as soon as the Food and Drug Administration (FDA) grants marketing approval for a new product, even though no existing national code adequately describes the item being billed. These miscellaneous HCPCS codes can be used during the time when a new code is being considered for a specific product under the HCPCS review process. When listing a miscellaneous HCPCS code, payers may require reporting the drug name, strength, NDC number, dose administered and route of administration. In addition, for claim submissions with a miscellaneous HCPCS code, some payers may request supplemental information such as the prescribing information, published clinical trials, and/or the purchase invoice. Specific payer requirements may vary.
Product Information

LUTATHERA® (lutetium Lu 177 dotatate)
NDC: 69488-0003-01

Healthcare Common Procedure Coding System (HCPCS) Codes

Hospital Outpatient Department: CMS UB-04

<table>
<thead>
<tr>
<th>Product</th>
<th>Insurer</th>
<th>Code</th>
<th>Description</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUTATHERA</td>
<td>Medicare</td>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
<td>C9031</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 mCi</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td>Private*</td>
<td>A9699</td>
<td>Radiopharmaceutical, therapeutic, not otherwise classified</td>
<td>A9699</td>
<td>Radiopharmaceutical, therapeutic, not otherwise classified</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td></td>
<td>J3490</td>
<td>Unclassified Drugs</td>
<td>J3490</td>
<td>Unclassified Drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C9031</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 mCi</td>
</tr>
</tbody>
</table>

Antiemetic Coding depends on Physician’s choice of antiemetic
Amino Acids Coding depends on place of procurement and Physician’s choice of amino acid

Free Standing / Physician Office Sample Claim Form: CMS-1500

<table>
<thead>
<tr>
<th>Product</th>
<th>Insurer</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUTATHERA</td>
<td>Medicare</td>
<td>A9699</td>
<td>Radiopharmaceutical, therapeutic, not otherwise classified</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td>Private*</td>
<td>A9699</td>
<td>Radiopharmaceutical, therapeutic, not otherwise classified</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td></td>
<td>J3490</td>
<td>Unclassified Drugs</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td></td>
<td>C9031</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 mCi</td>
</tr>
</tbody>
</table>

Antiemetic Coding depends on Physician’s choice of antiemetic
Amino Acids Coding depends on place of procurement and Physician’s choice of amino acid

*Some private insurance plans may accept the C-code. You should contact individual plans to confirm acceptable billing HCPCS code.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies periodically and often change without warning. The health care provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

CPT codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT® is a registered trademark of the American Medical Association.³

Health care providers may use the following CPT codes to report medical services provided in a hospital outpatient setting, including LUTATHERA® (lutetium Lu 177 dotatate) administration.³

<table>
<thead>
<tr>
<th>Service</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of LUTATHERA</td>
<td>79101</td>
<td>Radiopharmaceutical therapy, by intravenous administration</td>
</tr>
<tr>
<td>Administration of Amino Acids (1st hour)</td>
<td>96365</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour</td>
</tr>
<tr>
<td>Administration of Amino Acid (2nd and subsequent hours)</td>
<td>96366</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis; additional hour</td>
</tr>
<tr>
<td>Antiemetic</td>
<td></td>
<td>CPT code(s) will depend upon the type of antiemetics utilized and their route of administration</td>
</tr>
</tbody>
</table>

Revenue Codes

The UB-04 claim form requires documentation of revenue codes associated with services provided to patients receiving LUTATHERA. Please confirm with your payers and their guidelines as other revenue codes may also be appropriate when submitting a claim for LUTATHERA.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUTATHERA</td>
<td>0344</td>
<td>Therapeutic Radiopharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>0636</td>
<td>Drugs requiring detailed coding</td>
</tr>
<tr>
<td>Administration of LUTATHERA</td>
<td>0510</td>
<td>Hospital Outpatient Clinic - General</td>
</tr>
<tr>
<td></td>
<td>0260</td>
<td>Hospital Outpatient IV Therapy - General</td>
</tr>
</tbody>
</table>

Note: Revenue codes are not required on CMS-1500 / 837P forms.
ICD-10 Codes

Appropriately coding and classifying your patient’s diagnosis and condition is important to support medical necessity for LUTATHERA and thus LUTATHERA reimbursement.

