NETSPOT®

Kit for the preparation of gallium Ga 68 dotatate injection for intravenous use

Coding and Billing Guide

February 2026

NEED MORE INFORMATION?

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INDICATION

NETSPOT®, kit for the preparation of gallium Ga 68 dotatate injection after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION

Radiation Risk

- Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides
- Ga 68 dotatate contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer
- Ensure safe handling and preparation reconstitution procedures to protect patients and health care workers from unintentional radiation exposure
- Instruct patients to drink enough water to ensure adequate hydration prior to the administration of Ga 68 dotatate. Patients should drink and void frequently during the first hours following administration to reduce radiation exposure
- Patients should avoid close contact with infants and pregnant women during the first 12 hours after the administration of Ga 68 dotatate

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

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

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.

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 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 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

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Executive Summary

Coding for HCP-administered RLIs like NETSPOT 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 NETSPOT. CLICK on each topic below for additional information.

	Code	Notes
HCPCS Code Level I (CPT)[2]*	For PET: • 78812, 78813 For PET with CT: • 78815, 78816	Used to report medical procedures and services under public and private health insurance programs
HCPCS Code Level II[3]	A9587	Used to identify drugs, supplies, medical procedures, and other services **Radiopharmaceuticals like NETSPOT are billed under A-codes, not J-codes**
NDC Numbers[4]	10 digit: 69488-001-40 11 digit: 69488-0001-40	Used to identify a specific drug
POS Codes[5]	11: Office 22: On-Campus Outpatient Hospital 49: Independent Clinic	Used to indicate the setting in which a service was provided
Revenue Codes[6]	0240: All inclusive ancillary, general 0340: Nuclear medicine, general 0341: Nuclear medicine, diagnostic 0343: Nuclear medicine, diagnostic radiopharmaceuticals 0636: Pharmacy, drugs requiring detailed coding	Used for processing product claims. Review individual payer guidance to determine the appropriate codes
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[†]	
PI Modifier[8]	Only for PET tumor initial treatment	Indicates that a PET scan is being performed for an oncology indication
PS Modifier[8]	Only for PET tumor subsequent anti-tumor strategy	

CPT, Current Procedural Terminology; CT, computed tomography; HCP, health care professional; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; PET, positron emission tomography; POS, Place of Service; RLI, radioligand imaging.
*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.

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Appropriate reimbursement for the administration of NETSPOT depends on accurate coding and documentation. Review the following information to help you understand and navigate the overall access and reimbursement process.

✓ **CARE COORDINATION**
Work with imaging centers to accurately complete paperwork and determine if HCPs should receive the results. For reimbursement and patient cost-sharing purposes, confirm if imaging is performed according to the patient's insurer/health plan.

✓ **PATIENT BENEFITS INVESTIGATION**
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 policies may differ across health plans. If there is a need to challenge the payer's coverage policy, it may be helpful to refer the payer to a Radiology Benefit Manager (RBM).

✓ **PLAN CONTRACT REVIEW**
Imaging centers should review provider contracts to understand specifics about interfacing with RBMs and how to determine expected reimbursement.

✓ **PATIENT EDUCATION**
Educate patients on key aspects of the insurance approval process. For example, approval requires time, and your office works with payers to answer questions about the procedure. Appeals may be available if coverage is initially denied. Keep in contact with patients throughout the process.

✓ **FINANCIAL ASSISTANCE OPTIONS**
Help patients understand out-of-pocket (OOP) costs based on their plan's benefit policy. Provide any information on financial assistance options available to help patients with OOP costs.

✓ **PA OR APPEAL**
If the payer requires a PA, review payer guidance to ensure all requirements are met. If a PA submission is incomplete, then imaging procedures and reimbursement may be delayed.

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.

HCP, health care professional; PA, prior authorization.

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Product Details

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

Indication

NETSPOT®, kit for the preparation of gallium Ga 68 dotatate injection after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients.

