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

Coding and Billing Guide

January 2026

NEED MORE INFORMATION?

VISIT: lutathera-hcp.com/novartis-patient-support

CALL: 1-844-638-7222

FAX: 1-844-638-7329

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 16 and 17.
Please see full Prescribing Information.

Introduction

NEED MORE INFORMATION?
CALL 1-844-638-7222

Novartis has developed this resource to provide you and your office staff with general coding and reimbursement information for LUTATHERA.

Resource overview:

Please note that the current information is subject to change as new coding and reimbursement information becomes available. Individual payer guidance should be reviewed before submitting a claim.

Disclaimers

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 updated frequently
  - While Novartis Pharmaceuticals Corporation has made every effort to be current as of the issue date on 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 coverage and reimbursement policies and determination processes
- Consult your internal reimbursement specialist with 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. Novartis Pharmaceuticals Corporation does not guarantee success in obtaining reimbursement or financial assistance. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved

Coding for HCP-administered RLTs like LUTATHERA may require separate claims: one for product administration and one for the product itself.[1]

Below is a list of common codes to assist with coding and reimbursement for LUTATHERA. CLICK on each topic below for additional information.

	Code	Notes
HCPCS Code Level I (CPT)[2,3]*	79101: Radiopharmaceutical therapy, by intravenous administration	Used to report medical procedures and services under public and private health insurance programs
	96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour	
	96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis; additional hour	
HCPCS Code Level II[2]	A9513	Used to identify drugs, supplies, medical procedures, and other services **Radiopharmaceuticals like LUTATHERA are billed under A-codes, not J-codes**
NDC Numbers[4]	10-digit: 69488-003-01	Used to identify a specific drug
	11-digit: 69488-0003-01	
POS Codes[5]	11: Office	Used to indicate the setting in which a service was provided
	22: On-Campus Outpatient Hospital	
	49: Independent Clinic	
Revenue Codes[6]	0240: All inclusive ancillary, general	Used for processing product claims. Review individual payer guidance to determine the appropriate codes
	0340: Nuclear medicine, general	
	0342: Nuclear medicine, therapeutic	
	0344: Nuclear medicine, therapeutic radiopharmaceuticals	
	0636: Pharmacy, drugs requiring detailed coding	
JZ Modifier[7]	Zero drug amount discarded/not administered to any patient†	Applied to drugs payable under Medicare Part B that are described as a "single-dose" container or "single-use" package
JW Modifier[7]	Drug amount discarded/not administered to any patient†	

CPT, Current Procedural Terminology; HCP, health care professional; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; POS, place of service; RLT, radioligand therapy.
*Separate coding for the administration of therapy may be required under different CPT codes.
†Contact the health plan for questions about utilizing JZ/JW modifiers.

General Best Practices

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Appropriate reimbursement for the administration of LUTATHERA depends on accurate coding and documentation. The following information is designed to provide important tips to consider when filing a claim for LUTATHERA.

- ✓ Depending on your plan, reach out to your payer for any questions on utilizing JZ/JW modifiers
- ✓ Verify patient information (eg, name, address, member ID)
- ✓ Use the most appropriate codes to report the patient's diagnosis and care (eg, ICD-10-CM codes, CPT codes)
- ✓ Review the number of units of LUTATHERA administered
- ✓ Ensure medical record information includes appropriate documentation to support diagnosis and associated services. These may include the following:
  - Specific diagnosis for somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
  - Histology to support diagnosis
  - Relevant prior imaging documentation for tumor localization
  - All relevant laboratory tests
  - Start time, completion time, and total duration of amino acid infusion and the individual who administered the solution
- ✓ Recheck place of service (POS) and revenue codes
- ✓ Recheck claim prior to submission to ensure patient and coding information are accurate
- ✓ File claim in a timely manner
- ✓ Complete a PA form if required by payer
- ✓ Make sure to include CPT code 79101 (a separate PA may be required for CPT code 79101: Radiopharmaceutical therapy, by intravenous administration. Consult the payer directly for more information)
- ✓ File an appeal if PA is denied

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Individual payer guidance should be reviewed before submission of a claim. Consult with the payer for any other required documentation specific to your patient, as needed.

For any questions and additional support, visit lutathera-hcp.com/novartis-patient-support or call 1-844-638-7222.

The following key details about LUTATHERA are included to provide context concerning patient access, coding, and reimbursement.[4]

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.

