NETSPOT®

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

NETSPOT Reimbursement Guide

Updated January 2022

Please see Important Safety Information throughout and full Prescribing Information.

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

At Advanced Accelerator Applications (AAA), we focus on molecular imaging and therapy for patients with serious conditions. AAA is committed to providing you and your facility with information about billing, coding, and reimbursement for NETSPOT.

The NETSPOT Reimbursement Guide is a resource for physicians and administrators seeking to submit claims for NETSPOT and a tool to help troubleshoot any potential issues.

This reimbursement guide has been developed to provide you with:

- Coding and reimbursement overview
- Prior authorization checklist
- Product information, including Important Safety Information
- Full Prescribing Information

We hope this resource guide helps you navigate reimbursement and access for NETSPOT.

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 AAA 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; this information does not represent any statement, promise, or guarantee by AAA 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

Thank you,

Roger Estafanos
Head of Pricing and Market Access, North America
Advanced Accelerator Applications

INDICATION[1]

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.

Coding Information

The following reference pages feature relevant product, procedure, and diagnosis coding information that may be applicable for billing purposes.

Product Details[1]

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

HCPCS Coding[2]

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

HCPCS Code	Description
A9587	Gallium Ga 68 dotatate, diagnostic, 0.1 mCi

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.

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

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Coding Information

Procedure Coding[3]

CPT codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. To report a PET scan, providers should use the CPT code that is most specific for the procedure. See accompanying full Prescribing Information for complete information on dosing and administration.

CPT Codes Associated With PET Imaging	
Code	**Description**
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

For Ga 68 dotatate PET imaging, the acquisition must include a whole-body acquisition from skull to mid-thigh.[1]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Radiation Risk (continued)

- 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

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Coding Information

ICD-10-CM Coding[4]

In addition to procedure coding, accurate coding and classification of your patient's diagnosis and treatment is essential and is the responsibility of the provider.

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

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies periodically and often change without warning. The health care provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

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 PET for localization of somatostatin receptor–positive NETs in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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

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ICD-10-CM Codes Most Frequently Associated With Somatostatin-Bearing NET Imaging[4]

Code	Description	Code	Description
C7A.01	Malignant carcinoid tumors of the small intestine	D12.6	Benign neoplasm of colon, unspecified
C7A.010	Malignant carcinoid tumor of the duodenum	D12.7	Benign neoplasm of rectosigmoid junction
C7A.011	Malignant carcinoid tumor of the jejunum	D12.8	Benign neoplasm of rectum
C7A.012	Malignant carcinoid tumor of the ileum	D12.9	Benign neoplasm of anus and anal canal
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion	D13.1	Benign neoplasm of stomach
C7A.020	Malignant carcinoid tumor of the appendix	D13.2	Benign neoplasm of duodenum
C7A.021	Malignant carcinoid tumor of the cecum	D13.30	Benign neoplasm of unspecified part of small intestine
C7A.022	Malignant carcinoid tumor of the ascending colon	D13.39	Benign neoplasm of other parts of small intestine
C7A.023	Malignant carcinoid tumor of the transverse colon	D14.30	Benign neoplasm of unspecified bronchus and lung
C7A.024	Malignant carcinoid tumor of the descending colon	D15.0	Benign neoplasm of thymus
C7A.025	Malignant carcinoid tumor of the sigmoid colon	D30.00	Benign neoplasm of unspecified kidney
C7A.026	Malignant carcinoid tumor of the rectum	D3A.010	Benign carcinoid tumor of the duodenum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion	D3A.011	Benign carcinoid tumor of the jejunum
C7A.090	Malignant carcinoid tumor of the bronchus and lung	D3A.012	Benign carcinoid tumor of the ileum
C7A.091	Malignant carcinoid tumor of the thymus	D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
C7A.092	Malignant carcinoid tumor of the stomach	D3A.020	Benign carcinoid tumor of the appendix
C7A.093	Malignant carcinoid tumor of the kidney	D3A.021	Benign carcinoid tumor of the cecum
C7A.094	Malignant carcinoid tumor of the foregut, unspecified	D3A.022	Benign carcinoid tumor of the ascending colon
C7A.095	Malignant carcinoid tumor of the midgut, unspecified	D3A.023	Benign carcinoid tumor of the transverse colon
C7A.096	Malignant carcinoid tumor of the hindgut, unspecified	D3A.024	Benign carcinoid tumor of the descending colon
C7B.01	Secondary carcinoid tumors of distant lymph nodes	D3A.025	Benign carcinoid tumor of the sigmoid colon
C7B.02	Secondary carcinoid tumors of liver	D3A.026	Benign carcinoid tumor of the rectum
C7B.03	Secondary carcinoid tumors of bone	D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
C7B.04	Secondary carcinoid tumors of peritoneum	D3A.090	Benign carcinoid tumor of the bronchus and lung
C25.0	Malignant neoplasm of head of pancreas	D3A.091	Benign carcinoid tumor of the thymus
C25.1	Malignant neoplasm of body of pancreas	D3A.092	Benign carcinoid tumor of the stomach
C25.2	Malignant neoplasm of tail of pancreas	D3A.093	Benign carcinoid tumor of the kidney
C25.4	Malignant neoplasm of endocrine pancreas	D3A.094	Benign carcinoid tumor of the foregut, unspecified
C25.7	Malignant neoplasm of other parts of pancreas	D3A.095	Benign carcinoid tumor of the midgut, unspecified
C25.8	Malignant neoplasm of overlapping sites of pancreas	D3A.096	Benign carcinoid tumor of the hindgut, unspecified
C25.9	Malignant neoplasm of pancreas, unspecified	D49.511	Neoplasm of unspecified behavior of right kidney
D12.0	Benign neoplasm of cecum	D49.512	Neoplasm of unspecified behavior of left kidney
D12.1	Benign neoplasm of appendix	D49.519	Neoplasm of unspecified behavior of unspecified kidney

