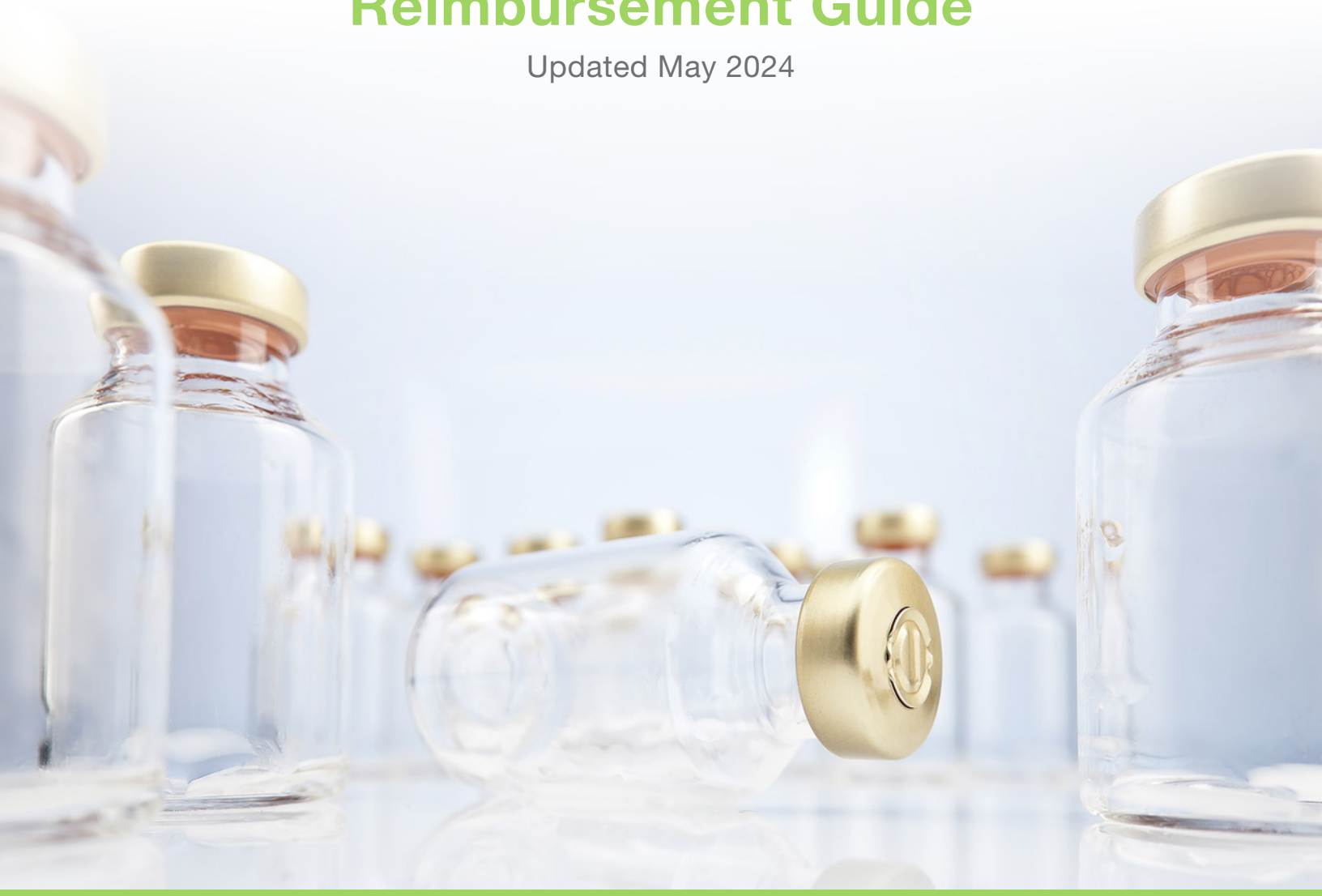
LUTATHERA®
(lutetium Lu 177 dotatate)
injection, for intravenous use

Reimbursement Guide

Updated May 2024



Novartis Patient Support™
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 15-16 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

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

*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 Form for details.

