

LUTATHERA[®]
(lutetium Lu 177 dotatate)
injection, for intravenous use

Reimbursement Guide

Updated July 2023



Novartis Patient Support™
www.Novartis-PatientSupport.com/RLT
Phone: 1-844-638-7222 | Fax: 1-844-638-7329

Image is not representative of an actual LUTATHERA vial.

Please see Important Safety Information on pages 17-18 and full [Prescribing Information](#).

Novartis Patient Support

Novartis Patient Support is committed to providing you and your facility with information about coding, billing, and reimbursement for LUTATHERA.

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

- LUTATHERA administration protocol
- Coding and billing
- Claim forms
- Prior authorization
- Financial support for eligible patients*

Information on access to LUTATHERA is available for both health care providers and patients through Novartis Patient Support.

**To speak with our Novartis Patient Support team,
call 1-844-638-7222**

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Enrollment Forms for details.

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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 Novartis Pharmaceuticals Corporation 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 Novartis about coverage, levels of reimbursement, payment, or charge
- Consult the payer organization(s) for local or actual 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

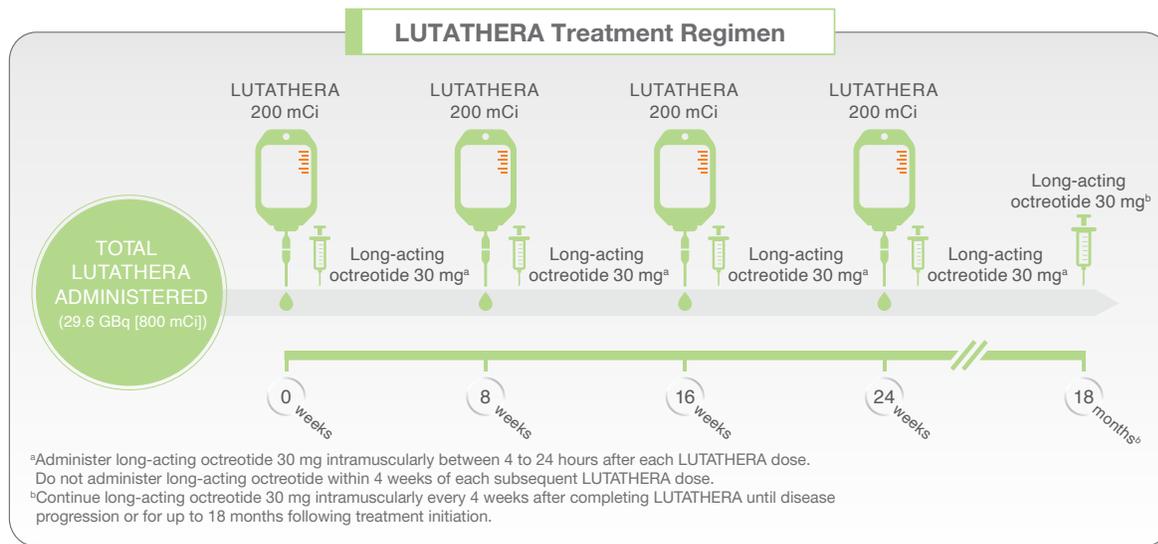
LUTATHERA Regimen and Administration Procedures¹

The 4-dose LUTATHERA regimen may be completed in 24 weeks* from treatment initiation

The recommended LUTATHERA dose is 7.4 GBq (200 mCi) intravenously, every 8 weeks, for a total of 4 doses.

- The LUTATHERA dose should be modified based on hematologic, renal, hepatic, or other adverse reactions (see full Prescribing Information)
 - For dose administration instructions including reduced dose administration instructions, refer to section 2.5 (Preparation and Administration) of the full Prescribing Information
- Discontinue long-acting somatostatin analogs for at least 4 weeks prior to initiating LUTATHERA
- Administer short-acting octreotide as needed for symptom management; discontinue at least 24 hours prior to initiating LUTATHERA

*Withhold, reduce dose, or permanently discontinue based on the severity of adverse reactions. Refer to the recommended dose modifications for adverse reactions in Table 2 of the full Prescribing Information.



Administer premedications and concomitant medications as recommended in the Prescribing 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.

IMPORTANT SAFETY INFORMATION

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, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.

Please see additional Important Safety Information on pages 17-18 and full [Prescribing Information](#).