The table below lists potential ICD-10 patient diagnosis codes which may be considered for LUTATHERA treatment. This is not a complete list of all codes possible. The code most specific to your patient’s disease should be utilized.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C7A.00</td>
<td>Malignant carcinoid tumor of unspecified site</td>
</tr>
<tr>
<td>C7A.010</td>
<td>Malignant carcinoid tumor of the duodenum</td>
</tr>
<tr>
<td>C7A.011</td>
<td>Malignant carcinoid tumor of the jejunum</td>
</tr>
<tr>
<td>C7A.012</td>
<td>Malignant carcinoid tumor of the ileum</td>
</tr>
<tr>
<td>C7A.019</td>
<td>Malignant carcinoid tumor of the small intestine, unspecified portion</td>
</tr>
<tr>
<td>C7A.020</td>
<td>Malignant carcinoid tumor of the appendix</td>
</tr>
<tr>
<td>C7A.021</td>
<td>Malignant carcinoid tumor of the cecum</td>
</tr>
<tr>
<td>C7A.022</td>
<td>Malignant carcinoid tumor of the ascending colon</td>
</tr>
<tr>
<td>C7A.023</td>
<td>Malignant carcinoid tumor of the transverse colon</td>
</tr>
<tr>
<td>C7A.024</td>
<td>Malignant carcinoid tumor of the descending colon</td>
</tr>
<tr>
<td>C7A.025</td>
<td>Malignant carcinoid tumor of the sigmoid colon</td>
</tr>
<tr>
<td>C7A.026</td>
<td>Malignant carcinoid tumor of the rectum</td>
</tr>
<tr>
<td>C7A.029</td>
<td>Malignant carcinoid tumor of the large intestine, unspecified portion</td>
</tr>
<tr>
<td>C7A.092</td>
<td>Malignant carcinoid tumor of the stomach</td>
</tr>
<tr>
<td>C7A.094</td>
<td>Malignant carcinoid tumor of the foregut NOS</td>
</tr>
<tr>
<td>C7A.095</td>
<td>Malignant carcinoid tumor of the midgut NOS</td>
</tr>
<tr>
<td>C7A.096</td>
<td>Malignant carcinoid tumor of the hindgut NOS</td>
</tr>
<tr>
<td>C7A.098</td>
<td>Malignant carcinoid tumors of other sites</td>
</tr>
<tr>
<td>C7A.1</td>
<td>Malignant poorly differentiated neuroendocrine tumors</td>
</tr>
<tr>
<td>C7A.8</td>
<td>Other malignant neuroendocrine tumors</td>
</tr>
<tr>
<td>C7B.00</td>
<td>Secondary carcinoid tumors, unspecified site</td>
</tr>
<tr>
<td>C7B.01</td>
<td>Secondary carcinoid tumors of distant lymph nodes</td>
</tr>
<tr>
<td>C7B.02</td>
<td>Secondary carcinoid tumors of liver</td>
</tr>
<tr>
<td>C7B.04</td>
<td>Secondary carcinoid tumors of peritoneum</td>
</tr>
<tr>
<td>C25.0</td>
<td>Malignant neoplasm of head of pancreas</td>
</tr>
<tr>
<td>C25.1</td>
<td>Malignant neoplasm of body of pancreas</td>
</tr>
<tr>
<td>C25.2</td>
<td>Malignant neoplasm of tail of pancreas</td>
</tr>
<tr>
<td>C25.4</td>
<td>Malignant neoplasm of endocrine pancreas</td>
</tr>
<tr>
<td>C25.7</td>
<td>Malignant neoplasm of other parts of pancreas</td>
</tr>
<tr>
<td>C25.8</td>
<td>Malignant neoplasm of overlapping sites of pancreas</td>
</tr>
<tr>
<td>C25.9</td>
<td>Malignant neoplasm of pancreas, unspecified</td>
</tr>
</tbody>
</table>
Other Coding Considerations

When coding and billing for LUTATHERA® (lutetium Lu 177 dotatate) and drug administration services, providers may also need to report concomitant services or supplies, discarded drug amounts, or modifications to a service. This section reviews some of those additional considerations.

Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They provide additional information about a service or procedure and help to eliminate the appearance of duplicate billing or unbundling. This could include using modifiers to designate a specific site of service, or to document an interrupted procedure, wasted product, same-day procedure, etc.

Used appropriately, modifiers improve coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to the provision of LUTATHERA in hospital outpatient and free standing facilities.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Description and Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Significant, separately identifiable evaluation and management service by the same physician or other qualified health care professional on the same day of the procedure or other service</td>
<td>• Patient requires distinct evaluation and management (E/M) service in addition to the infusion procedure • Must be substantiated with relevant documentation • Append the modifier to the relevant E/M code</td>
</tr>
<tr>
<td>JW</td>
<td>Drug amount discarded/not administered to any patient</td>
<td>• Unused drug remains after applicable dose is administered from single-use vial • CMS has issued a discarded drug policy; local maximum allowable cost (MAC)/other payer requirements may vary • Append the modifier to the drug code on a line separate from that reporting the administered dose</td>
</tr>
<tr>
<td>PO</td>
<td>Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments [not applicable to CMS-1500 submission]</td>
<td>• Outpatient hospital items and services furnished in an off-campus provider-based department of a hospital* • CMS has issued a policy for off-campus outpatient hospital departments; other payer requirements may vary • Append the modifier to the relevant HCPCS/CPT code(s)</td>
</tr>
<tr>
<td>JG</td>
<td>Drug or biological acquired with 340B drug pricing program discount</td>
<td>Must meet ALL of the following criteria: • The drug is acquired by institutions subject to 340B payment adjustment: DSH Hospital, Medicare Dependent Hospital, Rural Referral Center, and Non-Rural Sole Community Hospital • The drug is a separately payable OPPS drug (assigned status indicator “K”) that meets the definition of “covered outpatient drug” as defined in the section 1927(k) of the Act • The drug is a vaccine (assigned status indicator “F”, “L” or “M”) and is not a drug on pass-through payment status (assigned status indicator “G”)</td>
</tr>
<tr>
<td>TB</td>
<td>Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes</td>
<td>Must meet either of the following criteria: • The drug is acquired by institutions exempted from 340B payment adjustment: Children’s Hospital, PPS-Exempt Cancer Hospital, and Rural Sole Community Hospital • The drug is vaccines (assigned status indicator “F”, “L” or “M”) and is not drugs on pass-through payment status (assigned status indicator “G”)</td>
</tr>
</tbody>
</table>

*The PO modifier should not be reported for remote locations of a hospital satellite, facilities of a hospital, or for services furnished in an emergency department*
Same-Day Evaluation and Management Services\textsuperscript{7,8}

It may be necessary to provide evaluation and management (E/M) services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate, and distinct from the infusion procedure and documented appropriately may be covered.

**Policy states:** For services furnished on or after January 1, 2004, do not allow payment for CPT code 99211, with or without modifier 25, if it is billed with a nonchemotherapy drug infusion code.

Partial Additional Hours of Infusion Time\textsuperscript{7}

CMS has a policy for reporting add-on infusion codes when less than a full hour of service is provided. CPT code 96366 is to be used for “infusion intervals of greater than 60 minutes beyond 1-hour increments.” If the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Document infusion start and stop times in the medical record. Some payers may require reporting the actual number of minutes on claims. The time associated with interruptions in the infusion process (i.e., when drug is not flowing, IV saline to keep a line open with no drug flowing) does not count toward billable infusion time.

