PYLARIFY TruVu™
Piflufolastat F 18 Injection

PYLARIFY TruVu (piflufolastat F 18) INJECTION FOR POSITRON EMISSION TOMOGRAPHY (PET)/COMPUTED TOMOGRAPHY (CT)

BILLING AND CODING GUIDE


Actor Portrayal

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

INDICATION

PYLARIFY TRUVU (piflufolastat F 18) Injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY TRUVU 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 TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY TRUVU 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 TRUVU 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, is recommended.

This information is provided for educational and informational purposes only and is not intended to provide legal, regulatory, coding, billing, reimbursement, or other professional advice. The information is based on publicly available sources and is subject to change without notice.

Coverage, coding, billing, and reimbursement policies vary by payer and are frequently updated. Payment is not guaranteed and is subject to satisfaction of applicable coverage, coding, medical necessity, documentation, and claims submission requirements.

Healthcare providers are solely responsible for determining the appropriate codes, charges, modifiers, units of service, and documentation requirements for each patient and for submitting accurate claims consistent with applicable laws, regulations, payer requirements, and medical record documentation.

Lantheus makes no representation or warranty regarding the completeness, accuracy, or timeliness of this information and disclaims any liability for decisions made or actions taken based on the information provided.

Product Codes

HCPCS Code[1]	Description
A9613*	Piflufolastat f 18 (pylarify truvu), diagnostic, 1 mCi
NDC[2†]	**Description**
85347-001-01	10-digit
85347-0001-01	11-digit

*For dates of service on or after October 1, 2026.
†Payer requirements regarding the use of NDCs may vary. The package insert lists the 10-digit NDC. Electronic claim submissions generally require use of the 11-digit NDC.

Note that billing units (also known as dose descriptors) are assigned by CMS to reflect the smallest amount that could be billed in multiple units to accommodate a variety of doses. Per CMS, this approach facilitates accurate payment and reporting of the exact dose administered. When submitting claims, the number of billing units reported should correspond to the administered dose. For example, a claim for a 9 mCi administered dose would be reported as 9 billing units. Please refer to payer-specific guidance on rounding and other billing and coding requirements.

The recommended dose of PYLARIFY TruVu is 9 mCi, with an acceptable range of 8-10 mCi, administered as a single bolus intravenous injection.[2]

CMS has granted PYLARIFY TruVu Transitional Pass-Through Status (TPT). This designation is designed to facilitate patient access to innovative technologies. TPT status is only applicable for Medicare Part B patients seen in the hospital outpatient setting, and PYLARIFY TruVu's TPT status is effective beginning October 1, 2026.[3]

Procedure Codes

Providers should choose the code that accurately describes the procedure performed and is supported by documentation in the medical record. The Current Procedural Terminology (CPT®) codes for PET/CT imaging are 78811-78816[4] and based on the PYLARIFY TruVu Prescribing Information. The following CPT codes should be considered for PYLARIFY TruVu PET or PET/CT imaging to manage patients with suspected metastasis who are candidates for initial definitive therapy or suspected recurrence based on elevated prostate-specific antigen (PSA) levels.[2]

CPT® Codes Associated With PET/CT Imaging[4]

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

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CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; mCi, millicurie; NDC, National Drug Code.

Select Modifiers and Codes Associated With Prostate-Specific Membrane Antigen (PSMA) PET

Modifiers[5-7]

Appropriate modifiers may include the following:

Modifier	Description
PI	Used to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic tests
PS	Used to inform the subsequent treatment strategy of cancerous tumors when the patient's treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy
JW	Drug amount discarded/not administered to any patient; used to report the discarded/wasted portion of a single-dose radiopharmaceutical
JZ	Zero drug amount discarded/not administered to any patient; used to indicate that no portion of a single-dose radiopharmaceutical was discarded/wasted
TC	Used to report the technical component of the PET or PET/CT scan
26	Used to report the professional component (ie, PET/CT scan interpretation)

Consult payer-specific guidance on whether to use the JW (drug amount discarded/not administered to any patient) and JZ (zero drug amount discarded/not administered to any patient) modifiers on claims for PYLARIFY TruVu.

ICD-10-CM Codes[8]

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

Examples of 2026 ICD-10-CM Codes Associated With PET/CT Scans of the Prostate

Primary Diagnosis Code

Code	Description
C61	Malignant neoplasm of prostate

Secondary Diagnosis Codes

Code	Description
C79.82	Secondary malignant neoplasm of genital organs
Z19.1	Hormone sensitive malignancy status
Z19.2	Hormone resistant malignancy status
Z85.46	Personal history of malignant neoplasm of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate

Coverage criteria may vary. Providers should confirm covered diagnoses with patient's health plan.

