LUTATHERA® (lutetium Lu 177 dotatate) Reimbursement Guide

Updated January 2019

*Image is not representative of an actual LUTATHERA vial

Please see Important Safety Information on page 16.
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 about billing, coding, and reimbursement for LUTATHERA® (lutetium Lu 177 dotatate).

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

- LUTATHERA Protocol
- Billing and Coding
- Claims Forms
- Prior Authorization
- Financial Assistance for Eligible Patients*

Information on access to 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.

- Consult the payer organization(s) for coverage and reimbursement policies and determination processes.

- Consult with your internal reimbursement specialist for any reimbursement or billing questions specific to your institution.

- IT IS THE PROVIDER’S RESPONSIBILITY TO DETERMINE AND SUBMIT ACCURATE INFORMATION ON CLAIMS AND COMPLY WITH PAYER COVERAGE, REIMBURSEMENT, AND CLAIM SUBMISSION RULES.

- THE EXISTENCE OF BILLING CODES DOES NOT GUARANTEE COVERAGE AND PAYMENT.

*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 program are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay 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. Patients enrolled in the AAA PatientCONNECT™ Patient Assistance Program are not eligible for Co-pay Assistance.

**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).

Please see Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
Dosing Regimen

The recommended treatment regimen consists of 4 administrations of 7.4 GBq (200 mCi) IV infusion; 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 compete with the same receptors as LUTATHERA and may affect the binding 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 Intermuscular Injection (IM) must be administered between 4 to 24 hours after each LUTATHERA dose. Long-acting octreotide 30 mg IM must be continued every 4 weeks after completing LUTATHERA until disease progression or for up to 18 months following treatment initiation.

INDICATION
LUTATHERA is a radiolabeled somatostatin analog 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 beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
Administration Procedure\textsuperscript{1}

1 **Antiemetics:**
   To help address treatment-related nausea and vomiting, antiemetic drugs 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.

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\textsuperscript{1}

**Myelosuppression:** In LUTATHERA\textsuperscript{®} 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\textsuperscript{®} with long-acting octreotide compared to no patients receiving high-dose 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.

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
### Healthcare Common Procedure Coding System (HCPCS) Codes

The Centers for Medicare & Medicaid Services (CMS) has issued LUTATHERA a Healthcare Common Procedure Coding System (HCPCS) code for LUTATHERA effective January 1, 2019.¹⁶

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>NDC</th>
<th>Descriptor</th>
<th>Status Indicator</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9513</td>
<td>69488-0003-01</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 millicurie</td>
<td>G</td>
<td>9067</td>
</tr>
</tbody>
</table>

- HCPCS code (A9513) descriptor specifies 1 millicurie (1 mCi) as the lowest billable unit.¹⁶ Therefore, the amount of mCi administered should be accurately included on a submitted claim form.

- Transitional Pass-Through Code (C9031), previously issued for LUTATHERA, will be discontinued effective January 1, 2019¹⁶

- Timing of private payers’ adoption of HCPCS code (A9513) may vary. You should contact individual plans to confirm acceptable billing HCPCS code.

#### Between July 1, 2018 and December 31, 2018*
- **Medicare**
  - C9031: Lutetium Lu 177, dotatate, therapeutic, 1 mCi

#### On and After January 1, 2019*
- **Private**
  - A9699: Radiopharmaceutical, therapeutic, not otherwise classified
  - J3490: Unclassified Drugs
  - C9031: Lutetium Lu 177, dotatate, therapeutic, 1 millicurie

- **Antiemetic**
  - Coding depends on Physician’s choice of antiemetic

- **Amino Acids**
  - Coding depends on place of procurement and Physician’s choice of amino acid

*Based on date of service

It is the provider’s responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules.

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Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
**Current Procedural Terminology (CPT) Codes**

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 CPT codes to report medical services related to the pre-medication and the administration of LUTATHERA.³ See accompanying full Prescribing Information for complete information on dosing and administration including, safe handling of radiopharmaceuticals and dose modifications for adverse reactions.

<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) - concomitant infusion</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) - concomitant infusion</td>
<td>96366</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis; additional hour</td>
</tr>
<tr>
<td>Antiemetic - pre-medication to Amino Acid infusion</td>
<td></td>
<td>CPT code(s) will depend upon the type of antiemetics utilized and their route of administration</td>
</tr>
</tbody>
</table>

*See full prescribing information - included in this brochure - for additional information related to the administration of LUTATHERA

**Revenue Codes**

CMS 1400 (UB 04) claim form requires documentation of revenue codes associated with services provided to patients. Confirm the appropriate revenue code(s) with the payer. Note that Revenue codes are not required on CMS-1500 / 837P claim forms.¹⁷,¹⁸

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.

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
ICD-10 Codes

Accurate coding and classification of your patient’s diagnosis and treatment is essential and is the responsibility of the provider.

The table below lists potential ICD-10 patient diagnosis codes which may be considered for LUTATHERA treatment. It is the provider’s responsibility to identify the appropriate diagnosis code that is consistent with FDA approved indication.

<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>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>

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.

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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\(^5,6,12\)

Modifiers may be 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. Please consult applicable CMS manuals to determine whether a modifier may apply.

Consult with your internal reimbursement specialist for any reimbursement or billing questions specific to your institution. The existence of billing and coding information in this guide does not guarantee coverage and payment.

