Lantheus Welcomes CMS CY27 Final Rule Advancing Access to Diagnostic Radiopharmaceuticals

Nov 5, 2026

Final rule maintains separate payment for advanced diagnostic imaging agents and confirms PYLARIFY TruVu™ Transitional Pass-Through status through September 30, 2029; permanent HCPCS code A9613 now in effect

BEDFORD, Mass., Nov. 05, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus” or the “Company”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today welcomed the Centers for Medicare & Medicaid Services' (CMS) Calendar Year 2027 Hospital Outpatient Prospective Payment System (OPPS) final rule, which maintains separate payment for qualifying diagnostic radiopharmaceuticals. CMS also confirmed PYLARIFY TruVu (piflufolastat F 18) injection will receive Transitional Pass-Through (TPT) payment status through September 30, 2029, reflecting the full three-year TPT period available in the hospital outpatient setting. PYLARIFY TruVu has also been assigned permanent Healthcare Common Procedure Coding System (HCPCS) code A9613, effective October 1, 2026, facilitating billing and reimbursement for providers.

"The CMS final rule represents an important step in supporting patient access to advanced diagnostic imaging and the adoption of innovative radiopharmaceutical technologies," said Amanda Morgan, Chief Commercial Officer of Lantheus. “CMS’ confirmation that PYLARIFY TruVu will receive Transitional Pass-Through status for the full three-year period through September 30, 2029, together with its permanent HCPCS code, provides additional reimbursement certainty for hospitals while helping ensure patients can benefit from PSMA PET imaging to inform their prostate cancer care. Continued separate payment for diagnostic radiopharmaceuticals recognizes the important role advanced imaging plays in guiding treatment decisions and supporting patient care.”

Lantheus' commercial radiodiagnostic portfolio includes PYLARIFY®, PYLARIFY TruVu and NEURACEQ® (florbetaben F 18), alongside a broad pipeline of diagnostic radiopharmaceutical candidates across oncology, neurology and cardiology. The Company continues to support policies that enable appropriate reimbursement and patient access as new diagnostic radiopharmaceuticals reach clinical practice.

PYLARIFY TruVu (piflufolastat F 18) Injection

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 ≤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 "believe," "continue," "efforts," "enables," "expand," "improved," 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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