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Premedications and Concomitant Medications

1 Antiemetics

To help address treatment-related nausea and vomiting, administer antiemetics before the recommended amino acid solution.^{1,2}

2 Concomitant Amino Acid Infusion¹

Concomitant infusion of an amino acid solution containing indicated amounts of L-lysine HCl and L-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.² **Do not decrease the dose of the amino acid solution if the dose of LUTATHERA is reduced.**

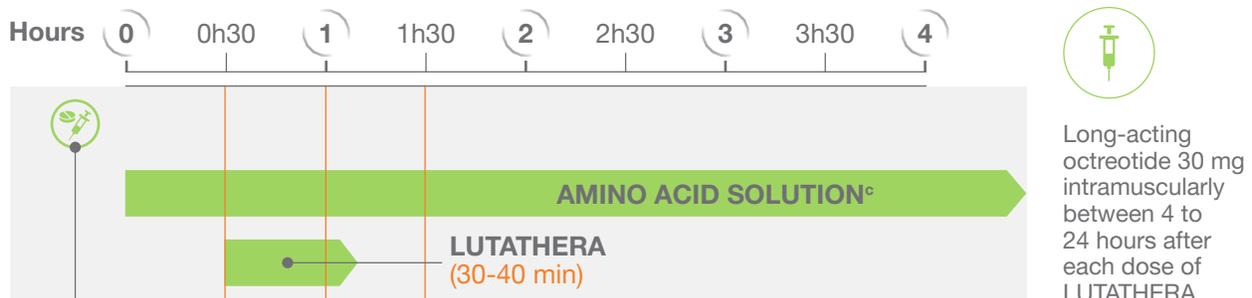
Item	Description
L-lysine HCl content	Between 18 and 25 g ^a
L-arginine HCl content	Between 18 and 25 g ^b
Volume	1 to 2 L
Osmolality	<1050 mOsmol/kg

^aEquivalent to 14.4 to 20 g lysine.

^bEquivalent to 14.9 to 20.7 g arginine.

3 LUTATHERA Infusion Time¹

LUTATHERA is administered by intravenous infusion over approximately 30 to 40 minutes (gravity method). **It is important to read the full Prescribing Information for LUTATHERA for complete information on dosing and administration, including safe handling of radiopharmaceuticals and dose modifications for adverse reactions.**



ANTIEMETIC

Administer antiemetics before amino acid.

^cThis 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.²

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.

Please see additional Important Safety Information on pages 17-18 and full [Prescribing Information](#).

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Product Information¹

LUTATHERA® (lutetium Lu 177 dotatate)
 Dosage Form: Injection
 National Drug Code: 69488-003-01

Reimbursement Components: Coding³

HCPCS Codes

The Centers for Medicare & Medicaid Services (CMS) has issued LUTATHERA an HCPCS code effective January 1, 2019.

HCPCS Code	National Drug Code	Descriptor	Ambulatory Payment Classification
A9513	69488-003-01	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	9067

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

Product	Insurer	Code	Description (On and After January 1, 2019 ^a)
LUTATHERA	Medicare	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 mCi
	Private		
Antiemetic	Coding depends on physician's choice of antiemetic		
Amino acids	Coding depends on place of procurement and physician's choice of amino acids		

^aBased 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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.

Please see additional Important Safety Information on pages 17-18 and full [Prescribing Information](#).

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Reimbursement Components: Coding³

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.⁴

Health care providers may use CPT codes to report medical services related to the premedication and administration of LUTATHERA.⁴ See accompanying full Prescribing Information for complete information on dosing and administration, including safe handling of radiopharmaceuticals and dose modifications for adverse reactions.

Service ^a	Code	Description
Administration of LUTATHERA	79101	Radiopharmaceutical therapy, by intravenous administration
Administration of amino acids (first h): concomitant infusion	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
Administration of amino acids (second h and subsequently): concomitant infusion	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis; additional hour
Antiemetic: premedication to amino acid infusion	CPT code(s) will depend upon the type of antiemetic utilized and the route of administration	

^aPlease see accompanying full [Prescribing Information](#).

Revenue Codes

The CMS-1450 (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.^{5,6}

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.

LUTATHERA ICD-10-CM Codes⁷

Accurate coding and classification of your patient's diagnosis and treatment are essential and are the responsibility of the provider.

The table below lists potential International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) patient diagnosis codes that may be considered for LUTATHERA treatment. It is the provider's responsibility to identify the appropriate diagnosis code that is consistent with the US Food and Drug Administration (FDA)-approved indication for each specific payer.

ICD-10-CM Code	Description
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.1	Malignant poorly differentiated neuroendocrine tumors
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

NOS, not otherwise specified.

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Other Coding Considerations

When coding and billing for LUTATHERA 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.