Patient Selection

Adult and pediatric patients with somatostatin receptor-positive neuroendocrine tumors.

Dosage and Administration*

In adults and pediatric patients, the recommended amount of radioactivity to be administered for PET imaging is 2 MBq/kg (0.054 mCi/kg) of body weight up to 200 MBq (5.4 mCi) by intravenous injection (bolus).

Image Acquisition*

For gallium Ga 68 dotatate PET imaging, the acquisition must include a whole body acquisition from skull to mid-thigh. Images can be acquired 40 minutes to 90 minutes after the intravenous administration of the gallium Ga 68 dotatate. Adapt imaging acquisition delay and duration according to the equipment used, and the patient and tumor characteristics, in order to obtain the best image quality possible.

Product Overview

Brand Name: NETSPOT
Generic Name: Kit for the preparation of gallium Ga 68 dotatate injection
National Drug Code (NDC): 69488-001-40

Storage and Handling

For prolonged storage, store NETSPOT in its original packaging at room temperature below 25°C (77°F) (do not freeze). After radiolabeling with activities of up to 1110 MBq (30 mCi), keep gallium Ga 68 dotatate injection upright with an appropriate shielding to protect from radiation, at a temperature below 25°C (77°F) (do not freeze), and use within 4 hours. The storage of the radiolabeled product must comply with regulatory requirements for radioactive materials.

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

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ICD-10-CM Codes Most Frequently Associated With Somatostatin-Bearing NET Imaging

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 NETSPOT. 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*.

Code[9]	Description[9]
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
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
C7A.092	Malignant carcinoid tumor of the stomach
C7A.093	Malignant carcinoid tumor of the kidney
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

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ICD-10-CM Codes Most Frequently Associated With Somatostatin-Bearing NET Imaging

Code[9]	Description[9]
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
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
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.6	Benign neoplasm of colon, unspecified
D12.7	Benign neoplasm of rectosigmoid junction
D12.8	Benign neoplasm of rectum
D12.9	Benign neoplasm of anus and anal canal
D13.1	Benign neoplasm of stomach
D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D14.30	Benign neoplasm of unspecified bronchus and lung
D15.0	Benign neoplasm of thymus

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ICD-10-CM Codes Most Frequently Associated With Somatostatin-Bearing NET Imaging

Code[9]	Description[9]
D30.00	Benign neoplasm of unspecified kidney
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D3A.021	Benign carcinoid tumor of the cecum
D3A.022	Benign carcinoid tumor of the ascending colon
D3A.023	Benign carcinoid tumor of the transverse colon
D3A.024	Benign carcinoid tumor of the descending colon
D3A.025	Benign carcinoid tumor of the sigmoid colon
D3A.026	Benign carcinoid tumor of the rectum
D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
D3A.090	Benign carcinoid tumor of the bronchus and lung
D3A.091	Benign carcinoid tumor of the thymus
D3A.092	Benign carcinoid tumor of the stomach
D3A.093	Benign carcinoid tumor of the kidney
D3A.094	Benign carcinoid tumor of the foregut, unspecified
D3A.095	Benign carcinoid tumor of the midgut, unspecified
D3A.096	Benign carcinoid tumor of the hindgut, unspecified
D49.511	Neoplasm of unspecified behavior of right kidney
D49.512	Neoplasm of unspecified behavior of left kidney
D49.519	Neoplasm of unspecified behavior of unspecified kidney

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Additional Important Codes

Healthcare Common Procedure Coding System (HCPCS) Codes

To report the use of NETSPOT to Medicare Administrative Contractors (MACs) and private/commercial plans, providers should use the following HCPCS code.

HCPCS Code[3]	Description[3]	Dosage[4]	Billing Units[3†]
A9587	Gallium Ga 68 dotatate, diagnostic, 0.1 mCi	Maximum dose = 5.4 mCi*	5.4 mCi = 54 billing units

*In adults and pediatric patients, the recommended amount of radioactivity to be administered for PET imaging is 2 MBq/kg (0.054 mCi/kg) of body weight up to 200 MBq (5.4 mCi) by intravenous injection (bolus).

