

# CODING AND REIMBURSEMENT

**AUGUST 2023**

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## Indication

LOCAMETZ<sup>®</sup> (kit for the preparation of gallium Ga 68 gozetotide injection), after radiolabeling with gallium-68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- for selection of patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated

## IMPORTANT SAFETY INFORMATION

### Risk for Misinterpretation

Image interpretation errors can occur with LOCAMETZ PET. Negative imaging does not rule out the presence of prostate cancer and a positive imaging does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as nonmalignant processes. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

**Please see additional Important Safety Information on page 2. Please see full [Prescribing Information](#).**



## IMPORTANT SAFETY INFORMATION (continued)

### Risk for Misinterpretation (continued)

*Imaging prior to initial definitive or suspected recurrence therapy*

The performance of LOCAMETZ® (kit for the preparation of gallium Ga 68 gozetotide injection) seems to be affected by serum PSA levels and by site of disease for imaging of biochemically recurrent prostate cancer, and by Gleason score for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy.

*Imaging to select patients for lutetium Lu 177 vipivotide tetraxetan therapy*

The interpretation of LOCAMETZ PET may differ depending on imaging readers. LOCAMETZ PET interpretations to select patients for lutetium Lu 177 vipivotide tetraxetan therapy may be more consistent when judging gallium Ga 68 gozetotide uptake in any 1 tumor lesion compared with judging uptake for all lesions larger than size criteria. Multidisciplinary consultation is recommended, particularly for LOCAMETZ imaging that a single reader finds borderline or difficult to interpret, or when patient eligibility hinges only on judgment of gallium Ga 68 gozetotide uptake for all lesions larger than size criteria.

### Radiation Risk

Gallium Ga 68 gozetotide contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to be well hydrated prior to gallium Ga 68 gozetotide administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure.

### Adverse Reactions

Adverse reactions  $\geq 0.5\%$  in the VISION study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%). Adverse reactions occurring at a rate of  $< 0.5\%$  were diarrhea, dry mouth, injection site reactions, and chills.



### Disclaimers

This document is presented for informational purposes only and 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 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. Novartis 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
- Providing information to obtain coverage is solely the responsibility of the HCP and staff



## INTRODUCTION

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

### This resource contains information about:

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Please note that the current information is subject to change as new coding and coverage information become available. Individual payer guidance should be reviewed before the submission of a claim.

### FOR ANY QUESTIONS AND ADDITIONAL SUPPORT



Visit [www.novartis-patientsupport.com/RLT](http://www.novartis-patientsupport.com/RLT) or



Call **1-844-638-7222**



## INFORMATION ON ACCESS AND REIMBURSEMENT

Identifying patients with mCRPC with PSMA-positive tumors is an important step toward choosing the most appropriate disease management path. LOCAMETZ is a radioactive diagnostic agent used with PET to detect PSMA-positive lesions in men with prostate cancer.

Review the following information to learn about navigating the overall access and reimbursement process.



### CARE COORDINATION

Work with the imaging center to ensure all paperwork is complete and accurate and determine whether any other HCPs should be notified of the imaging results. For reimbursement and patient cost-sharing purposes, check whether the imaging will be performed in or out of network according to the patient's insurer/health plan.



### PATIENT BENEFITS VERIFICATION

Complete a check of the patient's benefits eligibility to help streamline the coverage process with the imaging center.



### PAYER POLICY REVIEW

Precertification or prior authorization (PA) policies may differ based on the payer/insurance plan. If there is a need to challenge the payer's coverage policy, it may be helpful to refer the payer to an RBM.



### PLAN CONTRACT REVIEW

Imaging centers should review the provider contract to understand specifics about how to interface with the payer or RBM and how to determine expected reimbursement.

HCPs, health care professionals; mCRPC, metastatic castration-resistant prostate cancer; PET, positron emission tomography; PSMA, prostate-specific membrane antigen; RBM, radiology benefit manager.

Please see **Important Safety Information** on pages 1-2.  
Please see full [Prescribing Information](#).



## INFORMATION ON ACCESS AND REIMBURSEMENT (continued)



### PATIENT EDUCATION

Educate patients on key aspects of the insurance approval process. For instance, remind patients it may take time to receive approval but your office will work with the payer to answer any questions about the procedure. You should also mention that an appeal may be available if coverage is initially denied. Keep in contact with your patients throughout the process.



### FINANCIAL ASSISTANCE OPTIONS

Help patients understand any out-of-pocket costs based on their plan's benefit policy. If available, consider providing information on financial assistance options that may be available to help patients with their out-of-pocket costs.



### PA OR APPEAL

If PA is required by the payer, review payer guidance to ensure you are meeting all requirements. If a PA form submission is incomplete, then both the imaging procedure and reimbursement may be delayed.



