illuccix®
(kit for the preparation of gallium Ga 68 gozetotide Injection)

CONFIDENCE IN PSMA PET IMAGING

ILLUCCIX, after radiolabeling with Ga 68, is 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

Reimbursement Support Guide

Please see Indications and Important Safety Information on page 14.
Please see full Prescribing Information.

Illuccix® Reimbursement Support

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At Telix Pharmaceuticals (US) Inc., our customer's needs are top priority.

To assist with all your reimbursement and coding questions, we have established Illuccix Reimbursement Support.

Our customers are encouraged to set up an onboarding call prior to having a specific reimbursement need to get to know the Reimbursement Support Team. Customers can simply visit illuccixhcp.com/scheduling to set up a date and time convenient for them.

Illuccix Reimbursement Support can:

- ☑ Perform benefit investigations
- ☑ Provide information regarding prior authorizations and appealing denied claims
- ☑ Provide coverage policies from third-party payers
- ☑ Provide clinical guidelines from radiology benefit managers (RBMs)

Please contact Illuccix Reimbursement Support at (844) 45-TELIX or simply visit illuccixhcp.com/scheduling to schedule online

Support specialists are available Monday through Friday 9:00 AM to 5:00 PM ET.

Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor Illuccix Reimbursement Support is intended as legal advice or a substitute for a provider's independent professional judgment. Billing information in this resource is current as of October 2022.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Medicare Drug Pass-Through Status

illuccix®
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Recognized by CMS as of July 1, 2022 – Hospital Outpatient Setting

Illuccix® (HCPCS Code A9596, APC Code 9443) was granted Transitional Pass-Through status by CMS effective July 1, 2022. We expect this status may continue until June 30, 2025. The Pass-Through status allows for separate Medicare payments under OPPS for radiopharmaceuticals. This information can be found in the OPPS Addendum B quarterly update with Status Indicator (G).

Please note to use the correct Revenue Code when billing under OPPS. For more details, see page 6.

If you have any questions about Transitional Pass-Through status, please contact Illuccix Reimbursement Support at (844) 45-TELIX or email us.reimbursement@telixpharma.com

Actor portrayal.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Procedure must be coded correctly in order to obtain appropriate reimbursement from Medicare, Medicaid, and third-party payers.

The following describes the types of codes that may be applied when submitting claims for a positron emission tomography (PET)/computed tomography (CT) imaging study for initial treatment strategy or subsequent treatment strategy.

- **HCPCS – Healthcare Common Procedure Coding System:** Codes used to report the provision of supplies, materials, injections, and certain services and procedures.
- **CPT® – Current Procedural Terminology:** Codes used to report the service or procedure that was performed and reported
- **ICD-10 – International Classification of Diseases, Tenth Revision:** Codes used to describe signs or symptoms of the patient that would represent a medically necessary reason for performing the procedure
- **NDC – National Drug Code:** A universal product identifier for human drugs in the United States

HCPCS

The following code may be appropriate for use with Illuccix:

HCPCS Code	Descriptor
A9596	Gallium ga-68 gozetotide, diagnostic, (Illuccix), 1 millicurie

Effective July 1, 2022.

Billable Units

When submitting claims, be sure to enter the correct number of units. Per the Prescribing Information, Illuccix® doses range from 3 to 7 millicuries (mCi).

Example claim forms are included on pages 11 and 12 of this guide; however, it is imperative to review individual payer guidance.

When filling out a claim form, be sure to enter the correct 11-digit NDC number:

- NDC 74725-0100-25 for Ga-68 produced from a cyclotron and purified via GE FASTlab™ or Eckert & Ziegler GalliaPharm® Ge 68/Ga-68 generator
- NDC 74725-0100-64 for Ga-68 produced from an IRE Galli Eo® Ge 68/Ga-68 generator

CPT® is a registered trademark of the American Medical Association.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

CPT®

The choice of procedure code to report the procedure should be based on which code most accurately describes the procedure performed and is properly documented in the medical record/procedure report.

The following codes may be used for Illuccix® PET or PET/CT imaging:

CPT Code	Descriptor
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78815	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

Medicare recommends the use of a modifier when submitting claims for PET or PET/CT procedures. These modifiers specify critical information needed to process coverage for staging and oncologic PET imaging. For the latest guidance please visit cms.gov.