†The number of billing units is dependent on the number of mCis administered.

Note:
- According to the July 2019 Centers for Medicare & Medicaid Services (CMS) Addendum, 0.1 mCi is the lowest billable unit for NETSPOT. Therefore, the amount of millicuries administered should be accurately included on a submitted claim form

It is the provider's responsibility to determine and submit accurate information on claims and comply with payer coverage, reimbursement, and claim submission rules.

JZ and JW 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.

PI and PS Modifiers

Modifiers PI and PS indicate that a PET scan using (2-[F18] fluoro-2-deoxy-D-glucose) (FDG) is being performed for an oncology indication. Medicare requires one of these modifiers on all FDG-PET oncology claims, including the associated radiopharmaceutical/tracer codes.

Modifier[8]	Description[8]
PI	PET or PET/CT to inform the initial treatment strategy of tumors that are biopsy-proven or strongly suspected of being cancerous based on other diagnostic testing
PS	PET or PET/CT to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy

The PI modifier is only for PET tumor initial treatment. The PS modifier is only for PET tumor subsequent anti-tumor strategy.

CT, computed tomography; HCP, health care professional; PET, positron emission tomography.

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National Drug Code (NDC)

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

10-Digit NDC Number[4]	11-Digit NDC Number[4]	Description[4]
69488-001-40	69488-0001-40	Kit for the preparation of gallium Ga 68 dotatate injection for intravenous use

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 NETSPOT.

Code[2]	Description[2]
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
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

For Ga 68 dotatate PET imaging, the acquisition must include a whole-body acquisition from skull to mid-thigh.[4]

Current Procedural Terminology (CPT) is © 2026, 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.

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.

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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 for 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 (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), 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, 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 NETSPOT. 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 NETSPOT.

Code[6]	Description[6]
0240	All inclusive ancillary, general
0340	Nuclear medicine, general
0341	Nuclear medicine, diagnostic
0343	Nuclear medicine, diagnostic radiopharmaceuticals
0636	Pharmacy, drugs requiring detailed coding

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Sample Claim Forms

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

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[10]

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

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

Section	Description
Item 19*	Enter the drug name, route of administration, and dose administered (do not use any punctuation in the box)
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 24B	Enter the appropriate Place of Service (POS) code to indicate the setting where a service was provided
Item 24D	Enter the appropriate CPT code(s) and HCPCS code
Item 24G	Enter the appropriate number of billing units for NETSPOT, noting that 1 mCi = 10 billing units. Number of units is dependent on the mCis administered

CPT, Current Procedural Terminology; HCP, health care professional; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.
*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.

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Sample CMS-1500 Claim Form[10]

Item 19: Claim information

Item 21: Diagnosis codes

Item 23: Prior authorization number

Item 24B: Place of Service codes

Item 24D: CPT and HCPCS* codes

Item 24G: Number of units

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.
*The HCPCS code must be accompanied by the JZ modifier indicating zero drug wasted.

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UB-04 (CMS-1450) Claim Form[11]

The UB-04 form, also known as the CMS-1450 form, is a Medicare claim form used by institutions when NETSPOT 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	Description
Form Locator (FL) 42	Enter the appropriate revenue codes corresponding to the HCPCS code in FL 44
FL 43	Enter the description corresponding to the revenue code in FL 42
FL 44	Enter the appropriate CPT code(s) and HCPCS code
FL 45	Enter the dates of service
FL 46	Enter the appropriate number of billing units for NETSPOT, noting that 1 mCi = 10 billing units. Number of units is dependent on the mCis administered
FL 63	Enter the treatment authorization code(s)
FL 67	Enter the appropriate primary and secondary diagnosis codes (eg, relevant ICD-10-CM codes)

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.
Individual payers may require you to enter total dosage in the remarks or comment box when submitting the claim.