## PRODUCT DETAILS

The following key details about LOCAMETZ, are included to provide context concerning patient access, coding, and reimbursement.<sup>1</sup>



### Indication

LOCAMETZ, after radiolabeling with gallium-68, is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- for selection of patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated



### Dosage and Administration\*

The recommended amount of radioactivity to be administered for PET is 111 MBq to 259 MBq (3 mCi to 7 mCi) by slow intravenous injection.



### Patient Preparation

Advise patients to be well hydrated prior to gallium (<sup>68</sup>Ga) gozetotide administration and to void immediately prior to and frequently during the first hours after image acquisition to reduce radiation exposure.



### Image Acquisition

Begin PET scanning 50 minutes to 100 minutes after the intravenous administration of gallium Ga 68 gozetotide injection. Patients should void immediately prior to image acquisition, and image acquisition should begin at the mid-thighs and proceed cranially to the skull base or skull vertex. Adapt imaging technique according to the equipment used and patient characteristics in order to obtain the best image quality possible.



### How Supplied

NDC: 69488-017-61

Dosage form and strength: 25 micrograms as powder for solution for injection.



### Storage and Handling

Before reconstitution, store at 2°C to 25°C (36°F to 77°F).

After radiolabeling, store upright with an appropriate lead shielding to protect from radiation, below 30°C (86°F). Do not freeze. After radiolabeling, use within 4 hours.

This preparation is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

\*Please refer to the full Prescribing Information for complete information on dosing and administration, including safe handling of radiopharmaceuticals.



## CODING AND BILLING

Coding and billing are essential to the patient access journey. This guide provides information on coding and classifying your patient’s diagnosis that may be required for reimbursement.

### Diagnosis Codes

Diagnosis codes identify the patient’s medical condition and why a procedure needs to be performed. You should review the payer’s guidance to ensure appropriate codes are selected based on the patient’s medical record.

#### Primary Diagnosis Codes

ICD-10-CM Codes <sup>2</sup>	Description <sup>2</sup>
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate <i>(must be used with a C or R diagnosis code)</i>
R97.21	Rising PSA following treatment for malignant neoplasm of prostate

#### Secondary Diagnosis Codes

ICD-10-CM Codes <sup>2</sup>	Description <sup>2</sup>
C63	Malignant neoplasm of other and unspecified male genital organs
C69.90	Malignant neoplasm of unspecified site of unspecified eye
C77	Secondary and unspecified malignant neoplasm of lymph nodes
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face, and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; PSA, prostate-specific antigen.



## CODING AND BILLING (continued)

### Diagnosis Codes (continued)

#### Secondary Diagnosis Codes (continued)

ICD-10-CM Codes <sup>2</sup>	Description <sup>2</sup>
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78	Secondary malignant neoplasm of respiratory and digestive organs
C78.0	Secondary malignant neoplasm of lung
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.3	Secondary malignant neoplasm of other and unspecified respiratory organs
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct





## CODING AND BILLING (continued)

### Diagnosis Codes (continued)

#### Secondary Diagnosis Codes (continued)

ICD-10-CM Codes <sup>2</sup>	Description <sup>2</sup>
C78.8	Secondary malignant neoplasm of other and unspecified digestive organs
C78.80	Secondary malignant neoplasm of unspecified digestive organ
C78.89	Secondary malignant neoplasm of other digestive organs
C79	Secondary malignant neoplasm of other and unspecified sites
C79.0	Secondary malignant neoplasm of kidney and renal pelvis
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.1	Secondary malignant neoplasm of bladder and other and unspecified urinary organs
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.3	Secondary malignant neoplasm of brain and cerebral meninges
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges



## CODING AND BILLING (continued)

### Diagnosis Codes (continued)

#### Secondary Diagnosis Codes (continued)

ICD-10-CM Codes <sup>2</sup>	Description <sup>2</sup>
C79.4	Secondary malignant neoplasm of other and unspecified parts of nervous system
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.5	Secondary malignant neoplasm of bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.7	Secondary malignant neoplasm of adrenal gland
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.8	Secondary malignant neoplasm of other specified sites
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
Z19.2	Hormone-resistant malignancy status



## CODING AND BILLING (continued)

### 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. Health care professionals should contact third-party payers for specific information on their coding, coverage, and payment policies.

#### Effective October 1, 2022:

Code <sup>3</sup>	Description <sup>3</sup>	Lowest Billable Unit <sup>3</sup>
A9800	Gallium ga-68 gozetotide, diagnostic, (locametz)	1 millicurie

Prior to October 1, 2022, a not otherwise classified (NOC) HCPCS code was required in the absence of a product-specific code. A4641 (Radiopharmaceutical, diagnostic, not otherwise classified), A9597 (Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified), or A9598 (Positron emission tomography radiopharmaceutical, diagnostic, for nontumor identification, not otherwise classified) were used.