When billing Medicare and Commercial payers, attach either a PI or PS modifier:

- The -PI modifier is appropriate for PET/CT imaging for initial treatment strategy of tumors that are biopsy proven with suspected metastasis who are candidates for initial definitive therapy
- The -PS modifier is appropriate for PET/CT imaging of recurrent prostate cancer after completion of initial treatment with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level for the selection of patients with metastatic prostate cancer for whom PSMA-directed 177 Lu radioligand therapy is directed.

Additional payer-specific modifiers may also be required in addition to PI and PS. Please check with your payer and review their requirements for use of additional modifiers. See the below scenario from Noridian:

"The PI modifier is covered only when used in patients with suspected metastasis who are candidates for initial definite therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Providers must amend the KX modifier on the claim to attest that the use of the PI modifier is per guideline recommendations."

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

ICD-10 CM

Medicare requires a covered diagnostic code to be billed with any PET or PET/CT for prostate cancer. The provider should always follow their applicable billing procedures, which may include verifying a patient's individual benefits before scheduling a scan. For the latest guidance please visit your local Medicare contractor's website.

Below are examples of commonly covered ICD-10 codes for prostate. Follow the priority order of the DX code specific to your payer requirements and guidelines:

ICD-10 Code	Descriptor
C61	Malignant neoplasm of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs (must be accompanied by C61)
Z19.1	Hormone sensitive malignancy
Z19.2	Hormone resistance malignancy

When reporting a Z85 ICD-10 code, some payers also require a C or R ICD-10 code to accompany it on the claim form:

C or R ICD-10 Code	Descriptor
Z85.46	Personal history of malignant neoplasm of prostate

The use of this code informs payers that this scan is for recurrent prostate cancer. Please verify with the payer about the specific use of ICD-10 codes to determine medical necessity.

Reporting of Invoice Cost and/or Invoice on Claims

For Medicare, Medicaid, and other 3rd party payers that require either the cost of the invoice reported on claim forms (box 19 on CMS-1500 or 80 on CMS-1450) or a copy of the invoice, be sure to follow the specific payer's format and requirements. In some cases, in addition to the format with dollar sign ($), decimal, and thousands separator (eg, $4,700.00), the words "Invoice Cost," "Inv," etc. may be needed. The provider should always follow the specific payer's requirements.

Hospital Revenue Codes for Chargemaster – Hospital Outpatient Department

Revenue Code	Descriptor
0343	Diagnostic Radiopharmaceuticals
0404	Other Imaging Services – Positron Emission Tomography (PET)

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Prior Authorization

illuccix®
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The items listed below may be necessary to obtain a prior authorization decision:

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 include the Provider ID number in the letter

Documentation that supports the use of the agent

- Patient clinical notes detailing the relevant diagnosis
- Relevant laboratory results
- Product package insert/FDA product labeling

If a request is denied

- Review the reason for denial and address; the decision will inform if the denial issue is related to coverage policy, clinical appropriateness, or another reason, such as:
  - Incomplete submission
  - Incorrect prior authorization form
  - Payer determination that PET/CT or agent is not appropriate for the patient in question
  - Missing patient notes or other medical information
- Denied requests for prior authorization can be appealed and it is important to follow the process from the payer – online, appeal letter, or by phone to request a peer-to-peer review
- Denials should be addressed by the payer in 30 days or less
- Illuccix® Reimbursement Support can provide information regarding prior authorizations and appealing denied authorizations

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Prior Authorization (continued)

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For information regarding prior authorization, please contact Illuccix® Reimbursement Support at (844) 45-TELIX or email us.reimbursement@telixpharma.com

Most third-party payers require some type of prior authorization for advanced imaging, and it may be necessary to provide the following information when making a prior authorization request:

- Patient demographics 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
  - Independent diagnostic testing facility (IDTF)
  - Hospital inpatient
  - Hospital outpatient
- Date of service
- Patient diagnosis and relevant ICD-10 code(s)
- Patient clinical notes detailing the relevant diagnosis
- Relevant CPT® and HCPCS codes for services/products to be performed or provided
- NDC 74725-0100-25 for Ga-68 produced from a cyclotron and purified via GE FASTlab™ or Eckert & Ziegler GalliaPharm® Ge 68/Ga-68 generator
- NDC 74725-0100-64 for Ga-68 produced from an IRE Galli Eo® Ge 68/Ga-68 generator

When requesting prior authorization, since PET and PET/CT imaging authorizations do not usually include related radiopharmaceuticals, it is very important to specifically list (Illuccix – gallium Ga-68 gozetotide) with HCPCS code A9596 in the request for prior authorization or pre-determination reviews and approvals.