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Sample UB-04 (CMS-1450) Claim Form[11]

FL 42:
Revenue codes

FL 43:
Revenue code description

FL 44:
CPT and HCPCS* codes

FL 45:
Dates of service

FL 46:
Number of units

FL 63:
Treatment authorization code(s)

FL 67:
Diagnosis codes

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.
*The HCPCS code must be accompanied by the JZ modifier, indicating zero drug wasted.

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Completing Prior Authorizations

Prior authorizations (PAs) are meant to demonstrate to the payer that the health plan's specific requirements have been met or explain why NETSPOT 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, diagnostic agents, and more.

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

✓ NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection) HCPCS code (A9587) and NDC (69488-001-40)

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.

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

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Radiation Risk

- Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides
- Ga 68 dotatate contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer
- Ensure safe handling and preparation reconstitution procedures to protect patients and health care workers from unintentional radiation exposure
- Instruct patients to drink enough water to ensure adequate hydration prior to the administration of Ga 68 dotatate. Patients should drink and void frequently during the first hours following administration to reduce radiation exposure
- Patients should avoid close contact with infants and pregnant women during the first 12 hours after the administration of Ga 68 dotatate

Hypersensitivity Reactions

- Hypersensitivity reactions following the administration of somatostatin receptor imaging agents predominantly consisted of cutaneous reactions, such as rash and pruritus. Reactions reversed either spontaneously or with routine symptomatic management. Less frequently, hypersensitivity reactions included angioedema or cases with features of anaphylaxis

Risk for Image Misinterpretation

- The uptake of Ga 68 dotatate reflects the level of somatostatin receptor density in NETs. However, uptake can also be seen in a variety of other tumor types (eg, those derived from neural crest tissue)
- Increased uptake might also be seen in sites of splenosis or other pathologic conditions (eg, thyroid disease or subacute inflammation) or might occur as a normal physiologic variant (eg, uncinate process of the pancreas)
- PET images with Ga 68 dotatate should be interpreted visually and the uptake may need to be confirmed by histopathology or other assessments
- A negative scan after the administration of Ga 68 dotatate in patients who do not have a history of NETs, including in patients suspected of having ectopic ACTH-secreting tumors, does not rule out the presence of NETs

ADVERSE REACTIONS

- **Clinical Trial Experience:** The safety of Ga 68 dotatate was evaluated in 3 single-center studies and in a survey of the scientific literature. No serious adverse reactions were identified

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IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

- Nonradioactive somatostatin analogs competitively bind to the same somatostatin receptors as Ga 68 dotatate. Image patients with Ga 68 dotatate PET just prior to dosing with long-acting somatostatin analogs
- Short-acting somatostatin analogs can be used up to 24 hours before imaging with Ga 68 dotatate
- Corticosteroids can downregulate subtype 2 somatostatin receptors. Repeated administration of high doses of glucocorticoids prior to Ga 68 dotatate administration may result in false-negative imaging

SPECIFIC POPULATIONS

Pregnancy

- No studies exist with Ga 68 dotatate in pregnant women to inform any drug-associated risks; however, all radiopharmaceuticals, including Ga 68 dotatate, have the potential to cause fetal harm

Lactation

- No information exists on the presence of Ga 68 dotatate in human milk, the effect on the breastfed infant, or the effect on milk production
- Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for 12 hours after Ga 68 dotatate administration to minimize radiation exposure to a breastfed infant

OVERDOSAGE

- In the event of a radiation overdose, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by reinforced hydration and frequent bladder voiding. A diuretic might also be considered
- If possible, an estimate of the radioactive dose given to the patient should be performed

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or www.report.novartis.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on the previous page.
Please see full <u>Prescribing Information</u>.

NETSPOT®
Kit for the preparation
of gallium Ga 68 dotatate
injection for intravenous use   18

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 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 NETSPOT treatment.

To get started, submit an Enrollment Form, visit **lutathera-hcp.com/novartis-patient-support**, or call us at **1-844-638-7222**.

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

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