Additionally, **the Centers for Medicare & Medicaid Services (CMS) has granted LOCAMETZ transitional pass-through status effective October 1, 2022.** Transitional pass-through status is a temporary payment policy granted by CMS under the Hospital Outpatient Prospective Payment System as indicated by status indicator "G". This only applies when LOCAMETZ is administered to Medicare patients in the hospital outpatient setting.

### National Drug Code (NDC)

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

10-Digit NDC Number <sup>1</sup>	11-Digit NDC Number <sup>1</sup>	Description <sup>1</sup>
69488-017-61	69488-0017-61	Kit for the preparation of gallium Ga 68 gozetotide



## CODING AND BILLING (continued)

### Current Procedural Terminology (CPT®) Codes

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

Code <sup>4</sup>	Description <sup>4</sup>
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

*Current Procedural Terminology (CPT)* is © 2022, American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. The American Medical Association assumes no liability for data contained or not contained herein.



## CODING AND BILLING (continued)

### Modifiers<sup>5</sup>

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 Centers for Medicare and Medicaid Services (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. Beginning July 1, 2023, HCPs and suppliers are required to report the JZ modifier when billing for drugs from single-dose containers, such as NETSPOT, when there are no discarded amounts. The JW modifier will still be required to report if any amount of the drug is discarded.

Modifier <sup>5</sup>	Description <sup>5</sup>
JZ	Zero drug amount discarded/not administered to any patient
JW	Drug amount discarded/not administered to any patient



## CODING AND BILLING (continued)

### 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 for guidance to determine the correct code for your institution.

Service <sup>6</sup>	Code <sup>6</sup>	Description <sup>6</sup>
Office	11	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
On Campus- Outpatient Hospital	22	A portion of a hospital's main campus which 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, like the UB-04 (CMS-1450), require documentation of revenue codes associated with services provided to patients. These should be confirmed with the payer.

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

Code <sup>7</sup>	Description <sup>7</sup>
341	Nuclear medicine, diagnostic
343	Nuclear medicine, diagnostic radiopharmaceuticals
636	Pharmacy, drugs requiring detailed coding



## SAMPLE CLAIM FORMS

The following section provides examples of completed forms (print or electronic) associated with health insurance claims for LOCAMETZ. 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

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

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

#### Section

Box 19*	Enter the drug name, route of administration, and dose administered (do not use any punctuation in the box)
Box 21	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)
Box 24B	Enter the appropriate code to indicate the setting where a service was provided
Box 24D	Enter the appropriate CPT code(s) and HCPCS code
Box 24G	Enter the appropriate number of units for LOCAMETZ

\*Some payers may require associated costs. Please consult your specific payer.

**Individual payers may require you to enter total dosage in the remarks or comment box when submitting the claim.**



## SAMPLE CLAIM FORMS (continued)

### Sample CMS-1500 Claim Form

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

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BENEFITING OTHER  
(Medicare#) (Medicaid#) (ID#) (Member ID#) (ID#) (ID#)

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)

8. RESERVED FOR NUCC USE

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

10. IS PATIENT'S CONDITION RELATED TO:  
a. EMPLOYMENT? (Current or Previous)  
b. AUTO ACCIDENT? PLACE (State)  
c. OTHER ACCIDENT?  
d. INSURANCE PLAN NAME OR PROGRAM NAME

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

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

15. OTHER DATE MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? \$ CHARGES

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

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

1	2	3	4	5	6
24B	24D	24G			

24. A. DATE(S) OF SERVICE FROM MM DD YY TO MM DD YY B. PLACE OF SERVICE EMG C. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGE G. DAYS OR VETS H. ICD-9-CM I. ID QUAL J. RENDERING PROVIDER ID. #

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For gov't claims, see back) YES NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rsvd. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE(S) OR CREDENTIALS (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. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED CMB-0938-1197 FORM 1500 (02-12)

- 19 Drug name, route of administration, and dose administered
- 21 Diagnosis code
- 24B Place of service
- 24D CPT and HCPCS\* codes
- 24G Number of units

\*The HCPCS code must be accompanied by the JZ modifier, indicating zero drug wasted.





## SAMPLE CLAIM FORMS (continued)

### UB-04 (CMS-1450) Claim Form

The UB-04 form, also known as the CMS-1450 form, is a standard Medicare claim form used by institutions when LOCAMETZ 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

Box 4	Enter the appropriate code to indicate the setting where a service was provided
Box 42	Enter the appropriate revenue codes corresponding to the HCPCS code in Box 44
Box 43	Enter the description corresponding to the revenue code in Box 42
Box 44	Enter the appropriate CPT code(s) and HCPCS code
Box 46	Enter the appropriate number of units for LOCAMETZ
Box 67	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)
Box 80*	Enter drug-identifying information, as required by the payer (eg, drug name, NDC 11-digit format, dosage, method of administration)

\*Some payers may require associated costs. Please consult your specific payer.