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- The list of ICD-10-CM codes provided above is not comprehensive. Please ensure you are following the CMS guidelines to choose a code that is as specific as possible
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Please see Important Safety Information throughout and full Prescribing Information.

Hospital Outpatient Department Sample Claim Form: CMS UB-04 (CMS-1450)

A

Patient-Specific Information

Include all relevant patient-specific information such as name, address, insurance information, etc.

B

Provided Service(s) Information

NETSPOT

- Effective January 1, 2017, CMS has issued NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection) an HCPCS code (A9587)
- The A9587 descriptor specifies 0.1 mCi as the lowest billable unit.[2] Therefore, the amount of millicuries administered should be accurately included on a submitted claim form

C

ICD-10-CM Codes

Refer to the ICD-10-CM codes included on page 6 of this reimbursement guide.

D

Procedure Codes

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

E

Remarks and Notes

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

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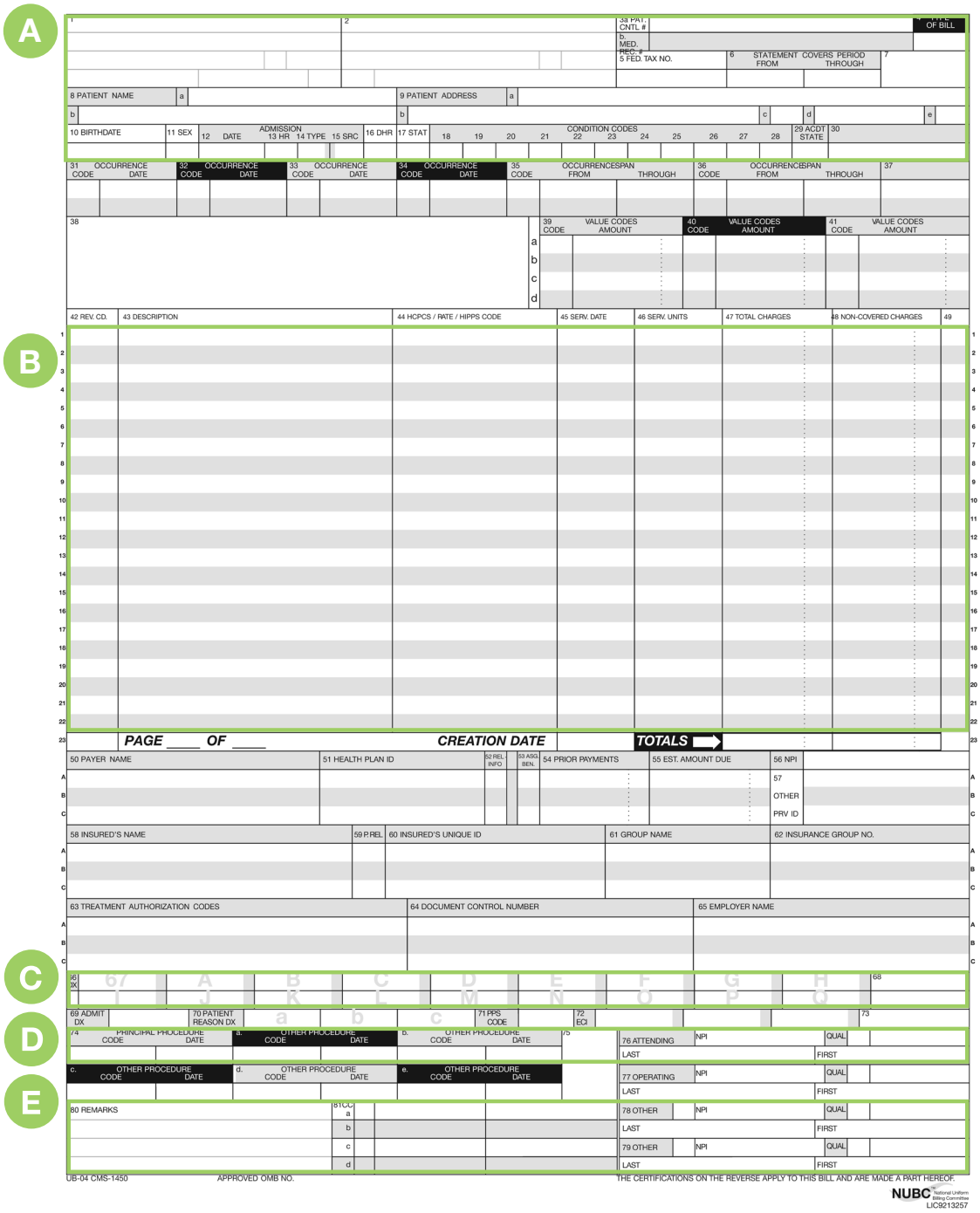
Sample UB-04 Claim Form