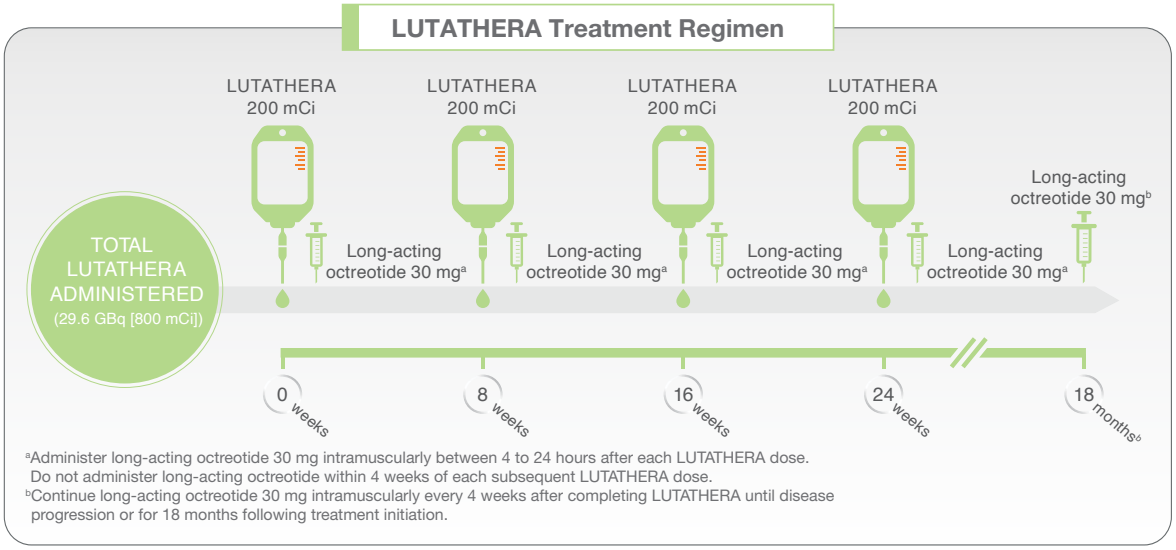
LUTATHERA Regimen and Administration Procedures[1]

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

The recommended LUTATHERA dose for adult and pediatric patients 12 years and older 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.



[a]Administer long-acting octreotide 30 mg intramuscularly between 4 to 24 hours after each LUTATHERA dose. Do not administer long-acting octreotide within 4 weeks of each subsequent LUTATHERA dose.
[b]Continue long-acting octreotide 30 mg intramuscularly every 4 weeks after completing LUTATHERA until disease progression or for 18 months following treatment initiation.

Administer premedications and concomitant medications as recommended in the Prescribing Information

INDICATION

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

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 15-16 and full Prescribing Information.

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

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 Infusion[1]

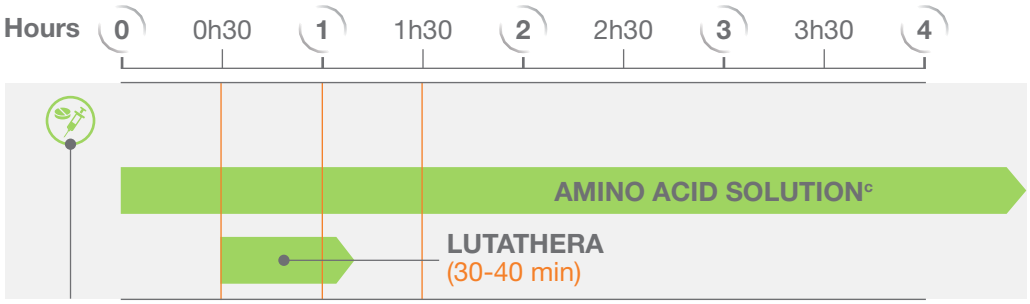
Concomitant infusion of an amino acid solution containing indicated amounts of L-lysine HCl and L-arginine HCl is required for renal protection. This intravenous amino acid infusion must be initiated 30 minutes before administering LUTATHERA and must be continued during and for at least 3 hours after 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	<1200 mOsmol/kg

[a]Equivalent to 14.4 to 20 g L-lysine.
[b]Equivalent to 14.9 to 20.7 L-arginine.