Modifiers⁸⁻¹¹

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.

Effective January 1, 2023, the JZ and JW modifiers will be applied to all drugs payable under Medicare Part B that are described as a “single-dose” container or “single-use” package. HCPs and suppliers are required to report the JZ modifier when billing for drugs from single-dose containers, such as LUTATHERA, when there are no discarded amounts beginning July 1, 2023. The JW modifier will still be required to report if any amount of the drug is discarded.

Modifier	Description
JZ	Zero drug amount discarded/not administered to any patient
JW	Drug amount discarded/not administered to any patient

Partial Additional Hours of Infusion Time¹²

Health care providers should consult CMS manuals 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 (eg, when drug is not flowing, intravenous saline to keep a line open with no drug flowing) may not count toward billable infusion time.

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.

WARNINGS AND PRECAUTIONS (continued)

- Renal Toxicity:** In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.

Please see additional Important Safety Information on pages 17-18 and full [Prescribing Information](#).

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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 an HCPCS code (A9513)
- The A9513 descriptor specifies millicurie as the lowest billable unit.³ Therefore, the number of millicuries may be included on a submitted claim form

Amino Acid (Concomitant Drug)

- The HCPCS code for the amino acid solution may vary based on the types of amino acids used
- Consult the CMS manual to report the administration of amino acids, as the health care provider may need to report the first hour of administration separately from subsequent hours

Antiemetics (Premedication)

- 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 antiemetic administration may vary based on mode of administration

Modifiers

- Enter the appropriate HCPCS code (A9513) for LUTATHERA use as required by the payer³
- The HCPCS code must be accompanied by the JZ modifier if there is no drug discarded or by the JW modifier if certain units of the drug are discarded
- Include the appropriate CPT code to report the administration procedure (79101)⁴

C

ICD-10-CM Codes

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

D

Procedure Codes

Enter principal ICD-10-Procedure Code System procedure code.

E

Remarks and Notes

Consult the payer if additional information may be required in comments field.

WARNINGS AND PRECAUTIONS (continued)

- **Hepatotoxicity:** In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of hepatotoxicity.

Information in this guide does not represent any statement, promise, or guarantee by Novartis Pharmaceuticals Corporation about coverage, levels of reimbursement, payment, or charge.

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

Sample UB-04 Claim Form

A

1 PATIENT IDENTIFICATION													38 PAT. CNTL #		FILE OF BILL																																																																																								
2													b MED. REC. #		6 STATEMENT COVERS PERIOD		7																																																																																						
8 PATIENT NAME													9 PATIENT ADDRESS		c		d		e																																																																																				
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42 REV. CD.													43 DESCRIPTION													44 HCPCS / RATE / HIPPS CODE													45 SERV. DATE													46 SERV. UNITS													47 TOTAL CHARGES													48 NON-COVERED CHARGES													49												

B

PAGE ____ OF ____													CREATION DATE													TOTALS																																																																
50 PAYER NAME													51 HEALTH PLAN ID													52 REL. INFO													53 AGO. BEN.													54 PRIOR PAYMENTS													55 EST. AMOUNT DUE													56 NPI												
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																																																																

C

D

E

69 ADMIT DX													70 PATIENT REASON DX													71 PPS CODE													72 ECI													73																									
74 PRINCIPAL PROCEDURE CODE													75 OTHER PROCEDURE CODE													76 ATTENDING													77 OPERATING													78 OTHER													79 OTHER												
80 REMARKS													81 CC													LAST													LAST													LAST													LAST												

Please see Important Safety Information on pages 17-18 and full Prescribing Information.



Freestanding/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, National Provider Identifier, etc
- Modifiers**
- Enter the appropriate HCPCS code (A9513) for LUTATHERA use as required by the payer³
 - The HCPCS code must be accompanied by the JZ modifier if there is no drug discarded or by the JW modifier if certain units of the drug are discarded
 - Include the appropriate CPT code to report the administration procedure (79101)⁴
- C Remarks and Notes**
Consult the payer if additional information may be required in comments field.
- D ICD-10-CM Codes**
Refer to the ICD-10-CM codes included on page 7 of this reimbursement guide.
- E Provided Service(s) Information**
- LUTATHERA**
- Effective January 1, 2019, CMS has issued LUTATHERA an HCPCS code (A9513)
 - The A9513 descriptor specifies millicurie as the lowest billable unit.³ Therefore, the number of millicuries may be included on a submitted claim form
- Amino Acid (Concomitant Drug)**
- The HCPCS code for the amino acid solution may vary based on the types of amino acids used
 - Consult the CMS manual to report the administration of amino acids, as the health care provider may need to report the first hour of administration separately from subsequent hours
- Antiemetics (Premedication)**
- 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 antiemetic administration may vary based on mode of administration