Billing for 340B-Acquired Drugs\textsuperscript{9}

As finalized in the CY 2018 OPPS/ASC final rule with comment period, separately payable Part B drugs (assigned SI “K”), other than vaccines (assigned SI “L” or “M”) and drugs on pass-through payment status (assigned SI “G”) that are acquired through the 340B Program or through the 340B prime vendor program, will be paid at the Average Sales Price (ASP) minus 22.5 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment.

Hospital types that are excepted from the 340B payment policy in CY 2018 include rural Sole Community Hospitals (SCHs), children’s hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals. These excepted hospitals will continue to receive ASP + 6 percent payment for separately payable drugs.

Medicare will continue to pay separately payable drugs that were not acquired under the 340B Program at ASP + 6 percent.

In addition, effective January 1, 2018, hospitals paid under the OPPS that are not excepted from the 340B payment policy for CY 2018 are required to report modifier “JG” on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. Since rural SCHs, children’s hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment in CY 2018, these hospitals will report informational modifier “TB” for 340B-acquired drugs, and will continue to be paid at the ASP + 6 percent.

Please see Important Safety Information on page 18.
Please see full Prescribing Information included in this brochure.
Hospital Outpatient Department Sample Claim Form: CMS UB-04

A  Patient Specific Information
Include all relevant patient specific information such as name, address, insurance information, etc.

B  LUTATHERA Information
Where applicable, use the Transitional Pass-Through Code (C9031). Check with your local payer before submitting the claim.

Note: When using C9031, you must use 200 units. Otherwise, you must use 1 unit and include the product NDC in Box 80 on Form UB-04. Please refer to comment G.

For appropriate Revenue Code options, refer to page 8 in this guide and check with your local payer for contracting guidance.

C  Amino Acid Information
The health care provider may choose either a compounded Amino Acid or commercially compliant amino acids solution.

- 96365: Intravenous infusion for therapy, prophylaxis, or diagnosis, initial, up to 1 hour
- 96366: Therapeutic, prophylactic or diagnostic infusion; all subsequent hours

Note: The number of units for CPT codes 96365 and 96366 should match the total time, in hours, for the amino acid infusion.

D  Antiemetics Information
The health care provider can choose antiemetics and mode of administration according to the patient’s case.

The following administration codes may be utilize depending on mode of administration:

- 96365: Intravenous infusion for therapy, prophylaxis, or diagnosis, initial, up to 1 hour
- 96372: Therapeutic, prophylactic or diagnostic injection (specify the antimetic drug); SUBQ or IM

E  ICD-10 Codes
Refer to the ICD-10 codes included on page 7 of this reimbursement guide.

F  Procedure Codes
Enter principal ICD-10-PCS procedure code.

G  Remarks and Notes
When using miscellaneous code, must include LUTATHERA NDC (69488-0003-01) along with other payer-specific NOC billing requirements.
For example: LUTATHERA (lutetium Lu 177 dotatate (69488-0003-01 200 mCi IV.
### LUTATHERA Reimbursement Guide

#### Sample UB-04 Claim Form

**A**

<table>
<thead>
<tr>
<th>ADMISSION CODES</th>
<th>DATE OF OCCURRENCE</th>
<th>OCCURRENCE DATE</th>
<th>CODE</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**B**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**C**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**D**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**E**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**F**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**G**

<table>
<thead>
<tr>
<th>CODE</th>
<th>VALUE CODES</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**UB-04 CMS-1450 APPROVED OMB NO. 0938-0997**

**Certifications on the reverse apply to this bill and are made a part thereof.**

**Lutetium Lu 177, dotatate, therapeutic, 1 mCi**

**Hospital Outpatient Clinic - General**

**Jane Doe**

**125 Main Street**

**04/14/1948**

**F**

**5693**

Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify Amino Acid Solution); initial, up to 1 hour

**5691**

Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify Amino Acid Solution); additional hour

**varies**

(Antiemetics - Physician’s choice) administration code(s) may be required

---

**CREATION DATE**

**TOTALS**

---

**Advanced Accelerator Applications**

**LUTATHERA**

Nutation Lu 177 dotatate

Rejection, for testosterone use
Free Standing / Physician Office Sample Claim Form: CMS-1500

A Patient Specific Information
Include all relevant patient specific information such as name, address, insurance information, etc.