Patient Selection

Select patients with SSTR-positive foregut, midgut, and hindgut GEP-NETs. Additional selection criteria were used in the NETTER-1 and ERASMUS studies.

Dosage and Administration

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.

Administer premedications and concomitant medications as recommended in the **Prescribing Information**.

Product Overview

NDC: 69488-003-01

Single-dose vial containing 370 MBq/mL (10 mCi/mL) of a colorless to slightly yellow solution for intravenous use.

Storage and Handling

Store below 25°C (77°F). Do not freeze LUTATHERA. Store in the original package to protect from ionizing radiation (lead shielding). The shelf life is 72 hours from the date and time of calibration. Discard appropriately at 72 hours.

SSTR, somatostatin receptor.

Diagnosis codes identify why a patient may need treatment (eg, conditions, diseases, related health problems, abnormal findings) and document the medical necessity for a patient to receive treatment with LUTATHERA.

You should review the payer's guidance to ensure appropriate codes are selected based on the patient's medical record.

When reporting ICD-10-CM codes, it is recommended to ***code to the highest level of specificity to avoid denials.***

ICD-10-CM codes[8]	Description[8]
C7A.01	Malignant carcinoid tumors of the small intestine
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

ICD-10-CM codes[8]	Description[8]
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.092	Malignant carcinoid tumor of the stomach
C7A.094	Malignant carcinoid tumor of the foregut unspecified
C7A.095	Malignant carcinoid tumor of the midgut unspecified
C7A.096	Malignant carcinoid tumor of the hindgut unspecified
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

Additional Important Codes

NEED MORE INFORMATION?
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Healthcare Common Procedure Coding System (HCPCS) Codes

HCPCS Level II codes are used to identify drugs, supplies, medical procedures, and other services. Payers may also require the National Drug Code. HCPs should contact third-party payers for specific information on their coding, coverage, and payment policies.

HCPCS Level II code[2]	Descriptor[2]	Dosage[4]*	Billing units[2]
A9513	Lutetium Lu 177, dotatate, injection therapeutic, 1 mCi	200 mCi	200 mCi = 200 billing units†

*100 mCi for dose modification for LUTATHERA.
†1 unit is the lowest billable unit.

Modifiers

JZ and JW modifiers should be applied to 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 when there are no discarded amounts. The JW modifier will still be required to report if any amount of the drug is discarded.

Modifier[7]‡	Description[7]
JZ	Zero drug amount discarded/not administered to any patient
JW	Drug amount discarded/not administered to any patient

‡Contact the health plan for questions about utilizing JZ/JW modifiers.

National Drug Code (NDC)

Some payers require an NDC, which is a 10- to 11-digit code used to identify a specific drug, such as LUTATHERA, in order to process claims.

10-digit NDC[4]	11-digit NDC[4]	Description[4]
69488-003-01	**69488-0003-01**	Lutetium Lu 177, dotatate, therapeutic

Current Procedural Terminology (CPT®) Code

CPT codes are the most widely accepted codes for reporting medical procedures and services under public and private health insurance programs. Below is the applicable code that relates to the administration of LUTATHERA.

Service[2,3]	Code[2,3]	Description[2,3]
Administration of amino acids (first hour) concomitant infusion	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
Administration of amino acids (second hour and subsequently)	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	
Administration of LUTATHERA	79101	Radiopharmaceutical therapy, by intravenous administration

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Place of Service (POS) Codes

POS codes are used to indicate the setting in which a service was provided. CMS maintains a database of POS codes commonly used in the health care industry. Below are POS codes you may use. Review the full listing of the POS codes on the CMS website and consult your payer's guidance to determine the correct code for your institution.

Service[5]	Code[5]	Description[5]
Office	**11**	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health professional provides health examinations, diagnosis, and treatment on an ambulatory basis.
On Campus–Outpatient Hospital	**22**	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
Independent Clinic*	**49**	Location, not part of a hospital or covered and not described by any other POS code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.

Revenue Codes

Specific forms, such as the UB-04 (CMS-1450), require documentation of revenue codes associated with services provided to patients.

Below are commonly used revenue codes for processing claims for products such as LUTATHERA. This is not an all-inclusive list of revenue codes that could be used, and it is recommended to review individual payer guidance to determine the appropriate codes for LUTATHERA.