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Freestanding/Physician Office Sample Claim Form: CMS-1500

A **Patient-Specific Information**
Include all relevant patient-specific information such as name, address, insurance information, etc.

B **Physician Information**
Include all relevant physician information such as name, address, National Provider Identifier, etc.

C **Remarks and Notes**
Consult the payer if additional information may be required in comments field.

D **ICD-10-CM Codes**
Refer to the ICD-10-CM codes included on page 6 of this reimbursement guide.

E **Provided Service(s) Information**

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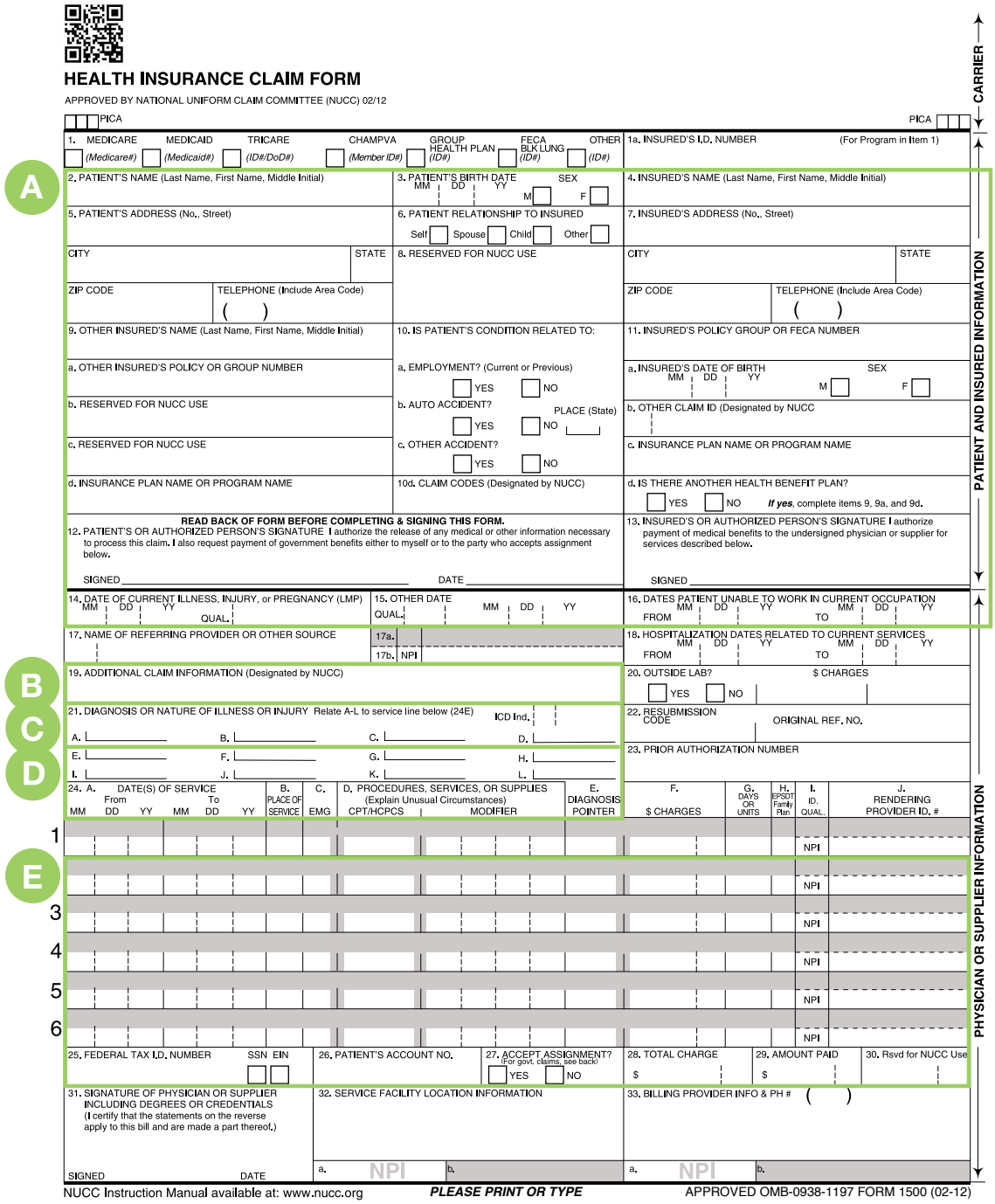
Sample CMS-1500 Claim Form



