



LUTATHERA[®] (lutetium Lu 177 dotatate) Reimbursement Guide

Updated January 2019



AAA PatientCONNECT[™]

www.aaapatientconnect.com

Phone: 1-844-NETS-AAA (1-844-638-7222) | FAX: 1-844-NETS-FAX (1-844-638-7329)

*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.³ CPT® is a registered trademark of the American Medical Association (AMA).

Please see Important Safety Information beginning on page 16.

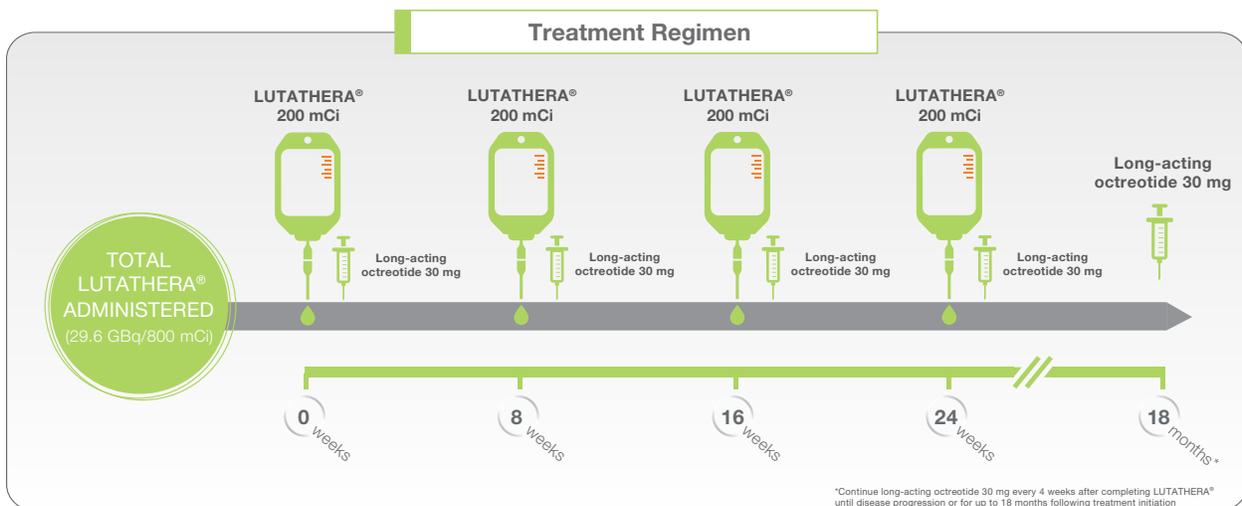
Please see accompanying full Prescribing Information in pocket.

Dosing Regimen¹

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 Intramuscular 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.



INDICATION¹

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 Information¹

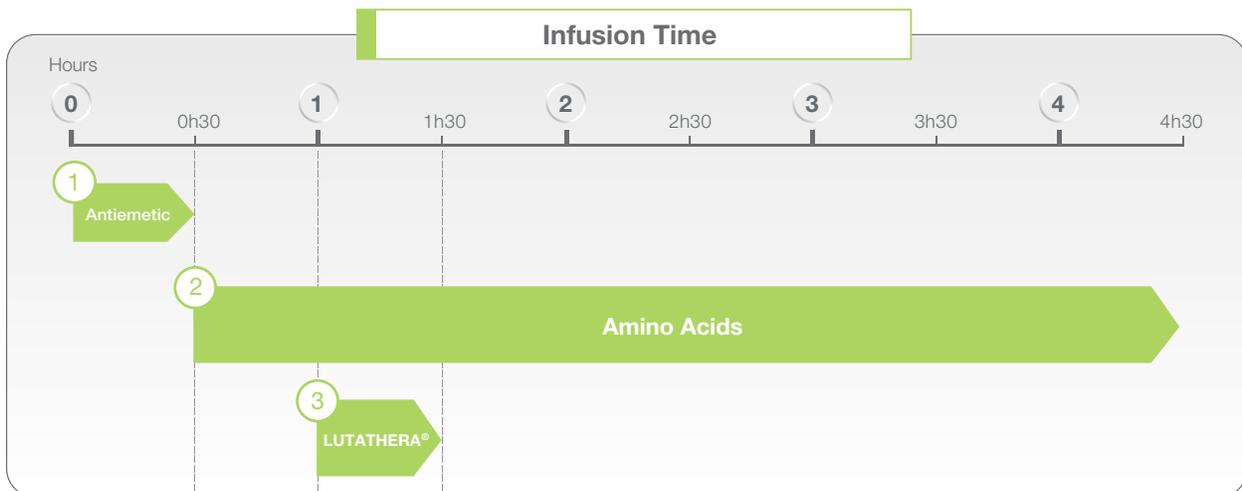
Radiation Exposure: Treatment with LUTATHERA contributes to a patient's overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, 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 Procedure¹

