



Lantheus Announces CMS Grants Transitional Pass-Through Status for PYLARIFY® TruVu (piflufolastat F 18)

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Designation, together with a permanent HCPCS code effective October 1, 2026, supports patient access and reimbursement for PYLARIFY TruVu, Lantheus' PSMA PET imaging agent

BEDFORD, Mass., Sept. 30, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus" or the "Company") (NASDAQ: LNTX), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the Centers for Medicare & Medicaid Services ("CMS") has granted Transitional Pass-Through ("TPT") payment status for PYLARIFY® TruVu™ (piflufolastat F18) injection, effective October 1, 2026. The designation enables separate reimbursement for PYLARIFY TruVu in the hospital outpatient setting and is intended to support access to innovative diagnostic radiopharmaceuticals for Medicare beneficiaries.

PYLARIFY TruVu is a new formulation of Lantheus' F 18 prostate-specific membrane antigen ("PSMA")-targeted PET imaging agent. PYLARIFY TruVu is indicated for positron emission tomography ("PET") imaging of PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. In addition to receiving TPT status, PYLARIFY TruVu has been assigned a permanent Healthcare Common Procedure Coding System ("HCPCS") code, effective October 1, 2026, facilitating billing and reimbursement for providers. Together, these milestones support patient access to PYLARIFY TruVu.

"The granting of Transitional Pass-Through status for PYLARIFY TruVu marks an important milestone as we prepare for commercial launch and the next phase of growth for our PSMA PET franchise," said Amanda Morgan, Chief Commercial Officer of Lantheus. "Building on the proven clinical utility and broad adoption of PYLARIFY, this designation supports and enables patient access to advanced PSMA PET imaging. As we move toward a phased geographic rollout, PYLARIFY TruVu's advantages have the potential to increase supply flexibility and expand geographic reach, helping us serve more patients while ensuring a seamless transition for customers."

More than 900,000 patients have received a PSMA PET scan with PYLARIFY since the FDA granted approval in May 2021. Building on that foundation, PYLARIFY TruVu was developed to maintain the proven diagnostic characteristics of PYLARIFY while introducing formulation enhancements designed to improve manufacturing efficiency, increase supply flexibility and support broader geographic reach. These enhancements have the potential to enable larger batch sizes at select manufacturing facilities and support access for more patients. Lantheus expects to introduce PYLARIFY TruVu through a phased geographic rollout to support a seamless transition for customers.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the U.S. An estimated 1 in 8 men will be diagnosed in their lifetime. The incidence rate for prostate cancer has been increasing since 2014 at a rate of 3% per year overall. For 2026, estimates suggest nearly 334,000 new cases and more than 36,000 deaths. Prostate cancer can be a serious disease and is the second-leading cause of cancer death in men (behind lung cancer), but most men diagnosed with prostate cancer do not die from it. In fact, more than 3.5 million men in the U.S. consider themselves prostate cancer survivors.¹

PYLARIFY TruVu™ (piflufolastat F 18) Injection

PYLARIFY TruVu™ (piflufolastat F 18) injection (also known as ¹⁸F-DCFPyL or PyL) is a fluorinated small molecule PSMA-targeted PET imaging agent that enables visualization of lymph nodes, bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer.^{2,3}

PYLARIFY TruVu was developed to build on the success of PYLARIFY®, the number one utilized PSMA PET imaging agent in the U.S. which has been used in over 900,000 scans across 48 states, Puerto Rico and Washington, D.C.⁴

INDICATION

PYLARIFY® (piflufolastat F 18) and PYLARIFY TRUVU™ (piflufolastat F 18) Injection are 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 and 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 and PYLARIFY TRUVU for imaging biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY and 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 and 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.

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 and PYLARIFY TRUVU, 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 $\leq 2\%$ 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 and PYLARIFY TRUVU in prostate cancer. The effect of these therapies on performance of PYLARIFY and PYLARIFY TRUVU PET has not been established.

To report suspected adverse reactions for PYLARIFY or 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](#) and [PYLARIFY TRUVU](#).

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as "can," "continue," "designed," "enables," "enhance," "ensuring," "expects," "improve," "intended," "next chapter," "phased," "potential," "prepare," "priority," "transition," "will," "work" and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) our ability to complete the technology transfer across our PET manufacturing facilities ("PMF") network for PYLARIFY TruVu and to obtain FDA approval for each PMF to manufacture PYLARIFY TruVu in accordance with our planned rollout plan and without disruption to our supply chain; (ii) our ability to have payers add HCPCS coding to their systems on a timely basis and to have customers adopt PYLARIFY TruVu; (iii) the ability of our PMF network to supply PYLARIFY TruVu to the market; (iv) the ability of PMF sites with high-energy cyclotrons to increase batch sizes or to reach more patients and serve broader geographic markets; (v) the intellectual property protection of PYLARIFY TruVu; and (vi) the risk and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada, Germany, Sweden, Switzerland and the United Kingdom, Lantheus has been providing radiopharmaceutical solutions for 70 years. For more information, visit www.lantheus.com.

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Multimedia assets for media are available [here](#).

¹American Cancer Society. Cancer Facts & Figures 2026. Atlanta: American Cancer Society; 2026.

²Pienta KJ, Gorin MA, Rowe SP, et al. A phase 2/3 prospective multicenter study of the diagnostic accuracy of prostate specific membrane antigen PET/CT with 18F-DCFPyL in prostate cancer patients (OSPReY). *J Urol*. 2021;206(1):52-61.

³Morris MJ, et al; CONDOR Study Group. Diagnostic Performance of 18F-DCFPyL-PET/CT in Men with Biochemically Recurrent Prostate Cancer: Results from the CONDOR Phase III, Multicenter Study. *Clin Cancer Res*. 2021 Jul 1;27(13):3674-3682. doi: 10.1158/1078-0432.CCR-20-4573. Epub 2021 Feb 23. PMID: 33622706; PMCID: PMC8382991.

⁴Data on file.