3 LUTATHERA Infusion Time[1]

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.**



Long-acting octreotide 30 mg intramuscularly between 4 to 24 hours after each dose of LUTATHERA

ANTIEMETIC
Administer antiemetics before amino acid.

[c]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]

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 15-16 and full Prescribing Information.

Product Information[1]

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

Reimbursement Components: Coding

HCPCS Code[3]

Code	Description	Dose	Lowest billable unit
A9513	Lutetium Lu 177, dotatate, therapeutic	200 millicuries	**LUTATHERA is billed at 1 unit per millicurie.**

Note: Diagnostic and therapeutic reimbursement for radiopharmaceutical products may vary.

- Coding for antiemetic and amino acid products are dependent on physician's choice and place of procurement

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.[4,5]

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.

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 15-16 and full Prescribing Information.

Reimbursement Components: Coding

CPT Codes[6,7]

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.

Health care providers may use CPT codes to report medical services related to the premedication and administration of LUTATHERA. 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	

[a]Please see full **Prescribing Information**.

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LUTATHERA ICD-10-CM Codes[8]

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.

LUTATHERA is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. Information in this guide does not represent any statement, promise, or guarantee by Novartis Pharmaceuticals Corporation about coverage, levels of reimbursement, payment, or charge.

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.

Modifiers[9-12]

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.

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 Time[13]

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.

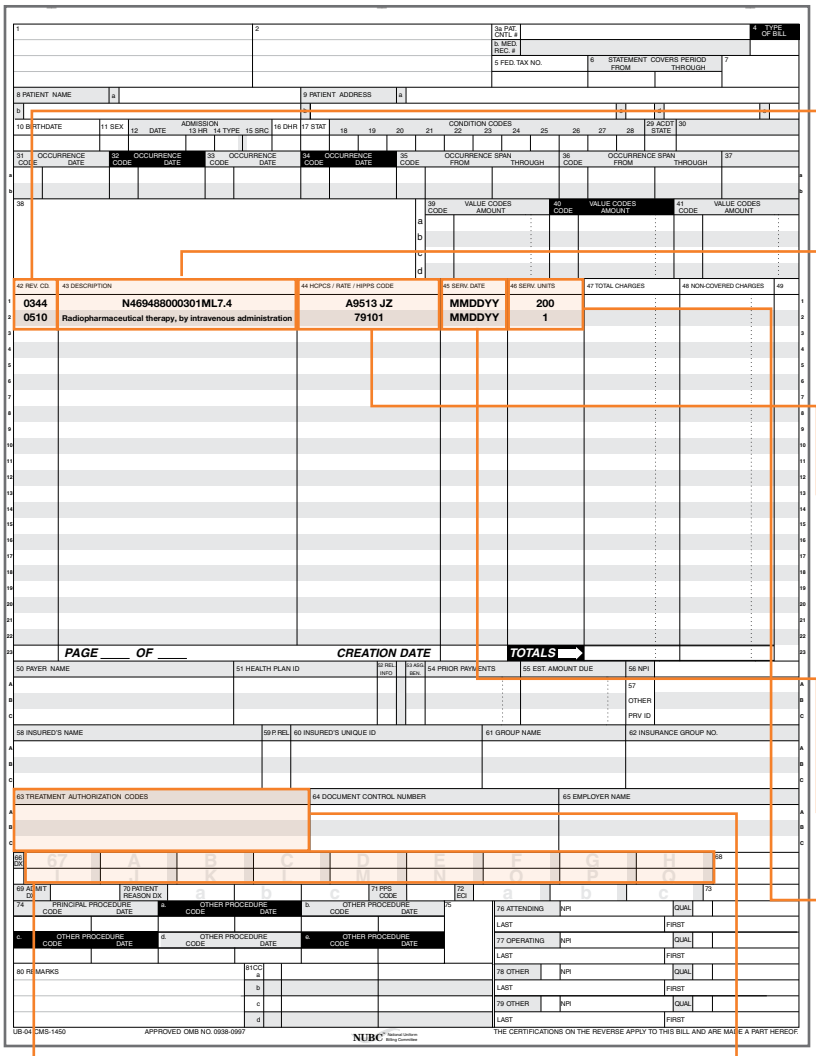
Consult with your internal reimbursement specialist for any reimbursement or billing questions specific to your institution. The existence of billing and coding information in this guide does not guarantee coverage and payment.

