



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

COVERAGE AND ACCESS BEST PRACTICES

Important Information for Referring
Physicians and Imaging Centers



Physicians and staff can use this resource to streamline access and reimbursement for PYLARIFY® (piflufolastat F 18) Injection for appropriate patients.

Please see Indication and Important Safety Information on page 6 and read the accompanying full [Prescribing Information](#) also available at [PYLARIFY.com](https://www.pylarify.com).



LANTHEUS™



Steps to Improve Your Patient's Experience and Help Your Practice

Quick Reference Guide: Know Before You Scan

Step	Referring Physician	Imaging Center
1. Coordination of care	✓	✓
2. Verify the patient's benefits	✓	✓
3. Check the payer's policies	✓	✓
4. Check your plan contract	✓	✓
5. Set patient expectations	✓	✓
6. Talk with the patient about out-of-pocket costs	✓	✓

- 1. Coordination of care.** This entails ensuring all paperwork between your office and the imaging center is in order. Also determine if any other providers will be notified of the scan results. For reimbursement and patient cost-sharing purposes, check whether the scan will be performed in-network or out-of-network according to the patient's insurer/health plan.
- 2. Verify the patient's benefits.** After deciding that a PET/CT scan with PYLARIFY® is the appropriate next step in the patient's care, do a simple check of the patient's benefit eligibility to streamline the coverage process.
- 3. Check the payer's policies.** Each insurer/health plan's precertification or prior authorization policies may be different. Remember that the payer could work with a radiology benefits manager (RBM) who can influence coverage policy.
- 4. Check your plan contract.** Your provider contract will specify how to interface with your payer or RBM and how to determine your expected reimbursement.
- 5. Set patient expectations.** Educate the patient on key aspects of the insurance approval process. The physician's office will work with the payer to obtain an approval but remind the patient it may take time to receive approval. Even if the initial coverage request is denied, this can be appealed. Touch base with the patient throughout the process, especially if initial approval is denied and an appeal is filed.
- 6. Talk to your patient about out-of-pocket costs.** Help him understand if there will be any out-of-pocket costs based on his plan's benefit policy and what that may entail.

Insights on Seeking Prior Authorization (PA)



Consider checking with the patient's plan policy for PA guidelines



Obtaining a PA is often required before payment can be requested, but it does not guarantee payment



Identify a convenient imaging center within his plan's delivery network that will conduct the scan



When filing a PA for use of a particular medication, payers will ask for patient-specific data, site-of-care information, and types of therapies used (past/present). A Letter of Medical Necessity may also be required. These criteria may vary among payers



Filing a PA electronically, if available, may speed up processing and reduce complexity



Once the PA has been approved, record any authorization confirmation provided, and reverify that the patient continues to be eligible under his plan

For more information, **visit www.pylarify.com**



What to Do if the PA Is Denied

- 1** Closely review the reason for denial. The denial may be a result of an incomplete submission, incorrect PA form, or a payer's determination that PET/CT or PYLARIFY® may not be appropriate for the patient in question.
 - If not filed electronically, try utilizing this method for completing the form fields automatically through the electronic medical record.

- 2** Consider requirements for appealing the decision. The PA decision will usually specify whether the issue is related to coverage policy, clinical appropriateness, or another reason.

- 3** Determine which appeals process will be used. Typically, PA rejections can be appealed through (1) a paper or electronic filing of an appeal letter, or (2) contacting the payer to request an in-specialty peer-to-peer appeals session.
 - An in-specialty peer-to-peer appeal allows for the opportunity for you to advocate for your patient directly with another healthcare professional who has knowledge of the use of radiopharmaceuticals.

- 4** Follow the Explanation of Benefits guidelines. The Explanation of Benefits letter should indicate where the appeal should be filed, which form to use, and any deadlines.
 - A templated appeals letter from Lantheus, found at www.pylarify.com or available from your PAL, may help address potential reasons for the rejection.

- 5** Comply fully with the payers' PA appeals criteria. Many PA requests have been rejected simply for not supplying all of the information required by the payer.
 - Inclusion of detailed physician notes, reflecting the need for using PYLARIFY® and PET/CT, may be helpful.

- 6** Focus on demonstrating medical necessity. Identify or highlight any additional clinical information to the payer that was not previously provided or used in the initial decision.
 - Speak to previous therapeutic approaches, laboratory and biopsy results, patient-specific clinical notes, etc.

If a decision has not been rendered within a reasonable period (usually 30 days), follow up with the health plan/insurer to confirm that the appeals filing has been received and its status.

What if the PA Denial Is Upheld on Appeal?

If the payer rejects the appeal, there are still some tools available to the provider to obtain PYLARIFY® coverage for the patient. For example, another appeal can be filed with additional information, or the provider can request a review by a more senior plan executive.



The provider can ask for a one-time exception with the health plan.



The provider may request an external appeal (the process for which varies by state law), in which an independent third-party reviews the claim and issues a final decision that is binding.



In some cases, the patient can assist in the appeal. This is especially true in employer-sponsored plans, where the patient can contact the corporation's human resources department for assistance.



Contact your Patient Access Leader for additional support.

It is the provider's responsibility to ensure that correct PA, appeal, and denial rules are followed, including accurate completion and submission of requested information, in accordance with payer and/or health system policies.



Consider waiting to send a patient an invoice/bill until after you have exhausted all avenues of appeal for coverage denials.

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 $\leq 2\%$ 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.

For important risk and use information about PYLARIFY Injection, please see full Prescribing Information, at www.PYLARIFY.com, from your local representative, or call customer service at 1-800-964-0446.