Since the HCPCS code (A9596) description is per 1 unit (mCi), it is essential that in your request you include the total units (eg, 5 units [5 mCi]) since Illuccix is priced and reimbursed on a per unit/mCi basis. This is to ensure that providers receive reimbursement for the total units billed.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Medicare Traditional/Original (Part B)

When billing for an IDTF, a Group Practice, Clinics, or other freestanding imaging facilities, some payers like some of the Medicare Administrative Contractors may require the radiopharmaceutical invoice cost and data. This can be provided in field 19 of the CMS-1500 claim form or 837 loop segment for electronic submission of claims (ie, 2300). Be sure to review the specific billing guidelines for your respective Medicare Administrative Contractor or other payers.

In most cases, a copy of the invoice is not needed. Just the invoice cost in the proper format, dose, and other drug information entered in field 19 or loop 2300.

Medicare Traditional/Original IDTF Enrollment

If you are enrolled with Medicare Part B as an IDTF, Medicare Administrative Contractors may require the Illuccix HCPCS code (A9596) be added to your enrollment when completing Medicare's PECOS or paper 855-B enrollment application before claims can be considered for processing.

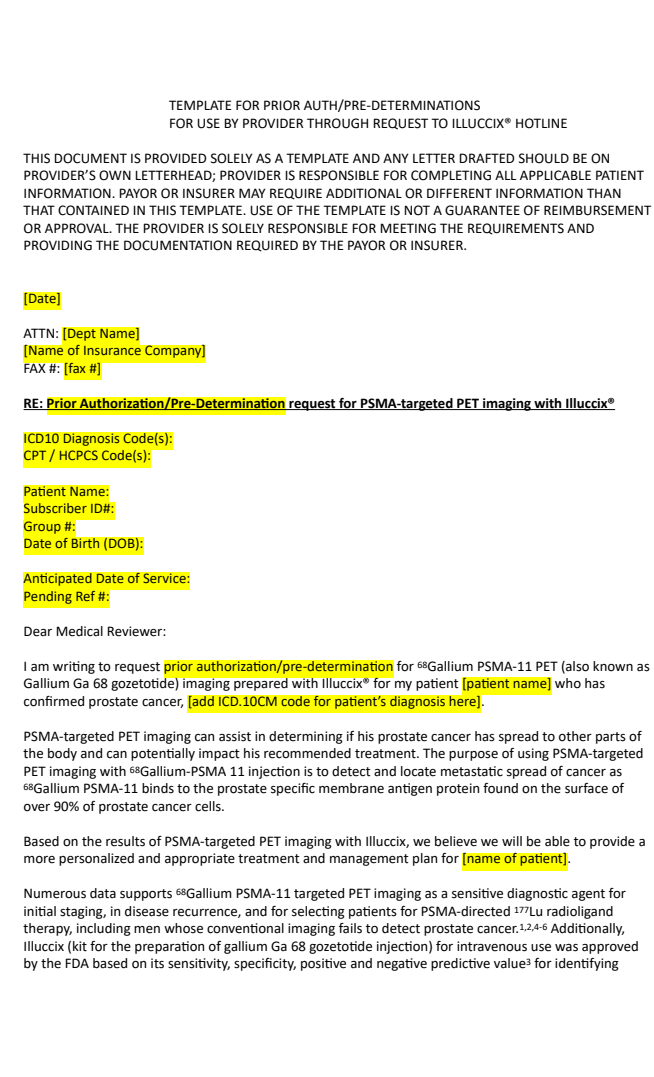

Actor portrayal.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

LETTER OF MEDICAL NECESSITY - for educational purposes only

You may need a letter of medical necessity in order to obtain a prior authorization decision for Illuccix® and any associated services. A sample letter of medical necessity is provided below.*