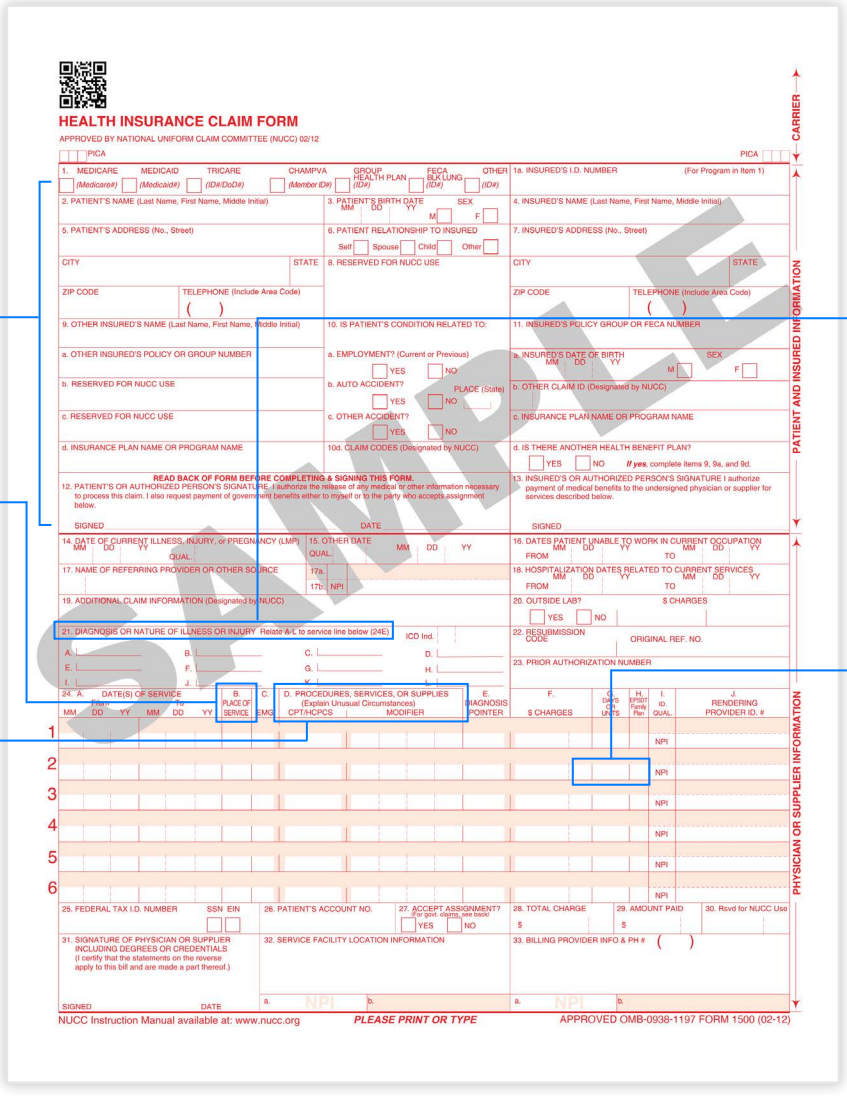
ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see Indication and Important Safety Information on page 6 and the full Prescribing Information for PYLARIFY TruVu.

Sample Claim Form: Nonhospital Setting

PYLARIFY TruVu and the associated services provided in a nonhospital setting (eg, physician office, imaging center, diagnostic testing facility) are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing PYLARIFY TruVu is provided below.

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.



Patient information and signature

Box 24B: Place of service

Box 24D:
Complete one line for the diagnostic radiopharmaceutical

Complete additional lines for the procedure, as needed

- CPT code for the PET scan itself
- Appropriate modifiers
  - PI (initial)
  - PS (recurrent)
- Other CPT codes needed to report associated procedures and/or services

Box 21: Include the appropriate diagnosis code(s) (ICD-10-CM)

Box 24G: # of units (ie, # of mCi)

Please see Indication and Important Safety Information on page 6 and the full Prescribing Information for PYLARIFY TruVu.

Sample Claim Form: Hospital Outpatient (UB-04)