B Physician Information
Include all relevant physician information such as name, address, NPI, etc.

C Remarks and Notes
When not using the Pass-Through Code (C9031), LUTATHERA NDC (69488-0003-01) must be included along with any other payer-specific NOC billing requirements, since a miscellaneous code is being reported.

D ICD-10 Codes
Refer to the ICD-10 codes included on page 7 of this reimbursement guide.

E LUTATHERA Information
Where applicable, use the Pass-Through Code (C9031). Check with your local payer before submitting the claim.

Note: When using C9031, you must use 200 units. Otherwise, you must use 1 unit and include the product NDC in Box 80 on Form UB-04. Please refer to comment C.

— Diagnosis Pointer (24E): Specify the diagnosis from Box 21, that relates to the product or product listed in 24D

F Amino Acid Information
The health care provider may choose either a compounded Amino Acid or commercially compliant amino acid solutions.

— 96365: Intravenous infusion for therapy, prophylaxis, or diagnosis, initial, up to 1 hour
— 96366: Therapeutic, prophylactic or diagnostic infusion; all subsequent hours
  Note: The number of units for CPT codes 96365 and 96366 should match the total time, in hours, for the amino acid infusion
— Diagnosis Pointer (24E): Specify the diagnosis from Box 21, that relates to the product or product listed in 24D

G Antiemetics Information
The health care provider may choose antiemetics and mode of administration according to the patient’s case. The following administration codes may be utilized depending on mode of administration:

— 96365: Intravenous infusion for therapy, prophylaxis, or diagnosis, initial, up to 1 hour
— 96372: Therapeutic, prophylactic or diagnostic injection (specify the antiemetic drug); SUBQ or IM
— Diagnosis Pointer (24E): Specify the diagnosis from Box 21, that relates to the product or product listed in 24D
**Sample CMS-1500 Sample Claim Form**

**HEALTH INSURANCE CLAIM FORM**

**APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 07/12**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Inpatient</td>
<td>Type</td>
<td>Inpatient</td>
</tr>
<tr>
<td>Name of Beneficiary</td>
<td>Doe, Jane B.</td>
<td>Name of Beneficiary</td>
<td>Doe, Jane B.</td>
</tr>
<tr>
<td>Address</td>
<td>125 Main Street</td>
<td>City</td>
<td>Some Town</td>
</tr>
<tr>
<td>State</td>
<td>OH</td>
<td>Zip Code</td>
<td>12345</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>1945-04-14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amino Acid Varies</td>
<td>[see note F on opposite page]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider Name</td>
<td>Lutathera (lutetium lu 177 dotatate) 69488-0003-01 200 mCi IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider NPI</td>
<td>123-456-7890</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Name</td>
<td>Dr. Jones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Address</td>
<td>555 Any Street, Anytown, AS 12345</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Phone</td>
<td>123-456-7890</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**D I R E C T I O N S**

1. **READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.**
2. **A. MEDICARE/ MEDICAID**
3. **B. PATIENT’S NAME (Last Name, First Name, Middle Initial)**
4. **C. PATIENT’S DATE OF BIRTH (MM/DD/YY)**
5. **D. INCLUDED SERVICES/ SUPPLIES**
6. **E. MEDICATION IDENTIFIER**
7. **F. CODES**
8. **G. SERVICE FACILITY LOCATION INFORMATION**
9. **H. BILLING PROVIDER INFO & PH#**

**NUCC Instruction Manual available at: www.nucc.org**

**APPROVED OMB-0938-1197 FORM 1500 (02-12)**
Prior Authorization

It is important to review a payer’s guidelines when obtaining a prior authorization, as these may differ depending upon the payer, the medication being prescribed, and other factors. The following may be necessary to obtain a prior authorization:

- Completed prior authorization request form (if required by the payer)
  - Some payers may require specific forms to be completed for certain medications or therapeutic areas — always verify that the correct form is completed.