**Individual payers may require you to enter total dosage in the remarks or comment box when submitting the claim.**



## SAMPLE CLAIM FORMS (continued)

### Sample UB-04 Claim Form

The image shows a sample UB-04 claim form with several callouts pointing to specific fields:

- 4** points to the "PLACE OF BILL" field (78).
- 42** points to the "REV. CD." and "DESCRIPTION" fields (42 and 43).
- 43** points to the "HCP/PCS / RATE / HPPS CODE" field (44).
- 44** points to the "SERV. DATE" field (45).
- 46** points to the "SERV. UNITS" field (46).
- 67** points to the "DIAGNOSIS CODE" field (67).
- 80** points to the "REMARKS" field (80).

- 4** Place of service
- 42** Revenue code
- 43** Revenue code description
- 44** CPT and HCPCS\* codes
- 46** Number of units

- 67** Diagnosis code
- 80** Drug-identifying information

\*The HCPCS code must be accompanied by the JZ modifier, indicating zero drug wasted.



## COMPLETING PRIOR AUTHORIZATIONS AND APPEALS

### Prior Authorization (PA)

PAs are meant to demonstrate to the payer that the health plan's specific requirements have been met or to explain why scanning with LOCAMETZ is appropriate 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, diagnostic agents, 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)
- If required by the plan, an imaging center within the plan's network that will conduct the scan

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 diagnostic procedures, including other laboratory and imaging results
- Relevant codes, specifically CPT and HCPCS, for services/products to be performed or provided
- LOCAMETZ Prescribing Information



#### Avoid further delays

Missing or incomplete information or documentation can lead to a PA being denied. Ensure all requested PA information is included.

#### FOR MORE INFORMATION



Visit [www.novartis-patientsupport.com/RLT](http://www.novartis-patientsupport.com/RLT) or



Call **1-844-638-7222**

ID, identification.

Please see **Important Safety Information** on pages 1-2.  
Please see full [Prescribing Information](#).



## COMPLETING PRIOR AUTHORIZATIONS AND APPEALS (continued)

### Appeals

If a patient is denied coverage for LOCAMETZ, it is important to first review the 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 ordering a diagnostic procedure using LOCAMETZ through a Letter of Appeal. This letter should address each specific reason cited in the denial and demonstrate why the health plan's preferred diagnostic options do not represent the most appropriate procedure for the patient.

It is also important to review the Explanation of Benefits, which will indicate where the appeal should be filed, which form to use, and any specific deadlines.

### Checklist for completing an appeal with payer

- 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
- A Letter of Medical Necessity and the US Food and Drug Administration approval letter for LOCAMETZ

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 Explanation of Benefits notification
- Other supporting documentation, such as chart notes and laboratory results

### FOR MORE INFORMATION



Visit [www.novartis-patientsupport.com/RLT](http://www.novartis-patientsupport.com/RLT) or



Call **1-844-638-7222**



## SUPPORT WITH NOVARTIS PATIENT SUPPORT™

Novartis Patient Support is a patient-centric support program committed to delivering assistance to eligible patients undergoing radioligand therapy.

### After enrollment, Novartis Patient Support can assist with:



#### Benefits verification

Once you've enrolled your patients in Novartis Patient Support, our team will conduct a benefits verification 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 LOCAMETZ treatment.

## FINANCIAL SUPPORT

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

We help make LOCAMETZ 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](http://www.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 LOCAMETZ treatment through other financial support, call Novartis Patient Support at **1-844-638-7222**, Monday through Friday, 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.

**References:** **1.** Locametz. Prescribing Information. Millburn, NJ: Advanced Accelerator Applications, Inc. **2.** Centers for Medicare & Medicaid Services. 2023 ICD-10-CM tabular list of diseases and injuries. Accessed June 22, 2023. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm> **3.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated May 24, 2023. Accessed June 22, 2023. <https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update> **4.** American Medical Association. CPT Professional Edition. Chicago, IL; 2023. **5.** Centers for Medicare & Medicaid Services. Billing and coding: positron emission tomography scans coverage. Article A54666. Accessed June 22, 2023. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=54666> **6.** Centers for Medicare & Medicaid Services. Place of service code set. Accessed June 22, 2023. [https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place\\_of\\_Service\\_Code\\_Set](https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set) **7.** Noridian Healthcare Solutions. Revenue codes. Accessed June 22, 2023. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>

Please see Important Safety Information on pages 1-2.

Please see full [Prescribing Information](#).

