Austin Radiological Association

AXUMIN PROSTATE STUDY
(F-18-Fluciclovine)

Overview

- Fluciclovine F 18 is a synthetic amino acid transported across mammalian cell membranes by amino acid transporters, such as LAT-1 and ASCT2, which are upregulated in prostate cancer cells. Fluciclovine F 18 is taken up to a greater extent in prostate cancer cells compared with surrounding normal tissues.

Indications

- Axumin™ (fluciclovine F-18) injection is indicated for positron emission tomography (PET) in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following treatment.

Medicare Oncologic PET Reimbursement Guidelines:

Indication	CPT	Coverage Guidelines
Suspected **recurrent** prostate cancer ICD-10	78815 C61	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh 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 hour for the entire Axumin 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. 20 - 30 minutes acquisition

Patient Preparation

- Instruct patients to avoid significant exercise for at least a day before the PET scan.

- Instruct patients not to eat or drink for at least 4 hours before the PET scan (other than small amounts of water for taking medications).

- Obtain Gleason Score and PSA levels.

Equipment & Energy Windows

- Imaging system:
  - Siemens Biograph 6 PET-CT scanner.
  - GE Discovery ST PET-CT scanner.
- Collimators:
  - 3D mode (septa out or absent) *(Siemens Biograph 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-fluciclovine

- Dosing:

	Siemens	**GE**
Average Adult	10 mCi (370 MBq)	10mCi (370MBq)

Pediatric Patients – not applicable

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

- Technique of administration: Whenever possible inject in RIGHT arm via standard intravenous injection or through an existing intravenous line.

Patient Positioning & Imaging Field

- Patient position: Supine, arms up after injection

- Imaging field of view: Scan caudal-cranial.

Acquisition Protocol

- Do **NOT** have the patient empty his/her bladder before image acquisition.

- Begin image acquisition 4 minutes +/- 1 minute following injection of F-18-fluciclovine

- Imaging times:

  Siemens Biograph 6

  - Emission data acquisition: 5 minutes per bed unless system has variable time option. Scanning caudal-cranial:

    - Bed 1 – 5 minutes
    - Bed 2 – 5 minutes
    - Bed 3 – 4 minutes
    - Bed 4 – 3 minutes
    - Bed 5 – 3 minutes
    - Bed 6 – 3 minutes

  GE Discovery ST

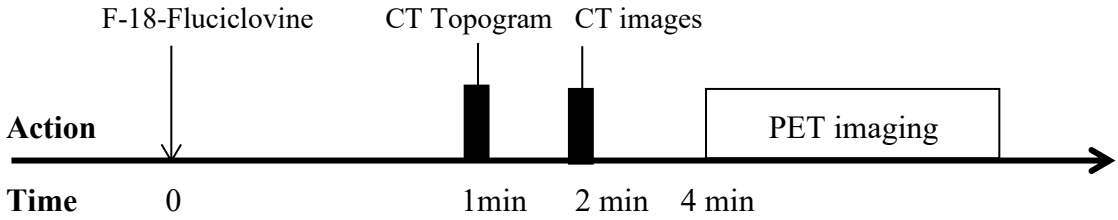
  - Emission data acquisition: 5 minutes per bed

- 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: 55 eff mAs, 120 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 168, 4 iterations, 10 subsets, Gaussian filter, filter FWHM 3.0, zoom 1.0. GE settings include: 128 matrix, 2 iterations, 20 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	100	250
Gamma ±	200	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.