- Letter of medical necessity
  - Be sure to note the proposed treatment plan and include the Provider ID number in the letter.

- Documentation that supports the treatment decision, such as:
  - Previously given treatments/therapies
  - Patient clinical notes detailing the relevant diagnosis
  - Relevant laboratory results
  - Product Prescribing Information/FDA product labeling

- Additional relevant documentation (if available) regarding the treatment decision
  - If applicable, compendia listing the product. For instance, inclusion of the product in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

It may be necessary to provide the following information when requesting a prior authorization:

- Patient information including: name, insurance policy number, and date of birth
- Physician information including: name and tax ID number
- Facility information including: name and tax ID number
- Setting of care
- Date of service
- Patient diagnosis and relevant ICD-10 code(s)
- Patient clinical notes detailing the relevant diagnosis
- Relevant CPT and HCPCS codes for services/products to be performed or provided
LUTATHERA Treatment Checklist:

Payers may require the inclusion of the following information in the patient’s records or charts:

Prior to LUTATHERA treatment*

- Specific diagnosis for the disease
- Histology to support diagnosis
- Relevant prior imaging for tumor localization
- Extent of the disease
- All relevant laboratory tests
- Dose order in the treatment cycle (ex. 1st, 2nd, 3rd, or 4th dose)
- Informed consent from the patient after a detailed discussion that includes both oral and written instructions, review of reasons for treatment, risk of treatment, necessary precautions to be taken, and radiation safety procedures

*Some of these items may be required during the prior authorization process

During LUTATHERA treatment

- Pre-medication of the patient with antiemetic
  - If IV formulation is used, start and stop times of antiemetic administration
- Start time of amino acid infusion and the individual who administered the solution
- The start time for LUTATHERA administration and the individual who administered the solution

After LUTATHERA treatment

- The completion time and total duration of amino acid infusion
- LUTATHERA dose administered and the route of administration
- Documentation of administration or referral for long-acting octreotide treatment
- Discharge instructions for the patient

Please see Important Safety Information on page 18.
Please see full Prescribing Information included in this brochure.
Claim Submission

AAA PatientCONNECT™ can research payer-specific coding requirements in performing patient insurance benefit verification for LUTATHERA patient financial assistance.

Providers should confirm the appropriate coverage, coding, and reimbursement with the applicable payer or claims processor before submitting claims for an item or service. Providers must ensure that all claims submitted to payers are accurate, complete, and adequately supported by documentation in the medical record.

Payers differ on guidelines and criteria required for billing an office visit on the same day as hospital outpatient services. It is important to verify appropriate coding with a patient’s health insurance plan before submitting the claim form for reimbursement. Additional information required by the payer may include, but not limited to:

- LUTATHERA Prescribing Information
- FDA approval letter for LUTATHERA
- Patient medical history/medical notes
- Letter of medical necessity
- Invoice for LUTATHERA
- Payer specific NOC billing requirements
- National Drug Code (NDC) for LUTATHERA (Medicaid and/or commercial payers)
AAA PatientCONNECT™

AAA PatientCONNECT™ provides services that may support your patient’s access to LUTATHERA® (lutetium Lu 177 dotatate) treatment.

This includes:

- Reimbursement Support Services
- Insurance Benefits Verification
- Prior Authorization Eligibility Check
- Claims Appeal Support
- Billing and Coding Support
- Payer Policy Support

Patient Financial Assistance

- Uninsured Patient Assistance and Commercial Insured Patient Copay Assistance**

Enrolling and Accessing Financial Assistance for your Patient

Enrolling your patient in AAA PatientCONNECT™ is a simple 3 step process:

**Step 1: Access the Enrollment Form**

Enrollment forms for AAA PatientCONNECT™ may be accessed online at www.aaapatientconnect.com, by calling 1-844-NETS-AAA (1-844-638-7222) Monday-Friday from 8AM-8PM, or by speaking with your local AAA representative.

**Step 2: Complete the Enrollment Form**

Complete all required sections of the enrollment forms (online or hard-copy).