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 TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

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										NPI	
										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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A

B

C

D

E

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Prior Authorization Checklist

It is important to review a payer's guidelines when obtaining a prior authorization, as these may differ by payer, the medication being prescribed, and other factors. **The following may be necessary to obtain a prior authorization.**

- **Completed prior authorization request form (if required by the payer)**
  - Some payers may require specific forms to be completed for certain medications or therapeutic areas—always verify that the correct form is completed
- **Letter of medical necessity**
  - Be sure to note the proposed treatment plan and include the provider identification (ID) number in the letter
- **Documentation that supports the treatment decision, such as:**
  - Previously given treatments/therapies
  - Patient clinical notes detailing the relevant diagnosis
  - Relevant laboratory results
  - Product Prescribing Information/FDA product labeling
- **It may be necessary to provide the following information when requesting a prior authorization:**
  - Patient information including name, insurance policy number, and date of birth
  - Physician information including name and tax ID number
  - Facility information including name and tax ID number
  - Setting of care
  - Date of service
  - Patient diagnosis and relevant ICD-10-CM code(s)
  - Patient clinical notes detailing the relevant diagnosis
  - Relevant CPT and HCPCS codes for services/products to be performed or provided
  - NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection) HCPCS code (A9587) and NDC (69488-001-40)

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IMPORTANT SAFETY INFORMATION (continued)

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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Clinical Summary

The following pages provide important and meaningful information about the imaging techniques for the diagnosis and localization of somatostatin receptor–positive NETs and the role of NETSPOT.

Overview of Neuroendocrine Tumors

NETs are a relatively rare, heterogeneous group of tumors derived from neuroendocrine cells, most commonly occurring in the intestine, but also found in the pancreas, lung, and other organs.[5] The reported age-adjusted incidence of NETs has increased ~6-fold during the last 4 decades, according to the SEER Program data from 1973 to 2012.[6] Although sometimes considered slow-growing, NETs can progress and may lead to mortality.[7,8] Because symptoms of NETs may be absent or nonspecific, diagnosis is frequently delayed for years and the disease may be metastatic at diagnosis.[9-13]

SEER, Surveillance, Epidemiology, and End Results.

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

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Clinical Summary

NETSPOT Overview

NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection) is a radiolabeled dotatate-conjugated somatostatin analog that binds to somatostatin receptors (SSTRs), which are expressed in various normal tissues and are overexpressed in NETs.[1]

Indication

NETSPOT, after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for use with PET for localization of SSTR-positive NETs in adult and pediatric patients.

Mechanism of Action

Ga 68 dotatate binds to SSTRs, with highest affinity for subtype 2 receptors (SSTR2). It binds to cells that express SSTRs including malignant cells, which overexpress SSTR2 receptors. Gallium 68 (Ga 68) is a ß+ emitting radionuclide with an emission yield that allows PET imaging.