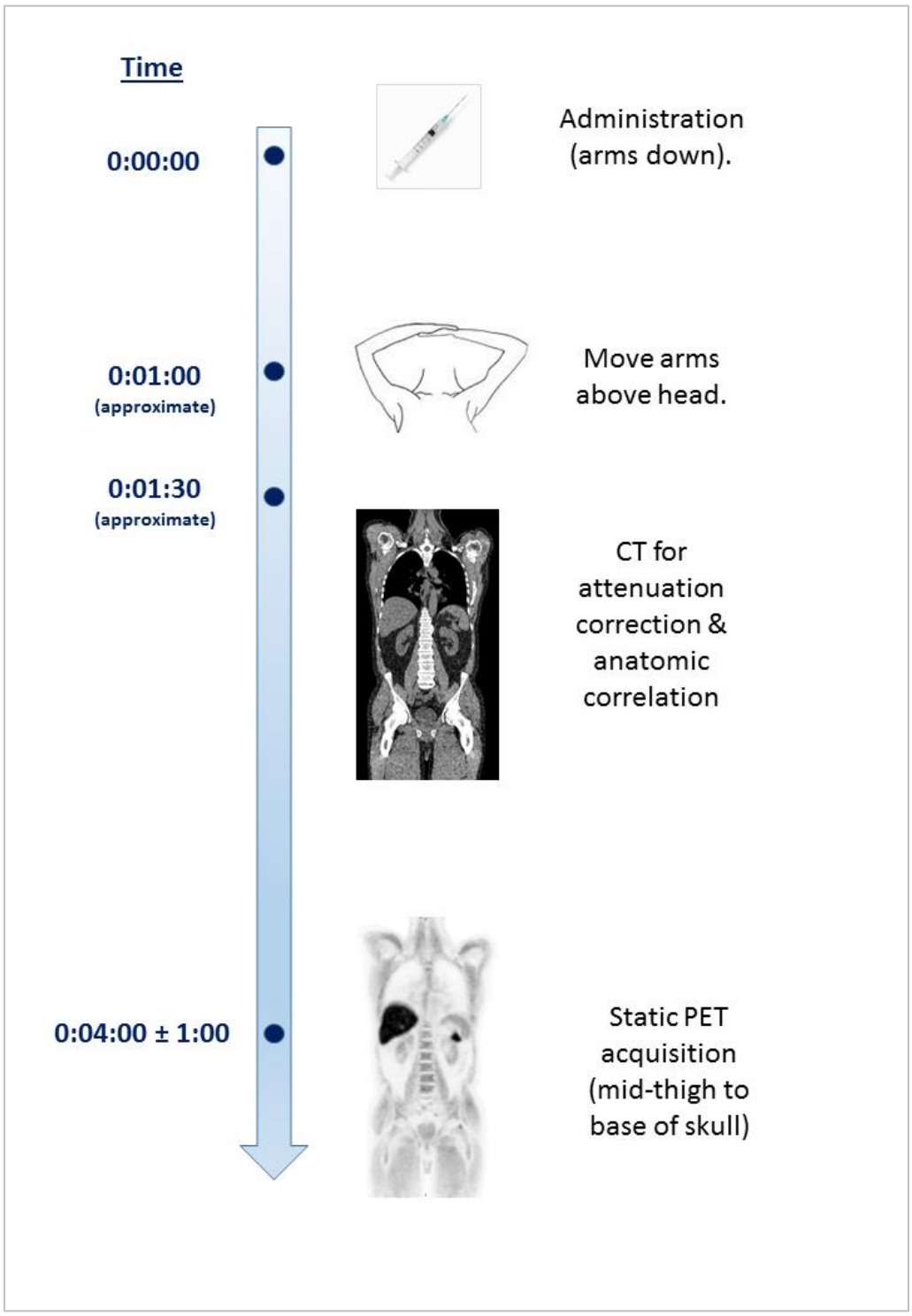
Effective dose	rem	mSv
Diagnostic CT	0.15	1.5
Low dose CT	0.01	0.1

The (radiation absorbed) effective dose resulting from the administration of the recommended activity of 370 MBq of Axumin is 8 mSv. For an administered activity of 370 MBq (10 mCi), the highest-magnitude radiation doses are delivered to the pancreas, cardiac wall, and uterine wall: 38 mGy, 19 mGy, and 17 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 Axumin

Organ/Tissue	**Mean Absorbed Dose per Unit Administered Activity (microGy/MBq)**
Adrenal glands	16
Brain	9
Breasts	14
Gallbladder wall	17
Lower large intestine wall	12
Small intestine wall	13
Stomach wall	14
Upper large intestine wall	13
Heart wall	52
Kidneys	14
Liver	33
Lungs	34
Muscle	11
Ovaries	13
Pancreas	102
Red bone marrow	25
Osteogenic cells	23
Skin	8
Spleen	24
Testes	17
Thymus gland	12
Thyroid	10
Urinary bladder wall	25
Uterus	45
Total body	13
Effective dose	**22 (microSv/MBq)**

Appendix A


Time
0:00:00
Administration (arms down).
0:01:00 (approximate)
Move arms above head.
0:01:30 (approximate)
CT for attenuation correction & anatomic correlation
0:04:00 ± 1:00
Static PET acquisition (mid-thigh to base of skull)