



Austin Radiological Association
POSLUMA PROSTATE STUDY
(F-18-FLOTUFOLASTAT)

Overview

- Flutufolastat 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

- POSLUMA (flutufolastat 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 POSLUMA 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 POSLUMA 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.
- Collimators:
 - 3D mode (septa out or absent) (*Siemens Horizon only has 3D function*)
- Energy windows (may vary with manufacturer and machine design): 30% window centered at 511 keV.

Radiopharmaceutical, Dose, & Technique of Administration

- Radiopharmaceutical: F-18-Flutofolastat

- Dosing:

| | |
|---------------|-----------------------|
| | <u>Siemens</u> |
| Average Adult | 8 mCi (296 MBq) |

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 through vertex of skull.

Acquisition Protocol

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

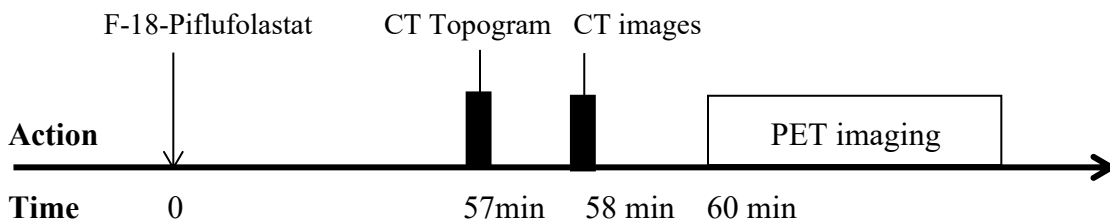
Siemens Horizon

- 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
- 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.
- 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.

| <u>Radiation</u> | <u>Mean % per disintegration</u> | <u>Mean energy (keV)</u> |
|------------------|----------------------------------|--------------------------|
| 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.

| <u>Effective dose</u> | <u>rem</u> | <u>mSv</u> |
|-----------------------|------------|------------|
| Diagnostic CT | 0.15 | 1.5 |
| Low dose CT | 0.01 | 0.1 |

The absorbed radiation dose for adult patients following intravenous injection of POSLUMA is shown in the table below. The effective radiation dose resulting for the administration of the recommended activity of 296 MBq of POSLUMA is 4.1 mSv. The radiation absorbed dose to the critical organs of adrenal glands, kidneys, and submandibular glands for the recommended activity of 296 MBq are 54.3 mGy, 51 mGy, and 43.8 mGy, respectively. When PET/CT is performed, exposure to radiations will increase by an amount dependent on the setting used in the CT acquisition.

| Table 1: Estimated Radiation Absorbed Doses in Various Organs/Tissues in Adults who Received POSLUMA | |
|---|---|
| Organ/Tissue | Absorbed Dose per Unit Administered Activity (microGy/MBq) |
| | Mean |
| Adrenal glands | 0.184 |
| Brain | 0.002 |
| Breasts | 0.004 |
| Gallbladder wall | 0.017 |
| Lower large intestine wall | 0.007 |
| Upper large intestine wall | 0.01 |
| Stomach wall | 0.012 |
| Small intestine wall | 0.012 |
| Heart wall | 0.02 |
| Kidneys | 0.172 |
| Liver | 0.062 |
| Lungs | 0.01 |
| Muscle | 0.006 |
| Lacrimal glands | 0.08* |
| Pancreas | 0.028 |
| Red bone marrow | 0.01 |
| Osteogenic cells | 0.012 |
| Skin | 0.002 |
| Spleen | 0.083 |
| Testes | 0.005 |
| Thymus gland | 0.01 |
| Thyroid | 0.01 |
| Urinary bladder wall | 0.006** |
| Sublingual glands | 0.065* |
| Parotid glands | 0.114* |
| Submandibular glands | 0.148* |
| Effective dose | 0.014** (microSv/MBq) |

*The absorbed dose value reflects self-irradiation only; no dose contribution from other regions to the Glands is added. ** A 1-hour bladder voiding interval is assumed.