Partial Additional Hours of Infusion Time\(^7\)

Health care providers should consult CMS manual for guidance on reporting add-on infusion codes when less than a full hour of service is provided. Payers may require the documentation of the infusion start and stop times in the medical record or the inclusion of 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) may not count toward billable infusion time.
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 Provided Service(s) Information
LUTATHERA:
• Effective January 1, 2019, CMS has issued LUTATHERA a HCPCS code (A9513).
• A9513 descriptor specifies 1 millicurie (1 mCi) as the lowest billable unit.¹ Therefore, number of mCi’s may be included on a submitted claim form.
• Transitional Pass-Through Code (C9031), previously issued for LUTATHERA, will be discontinued effective January 1, 2019.
• Timing of private payers’ adoption of HCPCS code (A9513) may vary. Consult individual payers to confirm acceptable billing HCPCS code.

Amino Acid (Concomitant Drug):
• HCPCS for the Amino Acid may vary based on the type of the Amino Acid used.
• Consult CMS manual to report the administration of Amino Acid, as the health care provider may need to report 1st hour of administration separately from subsequent hours.

Antiemetics (Pre-medication):
• The health care provider may choose the appropriate antiemetics and mode of administration according to the patient’s case.
• The CPT codes associated with the Antiemetics administration may vary based on mode of administration.

C ICD-10 Codes
Refer to the ICD-10 codes included on page 6 of this reimbursement guide.

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

E Remarks and Notes
Consult the payer if additional information may be required in comments field.

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The existence of billing codes does not guarantee coverage and payment.

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
Sample UB-04 Claim Form

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
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**
Consult the payer if additional information may be required in comments field.

**D ICD-10 Codes**
Refer to the ICD-10 codes included on page 6 of this reimbursement guide.

**E Provided Service(s) Information**

*LUTATHERA:*
- Effective January 1, 2019, CMS has issued LUTATHERA a HCPCS code (A9513).
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- HCPCS for the Amino Acid may vary based on the type of the Amino Acid used.
- Consult CMS manual to report the administration of Amino Acid, as the health care provider may need to report 1st hour of administration separately from subsequent hours.

*Antiemetics (Pre-medications):*
- The health care provider may choose the appropriate antiemetics and mode of administration according to the patient’s case.
- The CPT codes associated with the Antiemetics administration may vary based on mode of administration.

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Sample CMS-1500 Claim Form

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN HSA HMO OTHER
   [Medicare] [Medicaid] [TRICARE] [CHAMPVA] [Group Health Plan] [HSA] [HMO] [Other]

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
   3. PATIENT'S DATE OF Birth MM DD YYYY
   4. INSURED'S NAME (Last Name, First Name, Middle Initial)
   5. PATIENT'S ADDRESS (Inc., Street)
      CITY STATE ZIP CODE
   6. PATIENT'S RELATIONSHIP TO INSURED
      Spouse Child Other

7. INSURED'S ADDRESS (Inc., Street)
   CITY STATE ZIP CODE
   8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)
10. B PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER
12. OTHER INSURED'S POLICY OR GROUP NUMBER
   13. PERSON OR AUTHORIZED PERSON'S SIGNATURE. Authorizes release of any medical or other
       information necessary to process this claim. I also request payment of government benefits other than
       to myself or to the party who accepts assignment below.

14. INSURED'S DATE OF BIRTH
   15. OTHER PATIENT'S CONDITION RELATED TO:

16. OTHER CLAIM B (Designated by NUCC)
17. INSURED'S POLICY GROUP OR FECA NUMBER
   18. OTHER PATIENT'S CONDITION RELATED TO:

19. INSURANCE PLAN NAME OR PROGRAM NAME
   20. B THERE AND OTHER HEALTH BENEFIT PLANS

21. CLAIM CODES (Designated by NUCC)

22. B PATIENT'S CONDITION RELATED TO:

23. NPI

24. MEDICAL SERVICES/PROFESSIONAL SERVICES

25. SIGNATURE OF PHYSICIAN OR SUPPLIER (INCLUDES DEGREES OR CREDENTIALS)

26. PATIENT'S ACCOUNT NO.
27. ACCIDENT IDENTIFICATION NO.

28. TOTAL CHARGE
29. AMOUNT PAID
30. Reimbursement

NUCC Instruction Manual available at: www.nucc.org

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
Prior Authorization

It is important to review a payer’s guidelines when obtaining a prior authorization, as these may differ by 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

It is the provider’s responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules.

The existence of billing codes does not guarantee coverage and payment.
LUTATHERA Treatment Checklist:

Consider documenting the following information, as it may be required by the payer. Consult with the payer for required documentation:

**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 antiemetics
  - ✔ 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 treatment

**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 (see full Prescribing Information for details)
- ✔ Discharge instructions for the patient

Consult the payer organization(s) for coverage and reimbursement policies and determination processes.

Consult with your internal reimbursement specialist for any reimbursement or billing questions specific to your institution.

Please see additional Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
Claim Submission

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:

- Insurance Benefits Verification
- Prior Authorization Eligibility Check
- Financial Assistance for Eligible Patients
Patient Financial Assistance

Uninsured Patient Assistance and Commercial Insured Patient Co-pay 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)

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Important Safety Information

WARNINGS AND PRECAUTIONS

• **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient’s overall long-term 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 compared to no patients receiving high-dose 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 are rare but 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.

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.

Please see full Prescribing Information.

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References:

11. CMS Addendum B effective July 2018.
Please see Important Safety Information beginning on page 16.
Please see accompanying full Prescribing Information in pocket.
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