PYLARIFY®
Piflufolastat F 18 Injection

PYLARIFY® (PIFLUFOLASTAT F 18) INJECTION FOR PET/CT

CODING AND BILLING GUIDE

This resource highlights product, procedure, and diagnosis coding information relevant to the use of PYLARIFY® (piflufolastat F 18) Injection PET/CT that may be applicable for billing purposes.

Please see Indication and Important Safety Information on page 6 and read the accompanying full Prescribing Information also available at PYLARIFY.com.

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Product Codes

HCPCS Code	Description
A9595	piflufolastat F 18 diagnostic for intravenous use, 1 millicurie (mCi), per study, effective January 1, 2022
NDC	**Description**
# 71258-0022-00	PYLARIFY® (single-dose syringe)

Billable Units

A9595, piflufolastat F 18 injection, diagnostic, per study, bill per 9 mCi in box 24G.

Additional claim information: In the electronic equivalent to box 19 on the CMS-1500 form and the electronic equivalent to box 80 on the UB-04 Form, place the name Piflufolastat F-18, (PYLARIFY), JZ Modifier, the dose administered (9 mCi), the 11-digit NDC# (71258-0022-00) should be added in Loop 2400 SV-107 for electronic transmission, the method of administration (bolus IV injection), and invoice when requested. *Example claim forms are included on pages 4 and 5 of this guide; however, it is imperative to review individual payer guidance.*

Procedure Codes

Providers should choose the code that accurately describes the procedure performed and is supported by documentation in the medical record. The CPT codes for PET/CT imaging are 78811-78816 and based on the PYLARIFY® Prescribing Information. The following CPT codes should be considered for PYLARIFY® PET or PET/CT imaging to manage patients with suspected metastasis who are candidates for initial definitive therapy or suspected recurrence based on elevated PSA.

Current Procedural Terminology (CPT®) Codes Associated with PET/CT 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

PET/CT scan coding should be reported under the CPT code that is most specific for the procedure.

Modifiers With PET Imaging

Oncologic PET/CT imaging for Medicare may be billed using either the PI or PS modifier. The PS modifier is appropriate for PET/CT imaging of recurrent prostate cancer since recurrence occurs after the completion of initial treatment. The PI modifier is used to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic tests. Effective July 1, 2023, The Centers for Medicare and Medicaid Services (CMS) now requires Modifier JZ to be appended to HCPCS codes that are single use containers that have zero waste.

JZ Modifier zero drug amount discarded/not administered to any product.

*JW Modifier drug amount discarded/not administered to any product, should not be appended when the dose of the drug administered is less than the billing unit.

If there are any questions, providers should call their local Medicare Administrative Contractor (MAC).

ICD-10 Coding Associated With PET/CT Imaging in the Diagnosis and Management of Prostate Cancer

Diagnosis coding is at the provider's discretion. Providers should select the ICD-10 code(s) that most appropriately describes the patient's clinical condition, symptoms, and documented findings. Examples include:

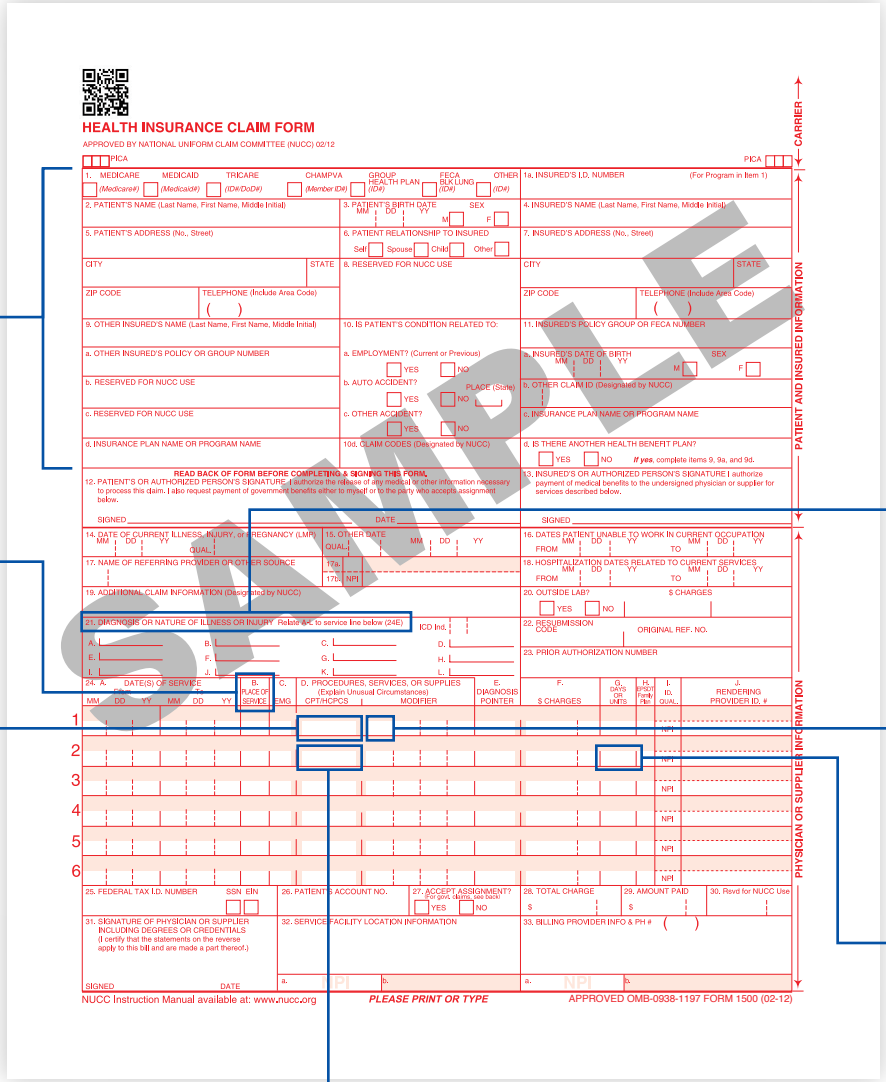
2024 ICD-10 Coding Guidelines Associated with PET/CT Scans of the Prostate

Code	Description
C61	Malignant neoplasm of prostate (Primary Code)
C79.82	Secondary malignant neoplasm of genital organs must be billed accompanied by C61
Z19.1	Hormone sensitive malignancy
Z19.2	Hormone resistant malignancy
Z85.46	Personal history of malignant neoplasm of prostate (must be used with C and R diagnosis)
R97.21	Rising PSA following treatment for malignant neoplasm of prostate Pre-Therapy and Post-Therapy, Code Annotations Back References (Use additional code C61 as primary)

Providers are encouraged to check with specific payer and/or health plan since coverage criteria and diagnosis may vary.

Sample Claim Form

PYLARIFY® and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing PYLARIFY® is provided below. This sample claim form is only an example. It is always the provider's responsibility to determine the appropriate health care 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.



Patient information and signature

Box 24B: Place of service

Box 24D: To submit claims for a non-discarded drug, submit one complete claim line.

- HCPCS code for drug given
- JZ modifier to indicate no waste
- Number of units given to the patient
- Calculate submitted price for the amount given

Box 24D: HCPCS code

Box 21: Diagnosis code (ICD-10)

Box 24D: Include the appropriate modifier

Box 24G: # of units

Please see Indication and Important Safety Information on page 6 and read the accompanying full Prescribing Information also available at PYLARIFY.com.

Sample Claim Form: Hospital Outpatient (UB-04)