- 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 Information¹

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.

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Product Information¹

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

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

HCPCS Code	NDC	Descriptor	Status Indicator	APC
A9513	69488-0003-01	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	G	9067

- 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.

Product	Insurer	Code	Description	Between July 1, 2018 and December 31, 2018*		On and After January 1, 2019*	
				Code	Description	Code	Description
LUTATHERA	Medicare	C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
	Private	A9699	Radiopharmaceutical, therapeutic, not otherwise classified				
		J3490	Unclassified Drugs				
		C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi				
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.

Please see additional Important Safety Information beginning on page 16.
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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.

Service*	Code	Description
Administration of LUTATHERA	79101	Radiopharmaceutical therapy, by intravenous administration
Administration of Amino Acids (1st hour) - concomitant infusion	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
Administration of Amino Acid (2nd and subsequent hours) - concomitant infusion	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis; additional hour
Antiemetic - pre-medication to Amino Acid infusion	CPT code(s) will depend upon the type of antiemetics utilized and their route of administration	

*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.
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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.⁴ It is the provider's responsibility to identify the appropriate diagnosis code that is consistent with FDA approved indication.

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

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 Time⁷

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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Sample UB-04 Claim Form

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58 INSURED'S NAME													59 P REL													60 INSURED'S UNIQUE ID													61 GROUP NAME													62 INSURANCE GROUP NO.																																																			
63 TREATMENT AUTHORIZATION CODES													64 DOCUMENT CONTROL NUMBER													65 EMPLOYER NAME																																																																													

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Please see additional Important Safety Information beginning on page 16.
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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).
 - A9513 descriptor specifies 1 millicurie (1 mCi) as the lowest billable unit. 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.

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Sample CMS-1500 Claim Form



HEALTH INSURANCE CLAIM FORM

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

PICA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>												
A 1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)												
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE MM DD YY			SEX M <input type="checkbox"/> F <input type="checkbox"/>				
5. PATIENT'S ADDRESS (No., Street)					6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>			7. INSURED'S ADDRESS (No., Street)				
CITY			STATE		8. RESERVED FOR NUCC USE			CITY				
ZIP CODE			TELEPHONE (Include Area Code) ()		9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)			10. IS PATIENT'S CONDITION RELATED TO:				
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO			a. INSURED'S DATE OF BIRTH MM DD YY				
b. RESERVED FOR NUCC USE					b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO			SEX M <input type="checkbox"/> F <input type="checkbox"/>				
c. RESERVED FOR NUCC USE					c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO			b. OTHER CLAIM ID (Designated by NUCC)				
d. INSURANCE PLAN NAME OR PROGRAM NAME					10d. CLAIM CODES (Designated by NUCC)			c. INSURANCE PLAN NAME OR PROGRAM NAME				
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____					13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____					11. INSURED'S POLICY GROUP OR FECA NUMBER		
										d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>		
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY					15. OTHER DATE MM DD YY			16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY				
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE					17a. _____			18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY				
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)					17b. NPI			20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO \$ CHARGES				
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) A. _____ B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____ K. _____					22. RESUBMISSION CODE			ORIGINAL REF. NO.				
23. PRIOR AUTHORIZATION NUMBER												
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY		B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER			E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSPDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
2										NPI		
3										NPI		
4										NPI		
5										NPI		
6										NPI		
25. FEDERAL TAX I.D. NUMBER			SSN EIN <input type="checkbox"/> <input type="checkbox"/>		26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		28. TOTAL CHARGE \$		29. AMOUNT PAID \$	30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED _____ DATE _____					32. SERVICE FACILITY LOCATION INFORMATION a. NPI			33. BILLING PROVIDER INFO & PH # () a. NPI				