Code[6]	Description[6]
0240	All inclusive ancillary, general
0340	Nuclear medicine, general
0342	Nuclear medicine, therapeutic
0344	Nuclear medicine, therapeutic radiopharmaceuticals
0636	Pharmacy, drugs requiring detailed coding

CMS, Centers for Medicare & Medicaid Services.

*An independent diagnostic testing facility shall not be allowed to bill for any CPT or HCPCS codes that are solely therapeutic.

Use the following section as an example of how to complete forms (print or electronic) associated with health insurance claims for LUTATHERA.

General information is provided for each form along with annotated thumbnails to visually identify key sections.

Reminder: The sample claim forms in this section are provided for illustrative purposes only and their 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.

CMS-1500 Claim Form[9]

The CMS-1500 form is a standard Medicare claim form used by HCPs for the administration of LUTATHERA in the HCP office setting.

Key components of this form are described below and illustrated on the sample form on the following page.

Section	
Item 21	Enter the appropriate primary and secondary diagnosis codes (eg, relevant ICD-10-CM codes)
Item 23	Enter the prior authorization number, if applicable
Item 24A	List the date of service in the non-shaded area. In the shaded area, enter the N4 indicator, then the 11-digit NDC, followed by the unit of measurement and quantity. Do not include dashes. The NDC unit of measure code for LUTATHERA is likely ML (for liquids, solutions, or suspensions).[4] Verify with the payer for specific formatting guidelines. Example: N469488000301ML7.4
Item 24B	Enter the appropriate Place of Service (POS) code to indicate the setting where a service was provided
Item 24D	Enter the appropriate HCPCS code, A9513, for LUTATHERA use as required by the payer.[2] The HCPCS code must be accompanied by the JZ or JW modifier.* Include the appropriate CPT code to report the administration procedure, 79101[2]
Item 24E	Enter the diagnosis code reference letter as shown in Item 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 Item 21
Item 24G	Include the appropriate number of billing units for LUTATHERA: 200 mCi=200 billing units† and 1 unit for the administration procedure

*Contact the health plan for questions about utilizing JZ/JW modifiers.

†1 unit is the lowest billable unit.

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LUTATHERA®
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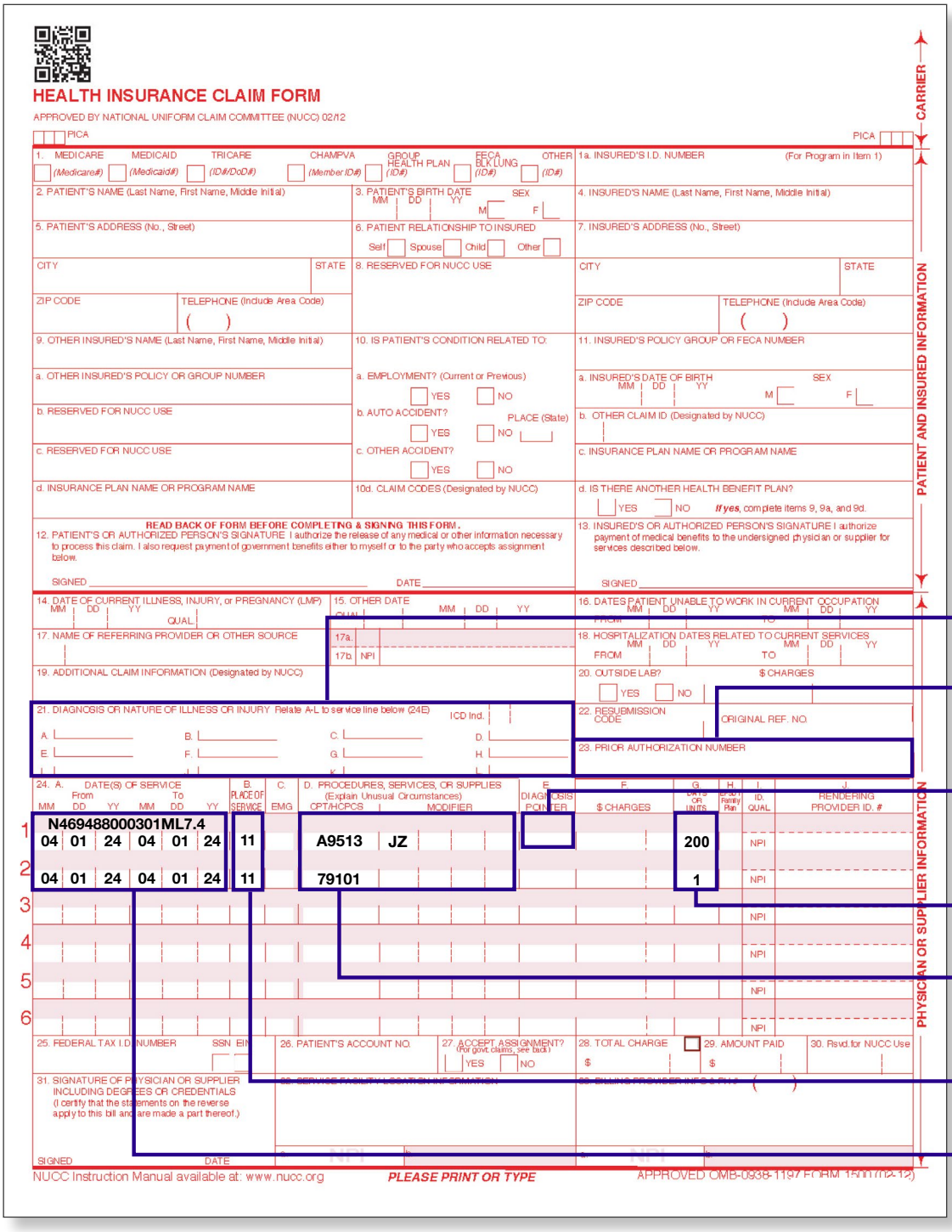
Sample CMS-1500 Claim Form[9]