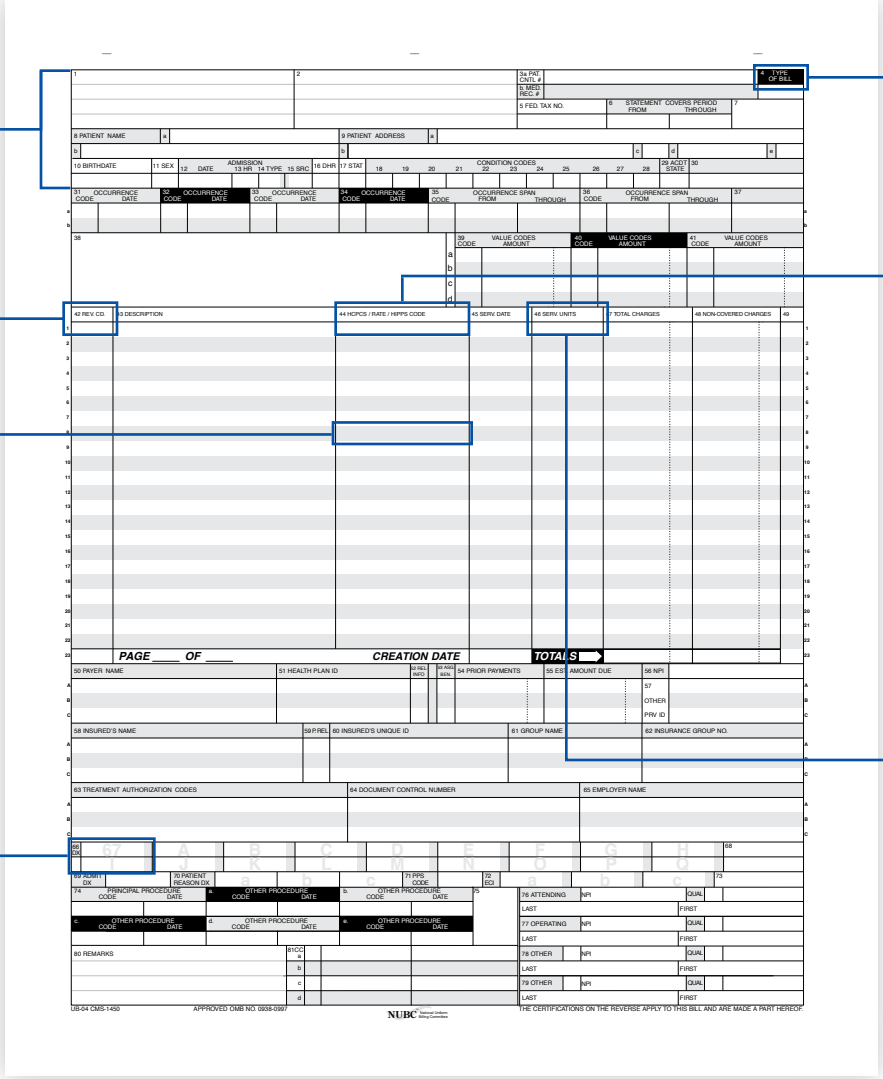
PYLARIFY® and the associated services provided in a hospital outpatient setting are billed on the UB-04 claim form or its electronic equivalent. A sample UB-04 claim form for billing PYLARIFY® is provided below. This sample claim form is only an example. It is always the provider's responsibility to determine the appropriate health care 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.

Patient information and signature

Box 42: Revenue code

Box 44: CPT code

Box 67: Diagnosis code (ICD-10)



Box 4: Place of service (4-digit code)

Box 44:
To submit claims for a non-discarded drug, submit one complete claim line.

- HCPCS code for drug given
- JZ modifier to indicate no waste
- Number of units given to the patient
- Calculate submitted price for the amount given

Box 46: # of units

This information is taken from publicly available sources. It is not intended to guarantee, increase, or maximize reimbursement by any payer. It is the provider's responsibility to report the codes that accurately describe the products and services furnished to individual patients. Reimbursement is dynamic. We recommend that providers consult their payer organizations regarding local policies and rates along with any required claim information.

Laws and regulations regarding reimbursement change frequently and providers 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 pre-authorization, if necessary. Lantheus 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 refer to the current CPT®, ICD-10-CM, and HCPCS manuals and follow the "Documentation Guidelines for Evaluation and Management Services" for the most detailed and up-to-date information. Current Procedural Terminology (CPT®) is a copyright and trademark of the American Medical Association (AMA). All Rights Reserved.

For additional support, please contact Lantheus Link at **844-339-8514**

INDICATION

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent 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.

IMPORTANT SAFETY INFORMATION

Contraindications

None.

Warnings and Precautions

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY for imaging of patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Hypersensitivity Reactions

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

Radiation Risks

Diagnostic radiopharmaceuticals, including PYLARIFY, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reactions

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of ≤2% during clinical studies with PYLARIFY. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

Drug Interactions

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

To report suspected adverse reactions for PYLARIFY, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please read the accompanying full Prescribing Information also available at PYLARIFY.com.

This information is intended for US healthcare professionals only.

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