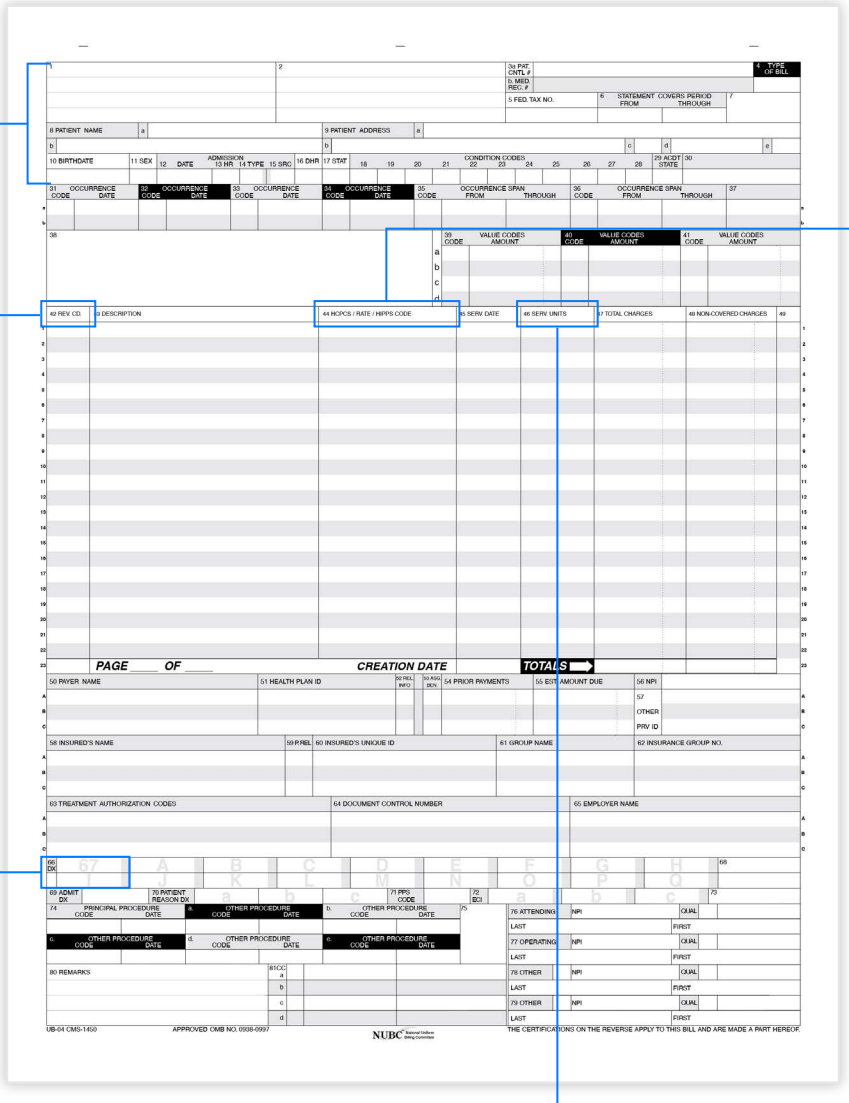
PYLARIFY TruVu and the associated services provided in a hospital outpatient setting are billed on the CMS-1450 (UB-04) claim form or its electronic equivalent. A sample UB-04 claim form for billing PYLARIFY TruVu is provided below.

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.

Patient information

Box 42: Revenue code

Box 67: Diagnosis code(s) (ICD-10-CM)



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

Complete additional lines for the procedure, as needed

- CPT code for the PET scan itself
- Appropriate modifiers
  - PI (initial)
  - PS (recurrent)
- Other CPT codes needed to report associated procedures and/or services

Box 46: # of units (ie, # mCi)

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Hypersensitivity Reactions

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

Radiation Risks

PYLARIFY TRUVU exposes 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. 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 TRUVU in prostate cancer. The effect of these therapies on performance of PYLARIFY TRUVU PET has not been established.

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

Please see the full Prescribing Information for PYLARIFY TruVu.

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.

Please call **Lantheus Link** Monday through Friday, 8:00 AM to 8:00 PM ET, at **844-339-8514**.
You may also visit www.lantheuslink.com or email support@lantheuslink.com.

References: 1. HCPCS Level II Coding Decisions. Centers for Medicare & Medicaid Services. Updated July 24, 2026. Accessed July 27, 2026. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/current-prior-years-level-ii-coding-decisions **2.** PYLARIFY TruVu™ [package insert]. North Billerica, MA: Aphelion LLC, a Lantheus company. **3.** Centers for Medicare & Medicaid Services. *Pub 100-04 Medicare Claims Processing Manual*. Published September 29, 2026. Accessed October 1, 2026. https://www.cms.gov/files/document/r13978cp.pdf **4.** American Medical Association. *CPT® 2026 Professional Edition*. American Medical Association; 2025. **5.** Positron emission tomography (FDG) for oncologic conditions and modifier usage. Novitas Solutions. Updated July 25, 2025. Accessed June 18, 2026. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00291987 **6.** Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed August 27, 2026. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **7.** Medical coding modifiers: CPT®, NCCI & HCPCS Level II. AAPC. Accessed August 27, 2026. https://www.aapc.com/resources/what-are-medical-coding-modifiers **8.** ICD-10. CMS.gov. Published April 1, 2026. Accessed June 5, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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