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.

Sample CMS-1450 (UB-04) Claim Form

Use the following annotated form as an example of how to complete the CMS-1450 form (print or electronic), a Medicare claim form used by institutions when LUTATHERA is administered in the inpatient or outpatient setting.



BOX 42
Enter the appropriate revenue code corresponding with the HCPCS code in Box 44 (eg, 0344 Nuclear Medicine—Therapeutic Radiopharmaceutical). Then enter the appropriate revenue code corresponding with the CPT code in Box 44 (eg, 0510 Clinic visit).

BOX 43
Enter the N4 indicator, then the 11-digit National Drug Code (NDC), followed by the unit of measurement and quantity. Do not include dashes. Verify with the payer for specific formatting guidelines.

Example: N469488000301ML7.4

BOX 44
Enter the appropriate HCPCS code, A9513, for LUTATHERA use as required by the payer.[3]

The HCPCS code must be accompanied by the JZ or JW modifier.* Include the appropriate CPT code to report the administration procedure, 79101, with a description of Radiopharmaceutical therapy, by intravenous administration.[6]

BOX 45
Enter the dates of service.

BOX 46
Include the appropriate number of billing units for LUTATHERA: 200 mCi=200 billing units and 1 unit for the administration procedure. Some payers may refer to the actual quantity administered via Box 43.

BOX 63
Enter treatment authorization codes.

BOX 67
Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes).

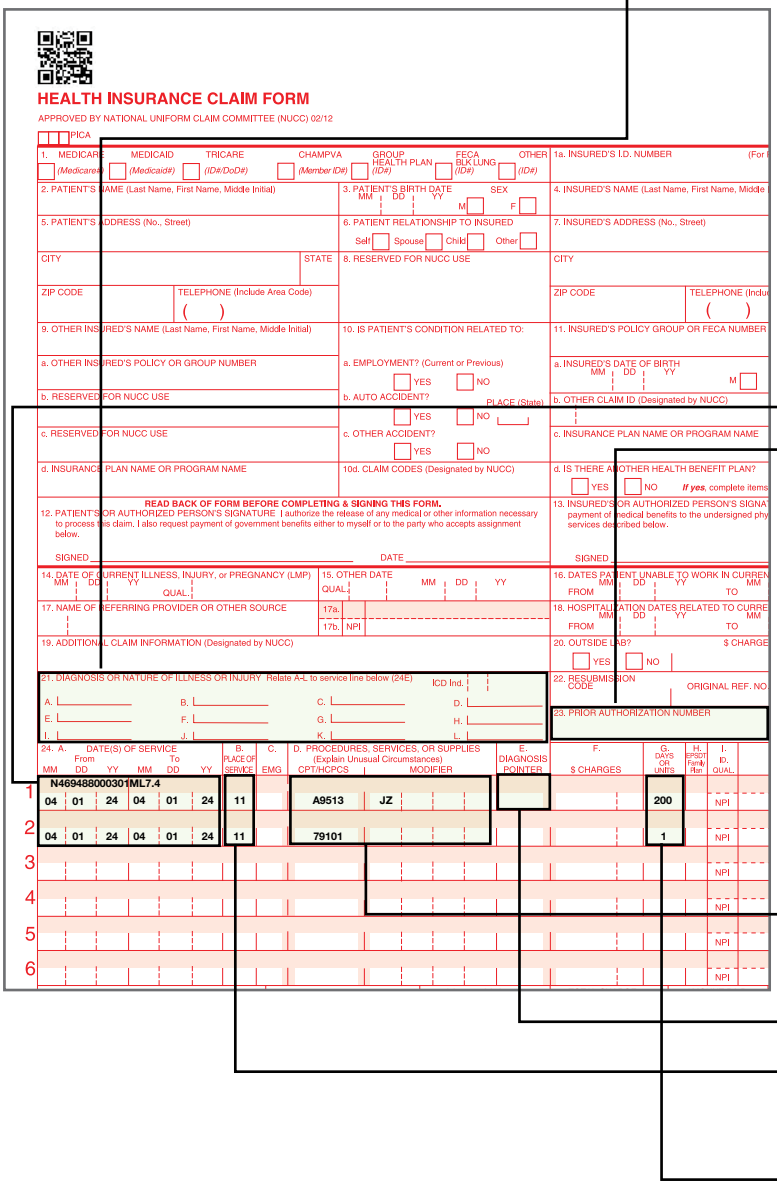
Reminder: This sample claim form is provided for illustrative purposes only, and its use is not a guarantee of reimbursement. It is your responsibility to determine the appropriate codes and submit true and correct claims for the products and services rendered. Contact payers directly for specific information on their coding requirements, coverage policies, payment policies, and fee schedules, if needed.