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 (For Program in Item 1)

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 Initial)

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 STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

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 SEX M F

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 9, 9a, and 9d.

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 SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for 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 CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

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	J. RENDERING PROVIDER ID. #
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	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES 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.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # ( )

SIGNED DATE

a. NPI b.

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 21: Diagnosis codes

Item 23: Prior authorization number

Item 24E: Diagnosis code reference letter

Item 24G: Number of units

Item 24D: CPT and HCPCS codes

Item 24B: Place of service

Item 24A: Date of service and NDC

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

UB-04 (CMS-1450) Claim Form[10]

The UB-04 form, also known as the CMS-1450 form, is a Medicare claim form used by institutions when LUTATHERA is administered in the inpatient or outpatient setting.

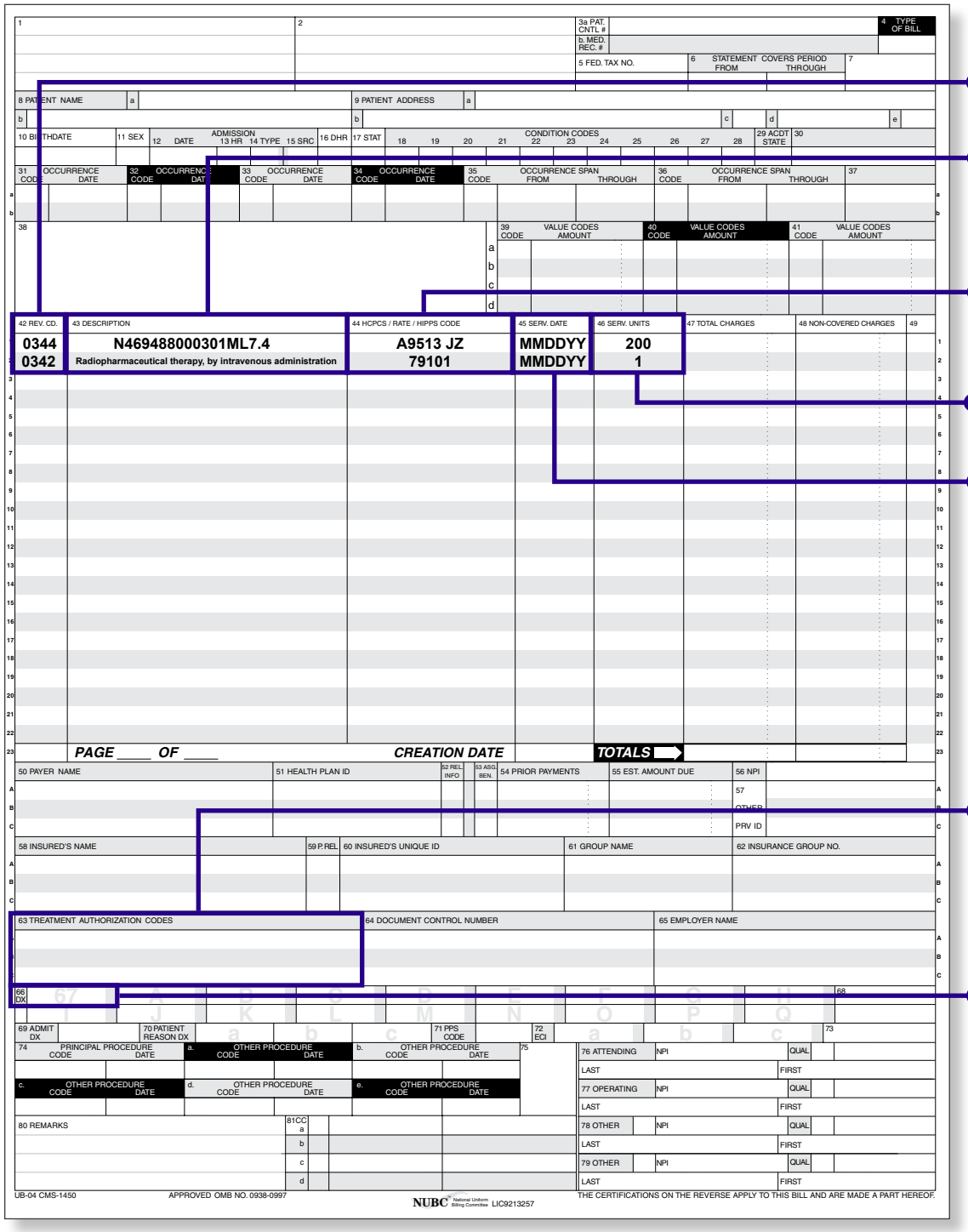
Key components of this form are described below and illustrated on the sample form on the following page.

Section	
Form Locator (FL) 42	Enter the appropriate revenue code corresponding with the HCPCS code in FL 44 (eg, 0344 Nuclear Medicine—Therapeutic Radiopharmaceutical).[6] Then enter the appropriate revenue code corresponding with the CPT code in FL 44 (eg, 0342 Nuclear Medicine—Therapeutic)[6]