**Step 3: Sign and Send the Enrollment Form**

Both you and your patient must sign the enrollment form prior to submitting it to AAA PatientCONNECT™ by fax at 1-844-NETS-FAX (1-844-638-7329). Electronic signature capture is possible for both you and your patients.

For questions, please contact AAA PatientCONNECT™ at 1-844-NETS-AAA (1-844-638-7222)

**Some restrictions apply. For full terms and conditions, please call AAA PatientCONNECT™ at 844-NETS-AAA. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., copay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, or restricted. Patients enrolled in the AAA PatientCONNECT™ Patient Assistance Program are not eligible for Copay Assistance.**
References:


11. CMS Addendum B effective July 2018.

**Important Safety Information**

**INDICATION**

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults.

**WARNINGS AND PRECAUTIONS**

- **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient’s overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices and patient management procedures.

- **Myelosuppression:** In LUTATHERA clinical trials, hematological adverse reactions occurred at the following rates (all grades/grade 3 or 4): anemia (81%/0), thrombocytopenia (53%/1%), and neutropenia (26%/3%). Blood cell counts must be monitored prior to, during, and after treatment. Dose modification or cessation of treatment may be necessary.

- **Secondary Myelodysplastic Syndrome and Leukemia:** With a median follow-up time of 24 months, myelodysplastic syndrome (MDS) was reported in 2.7% of patients receiving LUTATHERA with long-acting octreotide. In a Phase I/II clinical study, 15 patients (1.8%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to the development of MDS was 28 months (9 to 41 months) for MDS and 55 months (32 to 155 months) for acute leukemia.

- **Renal Toxicity:** Treatment with LUTATHERA will expose kidneys to radiation, which may impair renal function. In a Phase I/II clinical trial <1% of patients developed renal failure 3 to 36 months following LUTATHERA. Monitor serum creatinine and creatinine clearance to assess changes in renal function. Advise patients to urinate frequently during and after administration of LUTATHERA. A concomitant intravenous infusion of amino acids during LUTATHERA administration is mandatory for renal protection. Patients with baseline renal impairment may be at greater risk of toxicity. Perform more frequent assessments of renal function in patients with mild or moderate impairment. Withhold, reduce dose, or permanently discontinue based on severity of reaction.

- **Hepatotoxicity:** In LUTATHERA clinical trials, <1% of patients were reported to have hepatic tumor hemorrhage, edema, or necrosis, with one patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, and serum albumin during treatment. Withhold, reduce dose, or permanently discontinue based on severity of reaction.

- **Neuroendocrine hormonal crisis:** Manifesting with flushing, diarrhea, bronchospasm and hypotension, neuroendocrine hormonal crisis occurred in 1% of patients and typically occurred during or within 24 hours following the initial LUTATHERA dose. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogs, fluids, corticosteroids, and electrolytes as indicated.

- **Embryo-Fetal Toxicity:** LUTATHERA can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment and after. Verify pregnancy status of females of reproductive potential prior to initiating LUTATHERA.

- **Risk of Infertility:** Radiation absorbed by testis and ovaries from the recommended cumulative LUTATHERA dose falls within the range in which temporary or permanent infertility can be expected following external beam radiotherapy.
Important Safety Information cont.¹

ADVERSE REACTIONS
The most common Grade 3-4 adverse reactions observed in LUTATHERA clinical trials were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), elevated AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%).

The following serious adverse reactions have been observed with a median follow-up time of more than 4 years after treatment with LUTATHERA: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

DRUG INTERACTIONS
Somatostatin and its analogs competitively bind to somatostatin receptors and may interfere with the efficacy of LUTATHERA. Discontinue long-acting somatostatin analogs at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose. Administer short- and long-acting octreotide during LUTATHERA treatment as recommended.

Please see full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Advanced Accelerator Applications USA, Inc. at 1-844-863-1930, or us-pharmacovigilance@adacap.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Distributed by: Advanced Accelerator Applications USA, Inc., NJ 07041