*Effective January 1, 2023, the JZ and JW modifiers will be applied to all drugs payable under Medicare Part B that are described in a "single-dose" container or "single-use" package. Beginning July 1, 2023, health care providers 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. The JW modifier will still be required to report if any amount of the drug is discarded.[12]

Please see Important Safety Information on pages 15-16 and full Prescribing Information.

Sample CMS-1500 Claim Form

Use the following annotated form as an example of how to complete the CMS-1500 form (print or electronic), a standard Medicare claim form used by HCPs for the administration of LUTATHERA in the HCP office setting.



HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Indu ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY M

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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 SIGNA payment of medical benefits to the undersigned phy services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURREN MM DD YY FROM MM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRE MM DD YY FROM MM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGE

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

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. EPSDT Family Plan	I. ID. QUAL.	
1	N469488000301ML7.4 04 01 24	04 01 24	11		A9513	JZ			200		NPI
2	04 01 24	04 01 24	11		79101				1		NPI
3											NPI
4											NPI
5											NPI
6											NPI

BOX 21

Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes).

BOX 23

Enter the prior authorization number, if applicable.

BOX 24A

List the date of service in the non-shaded area. In the shaded area, enter the N4 indicator, then the 11-digit National Drug Code (NDC), followed by the unit of measurement and quantity. Do not include dashes. Verify with the payer for specific formatting guidelines.

Example: N469488000301ML7.4

BOX 24B

Enter the appropriate Place of Service (POS) code to indicate the setting where a service was provided.

BOX 24D

Enter the appropriate HCPCS code, A9513, for LUTATHERA use as required by the payer.[3] The HCPCS code must be accompanied by the JZ or JW modifier.* Include the appropriate CPT code to report the administration procedure, 79101.[6]

BOX 24E

Enter the diagnosis code reference letter as shown in Box 21 to relate the date of service and the procedures performed to the primary diagnosis. If there is more than one diagnosis required for a procedure code, only reference one letter from Box 21.

BOX 24G

Include the appropriate number of billing units for LUTATHERA: 200 mCi=200 billing units and 1 unit for the administration procedure.

Reminder: This sample claim form is provided for illustrative purposes only, and its use is not a guarantee of reimbursement. It is your responsibility to determine the appropriate codes and submit true and correct claims for the products and services rendered. Contact payers directly for specific information on their coding requirements, coverage policies, payment policies, and fee schedules, if needed.

*Effective January 1, 2023, the JZ and JW modifiers will be applied to all drugs payable under Medicare Part B that are described in a "single-dose" container or "single-use" package. Beginning July 1, 2023, health care providers 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. The JW modifier will still be required to report if any amount of the drug is discarded.[12]

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

Benefits Verification

Once you've enrolled your patients in Novartis Patient Support, our team will conduct a benefits verification to better understand your patient's coverage.

Prior Authorization

We'll help support your practice through the prior authorization and appeals processes to help you navigate access to LUTATHERA treatment.

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.

*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.

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 **Novartis-PatientSupport.com/RLT** or call us at **1-844-638-7222**.

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.

Getting Patients Started

3 simple steps for enrollment

1

Download the Enrollment Form

- Go to **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 adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

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 the19 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 analogues, 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 (≥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.

Adverse reactions observed in pediatric patients were similar to those observed in adults treated with LUTATHERA.

DRUG INTERACTIONS

Discontinue long-acting somatostatin analogues at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose.

SPECIFIC POPULATIONS

Lactation: Advise patients not to breastfeed during LUTATHERA treatment.