Download letter now



TEMPLATE FOR PRIOR AUTH/PRE-DETERMINATIONS
FOR USE BY PROVIDER THROUGH REQUEST TO ILLUCCIX® HOTLINE

THIS DOCUMENT IS PROVIDED SOLELY AS A TEMPLATE AND ANY LETTER DRAFTED SHOULD BE ON PROVIDER'S OWN LETTERHEAD; PROVIDER IS RESPONSIBLE FOR COMPLETING ALL APPLICABLE PATIENT INFORMATION. PAYOR OR INSURER MAY REQUIRE ADDITIONAL OR DIFFERENT INFORMATION THAN THAT CONTAINED IN THIS TEMPLATE. USE OF THE TEMPLATE IS NOT A GUARANTEE OF REIMBURSEMENT OR APPROVAL. THE PROVIDER IS SOLELY RESPONSIBLE FOR MEETING THE REQUIREMENTS AND PROVIDING THE DOCUMENTATION REQUIRED BY THE PAYOR OR INSURER.

[Date]

ATTN: [Dept Name]
[Name of Insurance Company]
FAX #: [fax #]

RE: Prior Authorization/Pre-Determination request for PSMA-targeted PET imaging with Illuccix®

ICD10 Diagnosis Code(s):
CPT / HCPCS Code(s):

Patient Name:
Subscriber ID#:
Group #:
Date of Birth (DOB):

Anticipated Date of Service:
Pending Ref #:

Dear Medical Reviewer:

I am writing to request prior authorization/pre-determination for ^{68}Gallium PSMA-11 PET (also known as Gallium Ga 68 gozetotide) imaging prepared with Illuccix® for my patient [patient name] who has confirmed prostate cancer, [add ICD.10CM code for patient's diagnosis here].

PSMA-targeted PET imaging can assist in determining if his prostate cancer has spread to other parts of the body and can potentially impact his recommended treatment. The purpose of using PSMA-targeted PET imaging with ^{68}Gallium-PSMA 11 injection is to detect and locate metastatic spread of cancer as ^{68}Gallium PSMA-11 binds to the prostate specific membrane antigen protein found on the surface of over 90% of prostate cancer cells.

Based on the results of PSMA-targeted PET imaging with Illuccix, we believe we will be able to provide a more personalized and appropriate treatment and management plan for [name of patient].

Numerous data supports ^{68}Gallium PSMA-11 targeted PET imaging as a sensitive diagnostic agent for initial staging, in disease recurrence, and for selecting patients for PSMA-directed ^{177}Lu radioligand therapy, including men whose conventional imaging fails to detect prostate cancer.[1,2,4-6] Additionally, Illuccix (kit for the preparation of gallium Ga 68 gozetotide injection) for intravenous use was approved by the FDA based on its sensitivity, specificity, positive and negative predictive value[3] for identifying

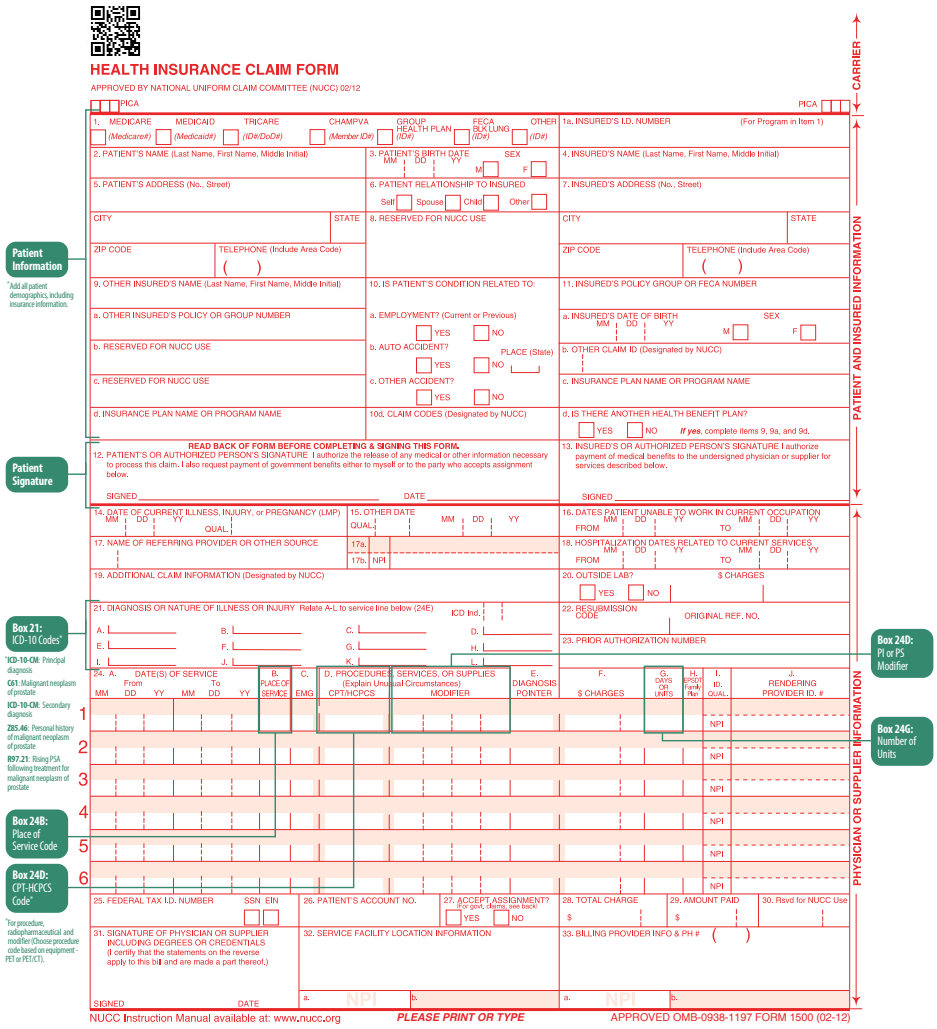
*This document is a modifiable template that can be used by providers when submitting a letter of medical necessity for prior authorization purposes. Provider is solely responsible for applying their clinical judgment and for providing true and accurate information to payers.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

