Austin Radiological Association

PYLARIFY PROSTATE STUDY
(F-18-piflufolastat)

Overview

- Piflufolastat F 18 binds to prostate-specific membrane antigen (PSMA) to indicate the presence of PSMA in tissues. Lesions should be considered suspicious if uptake is greater than physiologic uptake in that tissue or the adjacent background if no physiologic uptake is expected. Tumors that do not express PSMA will not be visualized. Increased uptake in tumors is not specific for prostate cancer.

Indications

- Pylarify® (piflufolastat F-18) 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.

Medicare Oncologic PET Reimbursement Guidelines:

Indication	CPT	Coverage Guidelines
Suspected **recurrent** prostate cancer	78815	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh
ICD-10	C61	Malignant neoplasm of prostate
	PS	Subsequent treatment strategy modifier

NOTE:
Private payer coverage for PET often reflects that of Medicare but may vary. Providers should obtain coverage and pre-authorization guidelines for PET from their private payers.

Examination Time

- Allow approximately 1.5 hours for the entire Pylarify PET/CT study.

- Prior to Scan: Allow 15 minutes for interview, IV, injection
- Image acquisition:
  1. 78815 (PET/CT skull base to mid-thigh)
     a. 12 - 40 minutes acquisition

Patient Preparation

- Adequately hydrate prior to administration of Pylarify and for the first few hours following administration to reduce radiation exposure
- Void bladder immediately prior to imaging.

Patient Uptake Phase

- 60 min uptake

Equipment & Energy Windows

- Imaging system:
  - Siemens Biograph Horizon PET-CT scanner.
  - GE Discovery ST PET-CT scanner.
- Collimators:
  - 3D mode (septa out or absent) *(Siemens Horizon 6 only has 3D function)*
  - 2D mode for GE Discovery ST, unless it has had the Dimension upgrade.

- Energy windows (may vary with manufacturer and machine design): 30% window centered at 511 keV.

Radiopharmaceutical, Dose, & Technique of Administration

- Radiopharmaceutical: F-18-piflufolastat

- Dosing:

	Siemens	**GE**
Average Adult	9 mCi (370 MBq)	9mCi (370MBq)

Pediatric Patients – not applicable

ARA RAM licensure allows +/- 20% dose variance.

- Technique of administration: Via standard intravenous injection or through an existing intravenous line.

Patient Positioning & Imaging Field

- Patient position: Supine, arms up
- Imaging field of view: Scan caudal-cranial from mid-thigh to vertex of skull.

Acquisition Protocol

- Have the patient empty his/her bladder before image acquisition.
- Begin image acquisition 60 minutes
- Imaging times:

Siemens Horizon

- Emission data acquisition: 2 minutes per bed unless system has variable time option. Scanning caudal-cranial:
  - Bed 1 – 2 minutes
  - Bed 2 – 2 minutes
  - Bed 3 – 2 minutes
  - Bed 4 – 2 minutes
  - Bed 5 – 2 minutes
  - Bed 6 – 2 minutes

GE Discovery ST

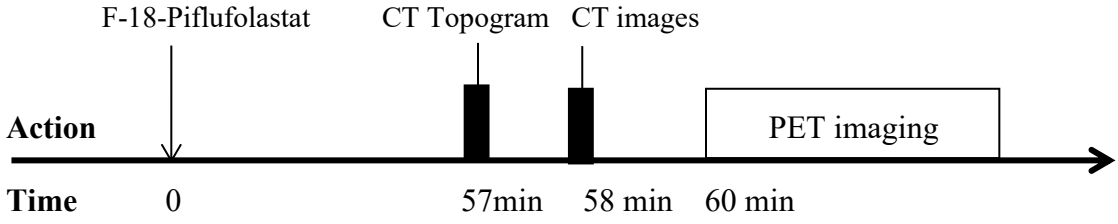
- Emission data acquisition: 5 minutes per bed

- Have the patient empty his/her bladder after image acquisition.

CT parameter values vary with patient size and machine specific factors:

1. Milliampere-seconds (mAs) and Kilovolts peak (kVp) guidelines:
   a. Average adult: 90 eff mAs, 130 kVp.
   b. Siemens Care Dose may be utilized if available.

Protocol Summary Diagram



Data Processing

- The PET images are reconstructed using iterative reconstruction. Siemens settings include: matrix 180, 4 iterations, 10 subsets, Gaussian filter, filter FWHM 3.0, zoom 1.0. GE settings include: 180 matrix, 4 iterations, 10 subsets, OSEM, post filter 86.0, loop filter 4.69, Z axis filter – yes, diameter 70, center L 0, center P 0, attenuation type is measured.
- A rotating maximum intensity projection (MIP) display and surface-rendered 3D displays facilitate lesion evaluation.

Principle Radiation Emission Data - F-18

- Physical half-life = 109.8 minutes.

Radiation	Mean % per disintegration	Mean energy (keV)
Positron	96.9	249.8
Gamma ±	193.5	511

Dosimetry - Computed Tomography

- Actual effective doses will depend on the user-specific exam protocols and the specific CT scanner used. It is important that each facility develop appropriate exam protocols and monitor the resultant patient doses for each machine in use.

Effective dose	rem	mSv
Diagnostic CT	0.15	1.5
Low dose CT	0.01	0.1

The (radiation absorbed) effective dose resulting from the administration of the recommended activity of 370 MBq of Pylarify is 4.3 mSv. For an administered activity of 370 MBq (10 mCi), the highest-magnitude radiation doses are delivered to the kidneys, liver and spleen: 45.5 mGy, 13.7 mGy, and 10 mGy, respectively. If a CT scan is simultaneously performed as part of the PET procedure, exposure to ionizing radiation will increase in an amount dependent on the settings used in the CT acquisition.

Table 1: Estimated Radiation Absorbed Doses in Various Organs/Tissues in Adults who Received Pylarify

Organ/Tissue	**Mean Absorbed Dose per Unit Administered Activity (microGy/MBq)**
Adrenal glands	13.1
Brain	2.1
Breasts	5.8
Gallbladder wall	14.1
Lower large intestine wall	7.3
Small intestine wall	8.9
Stomach wall	9.2
Upper large intestine wall	9.1
Heart wall	17.1
Kidneys	123.0
Liver	37.0
Lungs	10.2
Muscle	6.9
Ovaries	n/a
Pancreas	12.4
Red bone marrow	7.1
Osteogenic cells	9.9
Skin	5.2
Spleen	27.1
Testes	5.9
Thymus gland	7.0
Thyroid	6.2
Urinary bladder wall	7.2
Uterus	n/a
Total body	-
Effective dose	**11.6 (microSv/MBq)**