References

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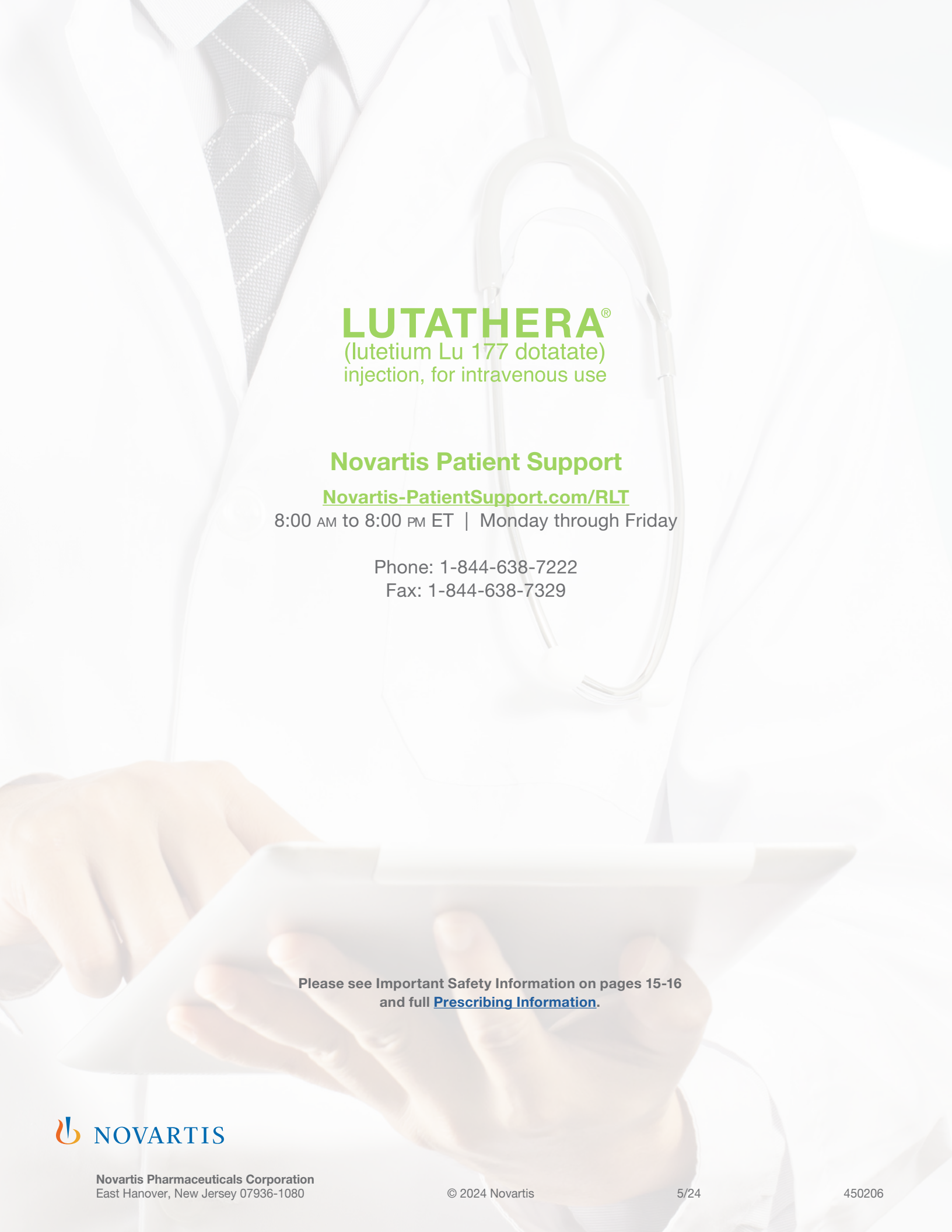

LUTATHERA®
(lutetium Lu 177 dotatate)
injection, for intravenous use

Novartis Patient Support

Novartis-PatientSupport.com/RLT
8:00 AM to 8:00 PM ET | Monday through Friday

Phone: 1-844-638-7222
Fax: 1-844-638-7329

Please see Important Safety Information on pages 15-16 and full Prescribing Information.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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