FL 43	Enter the revenue code description and NDC. Include the N4 indicator, then the 11-digit NDC, followed by the unit of measurement and quantity. Do not include dashes. The NDC unit of measure code for LUTATHERA is likely ML (for liquids, solutions, or suspensions).[4] Verify with the payer for specific formatting guidelines. Example: N469488000301ML7.4
FL 44	Enter the appropriate HCPCS code, A9513, for LUTATHERA use as required by the payer.[2] 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[2]
FL 45	Enter the dates of service
FL 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 FL 43
FL 63	Enter treatment authorization code(s)
FL 67	Enter the appropriate primary and secondary diagnosis codes (eg, relevant ICD-10-CM codes)

*Contact the health plan for questions about utilizing JZ/JW modifiers.
†1 unit is the lowest billable unit.

Please see Important Safety Information on pages 16 and 17.
Please see full Prescribing Information.

Sample UB-04 (CMS-1450) Claim Form[10]



FL 42:
Revenue codes

FL 43:
Revenue code description, N4 indicator and NDC

FL 44:
CPT and HCPCS codes

FL 46:
Number of units

FL 45:
Dates of service

FL 63:
Treatment authorization codes

FL 67:
Diagnosis codes

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

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Completing Prior Authorizations and Appeals

NEED MORE INFORMATION?
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Prior Authorizations (PAs)

PAs are meant to demonstrate to the payer that the health plan's specific requirements have been met or explain why LUTATHERA is the most appropriate treatment for the patient. It is important to review a payer's guidelines when completing a PA, as these requirements often differ between payers, health plans, prescribed medications, and more.