PHYSICIAN OFFICE (CMS-1500) – for educational purposes only

Illuccix® and the associated services provided in a physician office may be billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing Illuccix is provided below.*

Download form now



*This sample claim form is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

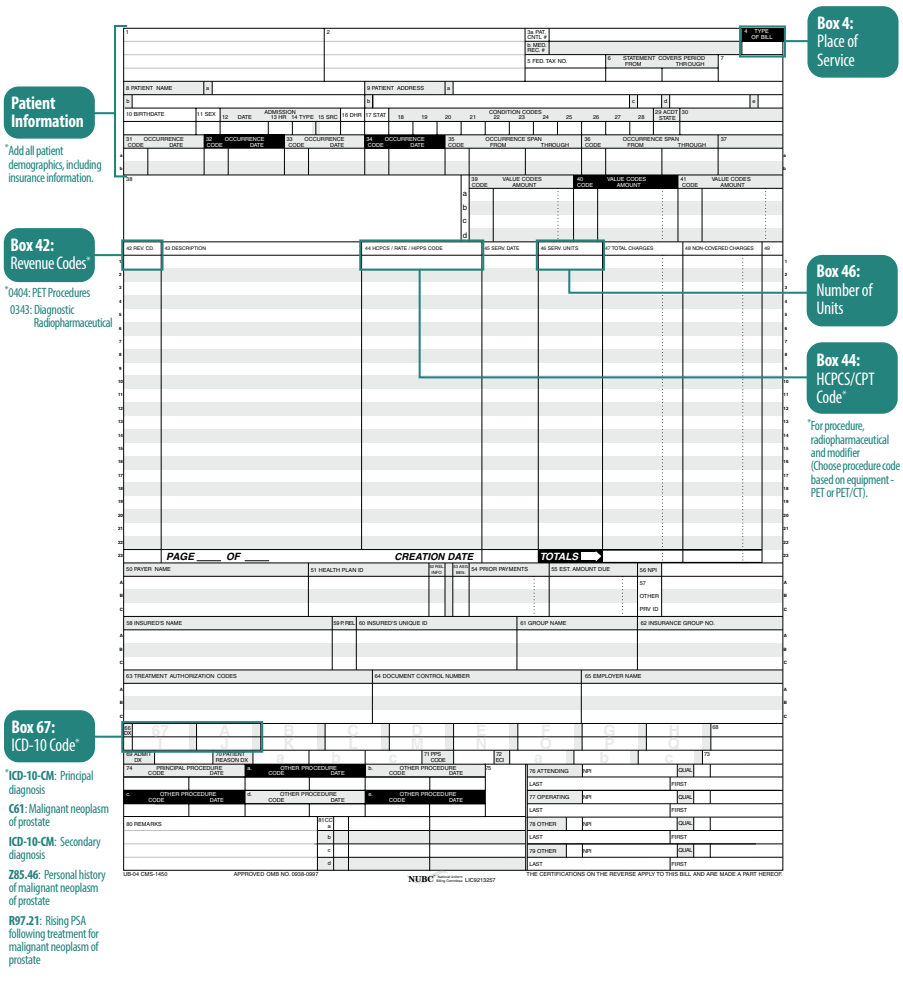
Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

