PYLARIFY®
Piflufolastat F 18 Injection

Scheduling Sheet

If you would like to refer a patient for a PYLARIFY® PET/CT scan, please complete this form and send it to a PYLARIFY imaging site. You may attach any additional information to this form and send over as a package. Locate a PYLARIFY Imaging Site.

PATIENT INFORMATION

Patient name	Date of birth	Phone
Primary insurance	**Subscriber ID**	**Prior authorization #**
Secondary insurance	**Subscriber ID**	**Prior authorization #**

CLINICAL SIGNS/SYMPTOMS

Diagnosis

ICD-10 code:
- ☐ C61
- ☐ C79.82
- ☐ Z19.1
- ☐ Z19.2
- ☐ Z85.46
- ☐ R97.21

Other:

CPT code:
- ☐ 78811
- ☐ 78812
- ☐ 78813
- ☐ 78814
- ☐ 78815
- ☐ 78816

SPECIFIC REASON FOR PYLARIFY PET STUDY

- ☐ Suspected metastasis patients who are candidates for initial definitive therapy
- ☐ Suspected recurrence based on elevated serum prostate-specific antigen
- ☐ Suspected locally recurrent or new/progressive metastatic prostate cancer with persistent elevated PSA level

Special instructions:

Preferred method of results delivery:

PRIOR TREATMENT

Radical prostatectomy	○ Yes ○ No	Physician		Date
Radiation therapy to prostate	○ Yes ○ No	Physician		Date
Chemotherapy	○ Yes ○ No	Physician		Date
Other treatments	○ Yes ○ No	Physician		Date

(describe)

PREVIOUS SCANS

☐ CT	Notes		Date
☐ MRI	Notes		Date
☐ Bone scan	Notes		Date
☐ PSMA PET	Notes		Date
☐ Other	Notes		Date

I verify that the above information is complete and accurate to the best of my knowledge and that I have prescribed PYLARIFY based on my independent professional judgment of medical necessity.

Physician or Advanced Practice Provider signature: Date NPI #

Questions regarding an exam? Contact: Email Phone

Please see Indications and Important Safety Information on page 2.
For important risk and use information about PYLARIFY Injection, please see Full Prescribing Information.

PATIENT PREPARATION AND PRECAUTIONS

Preparing for a PYLARIFY scan:

- There is no fasting requirement prior to the injection of PYLARIFY
- Patients are encouraged to be well hydrated prior to drug dosing and scan
- The recommended start time for image acquisition is 60 minutes after PYLARIFY injection, and the scan duration is 12 to 40 minutes

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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.

For important risk and use information about PYLARIFY Injection, please see Full Prescribing Information.

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