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

Sample CMS-1500 Claim Form



HEALTH INSURANCE CLAIM FORM

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

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A <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="3"> 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#) </td> <td colspan="7"> 1a. INSURED'S I.D. NUMBER (For Program in Item 1) </td> </tr> <tr> <td colspan="4"> 2. PATIENT'S NAME (Last Name, First Name, Middle Initial) </td> <td colspan="2"> 3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/> </td> <td colspan="4"> 4. INSURED'S NAME (Last Name, First Name, Middle Initial) </td> </tr> <tr> <td colspan="4"> 5. PATIENT'S ADDRESS (No., Street) CITY _____ STATE _____ </td> <td colspan="2"> 6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/> </td> <td colspan="4"> 7. INSURED'S ADDRESS (No., Street) CITY _____ STATE _____ </td> </tr> <tr> <td colspan="2"> ZIP CODE _____ </td> <td colspan="2"> TELEPHONE (Include Area Code) () _____ </td> <td colspan="2"> 8. RESERVED FOR NUCC USE </td> <td colspan="2"> ZIP CODE _____ </td> <td colspan="2"> TELEPHONE (Include Area Code) () _____ </td> </tr> <tr> <td colspan="4"> 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) </td> <td colspan="2"> 10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> </td> <td colspan="4"> 11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/> b. OTHER CLAIM ID (Designated by NUCC) _____ c. INSURANCE PLAN NAME OR PROGRAM NAME _____ </td> </tr> <tr> <td colspan="2"> a. OTHER INSURED'S POLICY OR GROUP NUMBER _____ </td> <td colspan="2"> b. RESERVED FOR NUCC USE </td> <td colspan="2"> c. RESERVED FOR NUCC USE </td> <td colspan="2"> d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> <i>If yes, complete items 9, 9a, and 9d.</i> </td> <td colspan="2"> 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 _____ </td> </tr> <tr> <td colspan="2"> 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 _____ </td> <td colspan="8"> 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. _____ </td> </tr> <tr> <td colspan="4"> 15. OTHER DATE MM DD YY QUAL. _____ </td> <td colspan="6"> 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY </td> </tr> <tr> <td colspan="4"> 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE </td> <td colspan="2"> 17a. _____ </td> <td colspan="4"> 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY </td> </tr> <tr> <td colspan="4"> 17b. NPI _____ </td> <td colspan="6"> 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) </td> </tr> <tr> <td colspan="4"> 20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____ </td> <td colspan="6"> 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. _____ </td> </tr> <tr> <td colspan="2"> A. _____ </td> <td colspan="2"> B. _____ </td> <td colspan="2"> C. _____ </td> <td colspan="2"> D. _____ </td> <td colspan="2"> 22. RESUBMISSION CODE _____ ORIGINAL REF. NO. _____ </td> </tr> <tr> <td colspan="2"> E. _____ </td> <td colspan="2"> F. _____ </td> <td colspan="2"> G. _____ </td> <td colspan="2"> H. _____ </td> <td colspan="2"> 23. PRIOR AUTHORIZATION NUMBER _____ </td> </tr> <tr> <td colspan="2"> I. _____ </td> <td colspan="2"> J. _____ </td> <td colspan="2"> K. _____ </td> <td colspan="4"> 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. EPSDT Family Plan _____ I. ID. QUAL. _____ J. 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NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Please see Important Safety Information on pages 17-18 and full Prescribing Information.

LUTATHERA[®]
(lutetium Lu 177 dotatate)
injection, for intravenous use

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 identification (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

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-CM 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 (eg, first, second, third, or fourth 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

During LUTATHERA treatment*

- ✓ Premedication of the patient with antiemetics
 - If intravenous 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

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

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 may not be limited to:

- ✓ LUTATHERA Prescribing Information
- ✓ FDA approval letter for LUTATHERA
- ✓ Patient medical history/medical notes
- ✓ Letter of medical necessity
- ✓ Invoice for LUTATHERA
- ✓ National Drug Code for LUTATHERA (Medicaid Fee-For-Service and/or commercial payers)
- ✓ Prior authorization, if needed

Novartis Patient Support

Novartis Patient Support is a comprehensive program that helps your patients start and stay on treatment

Insurance Support

Help with navigating the insurance process

 <p>Benefits Verification</p> <p>Once you've enrolled your patients in Novartis Patient Support, our team will conduct a benefits verification to better understand your patient's coverage.</p>	 <p>Prior Authorization</p> <p>We'll help support your practice through the prior authorization and appeals processes to help you navigate access to LUTATHERA treatment.</p>
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Financial Support

Co-pay savings* are available for patients with private insurance

We help make LUTATHERA treatment more affordable for your eligible patients through co-pay savings.