Recommended Dosing

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

IMPORTANT SAFETY INFORMATION (continued)

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

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Summary of Clinical Studies

Clinical Studies From NETSPOT Prescribing Information[1]

The efficacy of NETSPOT was established in 3 open-label, single-center studies (studies A-C).

In **Study A**, 97 adult patients with known or suspected NETs were evaluated with Ga 68 dotatate PET. The Ga 68 dotatate images were read by 2 independent readers blinded to clinical information. The reads were compared with CT and/or magnetic resonance (MR) images and with indium In 111 pentetreotide images obtained with single-photon emission CT (SPECT) within the previous 3 years. Among 78 patients in whom CT and/or MR images and In 111 pentetreotide images were available, Ga 68 dotatate PET was in agreement with the CT and/or MR images in 74 patients. Of 50 patients with NETs localized by CT and/or MR imaging, Ga 68 dotatate was positive in 48 patients, including 13 patients in whom In 111 pentetreotide was negative. Ga 68 dotatate was negative in 26 of 28 patients in whom CT and/or MR imaging was negative.

Study B was a published study that involved 104 patients with suspected NETs. Diagnostic performance of Ga 68 dotatate PET in localizing tumor sites was retrospectively assessed using a reference standard: histopathology (n = 49) or clinical follow-up of up to 5 months' duration (n = 55). Images were interpreted by consensus between 2 on-site readers who were not blinded to clinical information. NET sites were localized by reference standard in 36 patients (all by histopathology). Of these, Ga 68 dotatate was positive, correctly identifying a NET site, in 29 patients and was falsely negative in 7. In 68 patients with no NET identified by a reference standard, the images were negative in 61 patients and falsely positive in 7 patients.

Study C was a published study that involved 63 patients evaluated for NET recurrence using a reference standard as described for study B. Ga 68 dotatate images were interpreted independently by 2 central readers who were blinded to clinical information. Reader 1 correctly localized NETs in 23 of 29 reference standard–positive patients and reader 2 correctly localized NETs in 22 such patients. In 34 patients with no NET identified by a reference standard, reader 1 was correct in 29 patients and reader 2 in 32.

Image Interpretation and Risk of Image Misinterpretations[1]

Based upon the intensity of the signals, PET images obtained using Ga 68 dotatate indicate the presence and density of SSTRs in tissues. Tumors that do not bear SSTRs will not be visualized. Increased uptake in tumors is not specific for NET. The uptake of Ga 68 dotatate reflects the level of SSTR 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 (see section 2.7 Dosage and Administration in full Prescribing Information). 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 ectopic ACTH-secreting tumors, does not rule out the presence of NETs.

ACTH, adrenocorticotropic hormone.

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Summary of Clinical Studies

Additional Clinical Studies

Ga 68 dotatate PET is an imaging technique that has demonstrated sensitivity, specificity, and accuracy.[1]

PET imaging with NETSPOT® (kit for the preparation of gallium Ga 68 dotatate injection) is used for the localization of SSTR-positive NETs, which may help with the diagnosis and management of NETs.[13,14]

- In a retrospective study, the role of Ga 68 dotatate PET in 51 patients with negative or weakly positive findings on ^{111}In-DTPA-octreotide scintigraphy was evaluated to determine whether Ga 68 dotatate PET is able to detect additional disease and whether patient management is altered. The results showed that Ga 68 dotatate PET changed patient management in nearly 71% of patients with NETs[13]
- The impact of Ga 68 dotatate imaging on the management of NETs was evaluated in a study with 2 sets of questionnaires (pre-PET and post-PET) sent to 18 referring physicians for 100 consecutive patients. In the 88 complete sets of pre- and post-PET questionnaires that were returned, Ga 68 dotatate imaging resulted in intended management changes in 60.2% (n = 53) of patients[14]

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. Animal reproduction studies have not been conducted with Ga 68 dotatate.[1] The efficacy of Ga 68 dotatate PET imaging in pediatric patients with NETs is based on extrapolation from adult studies, from studies demonstrating the ability of Ga 68 dotatate to bind to SSTRs, and from a published study of Ga 68 dotatate PET imaging in pediatric patients with SSTR-positive tumors. The safety profile of Ga 68 dotatate is similar in adult and pediatric patients with SSTR-positive tumors. The recommended Ga 68 dotatate injection dose in pediatric patients is weight based, as in adults.[1]

IMPORTANT SAFETY INFORMATION (continued)

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.

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