Checklist for completing a PA

- ✓ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ✓ Patient's diagnosis and corresponding ICD-10-CM code(s)
- ✓ List of previous therapies
- ✓ Make sure to include CPT code 79101 (a separate PA may be required for CPT code 79101: Radiopharmaceutical therapy, by intravenous administration. Consult the payer directly for more information)

It may also be necessary to include the following information at the request of the payer:

- ✓ Physician information, including name and tax ID number
- ✓ Facility information, including name and tax ID number
- ✓ Setting of care
- ✓ Date of service
- ✓ Patient clinical notes detailing relevant diagnosis
- ✓ Supporting documentation for treatment decisions, including laboratory and imaging results
- ✓ Relevant codes, specifically CPT and HCPCS, for services/products to be performed or provided
- ✓ LUTATHERA Prescribing Information

AVOID DELAYS IN TREATMENT. Missing or incomplete information or documentation can lead to a PA being denied. Ensure all requested PA information is included, such as prior treatment history, testing history, and necessary code(s).

For more information on PAs and appeals for LUTATHERA visit lutathera-hcp.com/novartis-patient-support or call 1-844-638-7222.

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Appeals

If a patient is denied coverage for LUTATHERA, it is important to first review the denial letter and understand the payer's reason for denial, which is often related to the coverage policy or clinical appropriateness. You can then explain your clinical rationale for prescribing LUTATHERA through a Letter of Appeal. This letter should address each specific reason cited in the denial letter and demonstrate why the health plan's preferred or on-formulary treatment options do not represent the most appropriate treatment for the patient.

It is also important to review the remittance advice (RA), which will indicate where the appeal should be filed, which form to use, and any specific deadlines.

Checklist for completing an appeal

- ✓ Patient's name, date of birth, insurance ID number, insurance group number, and dates of service
- ✓ Patient's diagnosis and corresponding ICD-10-CM code(s)
- ✓ Copies of relevant medical records
- ✓ Clinical support for prescribing LUTATHERA
- ✓ A list of previous therapies, their duration, and explanation for discontinuation
- ✓ A Letter of Medical Necessity and the US Food and Drug Administration approval letter for LUTATHERA

It may also be necessary to include the following information at the request of the payer:

- ✓ Reference number of existing claim decision, if applicable
- ✓ Patient authorization and Notice of Release of Information
- ✓ Denial information, including the denial letter or RA notification
- ✓ Other supporting documentation, such as chart notes, current medications, and laboratory results

For more information on PAs and appeals for LUTATHERA visit lutathera-hcp.com/novartis-patient-support or call 1-844-638-7222.

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- **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.

Please see additional Important Safety Information on the following page.

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LUTATHERA®
(lutetium Lu177 dotatate)
injection, for intravenous use

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.

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Getting Started With Novartis Patient Support™

NEED MORE INFORMATION?
CALL 1-844-638-7222

Novartis Patient Support is a comprehensive program that is designed to help your patients start, stay, and save on LUTATHERA.

After enrollment, Novartis Patient Support can assist with:

Benefits investigation

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

Prior authorization information

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.

Co-pay savings start with enrollment

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

To complete and submit an Enrollment Form, visit **lutathera-hcp.com/novartis-patient-support** 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, 8 AM to 8 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.

References: 1. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS). Accessed September 24, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system **2.** Buy and Bill. LUTATHERA – A9513 – Code and Cost Information. Accessed December 8, 2025. https://buyandbill.com/lutathera-a9513 **3.** Buy and Bill. 'Buy and Bill' Drug Administration Codes. Accessed December 8, 2025. https://buyandbill.com/cpt-drug-administration-codes **4.** Lutathera. Prescribing information. Novartis Pharmaceuticals Corp. **5.** Centers for Medicare & Medicaid Services. Place of service codes for professional claims. Accessed November 18, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/downloads/website-pos-database.pdf **6.** Noridian Healthcare Solutions. Revenue codes. Accessed December 4, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **7.** Centers for Medicare & Medicaid Services. Discarded drugs and biologicals—JW modifier and JZ modifier policy: Frequently asked questions. Accessed November 18, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **8.** Centers for Medicare and Medicaid Services. ICD-10-CM. Accessed December 4, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **9.** Centers for Medicare & Medicaid Services. Professional paper claim form (CMS-1500). Accessed November 19, 2025. https://www.cms.gov/medicare/coding-billing/electronic-billing/professional-paper-claim-form **10.** Centers for Medicare & Medicaid Services. Institutional paper claim form (CMS-1450). Accessed November 19, 2025. https://www.cms.gov/medicare/coding-billing/electronic-billing/institutional-paper-claim-form

Please see Important Safety Information on pages 16 and 17.
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