HOSPITAL OUTPATIENT (CMS-1450) – for educational purposes only

Illuccix® and the associated services provided in a hospital outpatient setting may be billed on the UB-04 claim form or its electronic equivalent. A sample UB-04 claim form for billing Illuccix is provided below.*

Download form now

Sample Hospital Technical Billing Form
Hospital Outpatient Prospective Payment System (HOPPS) Setting



*This sample claim form is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

More Information

To learn more about Illuccix®, visit www.illuccixhcp.com.

Scan code with the camera on your mobile device to visit www.illuccixhcp.com.

For information, please contact Illuccix Reimbursement Support at (844) 45-TELIX or email us.reimbursement@telixpharma.com.

Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor Illuccix Reimbursement Support is intended as legal advice or a substitute for a provider's independent professional judgment.

HCPs are solely responsible for all decisions related to coding and billing including determining if and under what circumstances it is appropriate to seek reimbursement for products and services and obtaining preauthorization. Telix Pharmaceuticals (US) Inc. does not make any representation or warranty about the completeness or accuracy of this information and will bear no responsibility for the results or consequences of its application.

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Important Safety Information

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INDICATIONS AND USAGE

ILLUCCIX®, after radiolabeling with Ga 68, is 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

WARNINGS AND PRECAUTIONS

Risk for Misinterpretation

Image interpretation errors can occur with ILLUCCIX PET. A negative image does not rule out the presence of prostate cancer, and a positive image 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 non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy

The performance of ILLUCCIX for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of ILLUCCIX for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Imaging to Select Patients for Lutetium Lu 177 Vipivotide Tetraxetan Therapy

The interpretation of ILLUCCIX PET may differ depending on imaging readers. ILLUCCIX 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 one tumor lesion compared to judging uptake for all lesions larger than size criteria. Multidisciplinary consultation to select patients for lutetium Lu 177 vipivotide tetraxetan therapy is recommended, particularly for ILLUCCIX 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 Risks

Gallium Ga 68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

ADVERSE REACTIONS

The safety of gallium Ga 68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMA-BCR studies, each receiving one dose of gallium Ga 68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

In the VISION study, 1003 patients received one dose of gallium Ga 68 gozetotide intravenously with the amount of radioactivity 167.1 ± 23.1 MBq (4.52 ± 0.62 mCi). Adverse reactions occurring at ≥0.5% in patients with metastatic prostate cancer who received gallium Ga 68 gozetotide injection in the clinical study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%).

Adverse reactions occurring at a rate of < 0.5% in the VISION study were diarrhea, dry mouth, injection site reactions, including injection site hematoma and injection site warmth and chills.

DRUG INTERACTIONS

Androgen deprivation therapy and other therapies targeting the androgen pathway

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga 68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga 68 gozetotide PET has not been established.

Please note that this information is not comprehensive. Please see the Full Prescribing Information at illuccix.com/prescribinginformation

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report adverse reactions to Telix by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

Best Practices for Billing

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When using Illuccix®, follow these steps for successful billing:

Get to know how PET/CT scans with Illuccix will be covered by the major payers in your area

- Contact Illuccix Reimbursement Support for information, as they have a database of coverage policies for third-party payers

Review your contracts with the payers to see how they will cover Illuccix or if you need to amend your contracts for Illuccix

Perform a benefit investigation for every patient

- Confirm coverage, co-pay, if there is a deductible, and if prior authorization is required
- Illuccix Reimbursement Support can provide information regarding benefit investigations

Where prior authorization is required:

- Determine if the imaging facility you wish to refer your patient to is in network for the payer
  - Can you do the prior authorization online or is there a specific form to use?
- Is there an RBM to work with? Can you do that request online or do you need a specific form/worksheet

Please see Indications and Important Safety Information on page 14. Please see full Prescribing Information.

Telix