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A

B

C

D

E

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.

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)

** 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., 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, or restricted. Patients enrolled in the AAA **PatientCONNECT™** Patient Assistance Program are not eligible for Co-pay Assistance.

Please see additional Important Safety Information beginning on page 16.

Please see accompanying full Prescribing Information in pocket.

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 Information¹

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.

Please see additional Important Safety Information beginning on page 16.

Please see accompanying full Prescribing Information in pocket.

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.

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

References:

1. LUTATHERA® [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; July 2018.
2. Cms.gov. (2018). *2018 Alpha-Numeric HCPCS File - Centers for Medicare & Medicaid Services*. [online] Available at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-Alpha-Numeric-HCPCS-File.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending> [Accessed 24 Oct. 2018].
3. Ama-assn.org. (2018). *CPT® (Current Procedural Terminology) | American Medical Association*. [online] Available at: <https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology> [Accessed 24 Oct. 2018].
4. ICD-10-CM, 2018. (2017). CHICAGO: AMER MEDICAL ASSOCIATION.
5. Cms.gov. (2017). *Medicare Claims Processing Manual Chapter 4 - Part B Hospital*. [online] Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf> [Accessed 24 Oct. 2018].
6. Cms.gov. (2017). *Medicare Claims Processing Manual Chapter 17 - Drugs and Biologicals*. [online] Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf> [Accessed 24 Oct. 2018].
7. Cms.gov. (2018). *Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners*. [online] Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf> [Accessed 24 Oct. 2018].
8. Cms.gov. (2013). *Transmittal 2845*. [online] Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2845CP.pdf> [Accessed 24 Oct. 2018].
9. CMS Medicare Learning Networking (MLN) Matters Number: MM10417 [Accessed 7 Jan. 2018].
10. CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 4075 [Accessed 5 Jun. 2018].
11. CMS Addendum B effective July 2018.
12. Cms.gov. (2018). *Medicare-FFS Program - Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS)*. [online] Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf> [Accessed 1 Aug. 2018].
13. Cms.gov. (2015). *Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radiopharmaceuticals for Transitional Pass-Through Status under the Hospital Outpatient Prospective Payment System (OPPS)*. [online] Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/drugapplication.pdf> [Accessed 24 Oct. 2018].
14. Gpo.gov. (2012). *Centers for Medicare & Medicaid Services, HHS*. [online] Available at: <https://www.gpo.gov/fdsys/pkg/CFR-2012-title42-vol3/pdf/CFR-2012-title42-vol3-sec419-64.pdf> [Accessed 24 Oct. 2018].
15. Cms.gov. (2018). *July 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)*. [online] Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNmattersArticles/downloads/MM10781.pdf> [Accessed 24 Oct. 2018].
16. CMS.gov. (2019). *CMS-1695-FC*. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC.html> [Accessed 8 Nov. 2018].
17. CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 167 [Accessed 1 Dec. 2018].
18. CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 81 [Accessed 1 Dec. 2018].



AAA PatientCONNECT™

www.aaapatientconnect.com

8:00am to 8:00pm EST | Monday-Friday

Phone: 844-NETS-AAA

Fax: 844-NETS-FAX

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