Co-pay savings start with enrollment

Eligible patients are considered for co-pay savings when they enroll in Novartis Patient Support. Ensure patients have completed and signed the Enrollment Form for Novartis Patient Support to activate assessment eligibility.

To complete and submit an Enrollment Form, visit www.Novartis-PatientSupport.com/RLT or call us at **1-844-638-7222**.

Please see **Important Safety Information** on pages 17-18 and full **Prescribing Information**.

LUTATHERA[®]
(lutetium Lu 177 dotatate)
injection, for intravenous use

Additional financial support may be available for patients without private insurance

To find out if patients are eligible for LUTATHERA treatment through other financial support, call Novartis Patient Support at **1-844-638-7222**, Monday through Friday, from 8:00 AM to 8:00 PM ET.

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Enrollment Forms for details.

Getting Patients Started

3 simple steps for enrollment

- 1 Download the Enrollment Form**
 - Go to www.Novartis-PatientSupport.com/RLT to access and download the Novartis Patient Support Enrollment Form
- 2 Complete form, capture consent, and submit**
 - Fill out all required sections of the Enrollment Form with the patient. Ensure both you and the patient sign the form to capture enrollment consent
 - Submit the completed and signed Enrollment Form via fax to Novartis Patient Support at 1-844-638-7329
 - Please fill out the form completely as missing information may result in treatment delays. Novartis Patient Support will contact you to request any incomplete information
- 3 Connect with us**
 - Our Novartis Patient Support Team will contact you and your patient to confirm enrollment and provide information about program options that match your patient's treatment plan

**Questions? Call Novartis Patient Support at 1-844-638-7222,
Monday through Friday, from 8:00 AM to 8:00 PM ET.**

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.

IMPORTANT SAFETY INFORMATION

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, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.
- **Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.
- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.
- **Renal Toxicity:** In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.
- **Hepatotoxicity:** In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of hepatotoxicity.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, occurred in patients treated with LUTATHERA. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following LUTATHERA administration for a minimum of 2 hours in a setting in which cardiopulmonary resuscitation medication and equipment are available. Discontinue the infusion upon the first observation of any signs or symptoms consistent with a severe hypersensitivity reaction and initiate appropriate therapy. Premedicate patients with a history of grade 1/2 hypersensitivity reactions to LUTATHERA before subsequent doses. Permanently discontinue LUTATHERA in patients who experience grade 3/4 hypersensitivity reactions.
- **Neuroendocrine Hormonal Crisis:** Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm, and hypotension, occurred in <1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial LUTATHERA dose. Two (<1%) patients were reported to have hypercalcemia. 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 when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating LUTATHERA. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LUTATHERA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with LUTATHERA and for 4 months after the last dose.
- **Risk of Infertility:** LUTATHERA may cause infertility in males and females. Radiation absorbed by testes 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.

ADVERSE REACTIONS

The most common grade 3/4 adverse reactions ($\geq 4\%$ with a higher incidence in the LUTATHERA arm) observed in NETTER-1 were lymphopenia (44%), increased gamma-glutamyl transferase (20%), vomiting (7%), nausea (5%), increased aspartate aminotransferase (5%), increased alanine aminotransferase (4%), hyperglycemia (4%), and hypokalemia (4%).

In ERASMUS, the following serious adverse reactions have been observed with a median follow-up time of >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.

Glucocorticoids can induce downregulation of subtype 2 somatostatin receptors. Avoid repeated administration of high doses of glucocorticoids during treatment with LUTATHERA.

SPECIFIC POPULATIONS

Lactation: Because of the potential risk for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with LUTATHERA and for 2.5 months after the last dose.

References

1. Lutathera. Prescribing information. Advanced Accelerator Applications.
2. Hope TA, Abbott A, Colucci K, et al. NANETS/SNMMI procedure standard for somatostatin receptor-based peptide receptor radionuclide therapy with ¹⁷⁷Lu-DOTATATE. *J Nucl Med*. 2019;60(7):937-943. doi:10.2967/jnumed.118.230607
3. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Updated May 24, 2023. Accessed June 15, 2023. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>
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