Austin Radiological Association

cERianna™ BREAST STUDY
(F-18-fluoroestradiol)

Overview

- Fluoroestradiol F 18 has a high binding affinity for estrogen receptors to detect estrogen receptor (ER)-positive lesions in tissues. All lesions with an uptake greater than background are considered as positive. Uptake of 18F-FES depends on ER density and binding function in tumors and physiologic tissue, including in liver, ovary and uterus. Detection of ER-positive tumors should be based on comparison with tissue background outside of organs with high physiologic uptake and regions with high activity due to hepatobiliary and urinary excretion.

Indications

- Cerianna (fluoroestradiol F-18) is indicated for use with positron emission tomography (PET) for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.

Medicare Oncologic PET Reimbursement Guidelines:

Indication	CPT	Coverage Guidelines
Detection of ER+ lesions as an adjunct to biopsy for recurrent or metastatic breast 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
	C50.9	Malignant neoplasm of the breast of unspecified site
ICD-10	Z17.0	Estrogen receptor positive status [ER+]
Modifier	PS	Subsequent treatment strategy modifier
	KX	For >3 oncologic PET scans

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 Cerianna 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 - 30 minutes acquisition
        b. Scan top of skull to close to knees as possible

Patient Preparation

- No fasting is required.
- Adequately hydrate prior to administration of Cerianna and for the first few hours following administration to reduce radiation exposure.
- Void bladder immediately prior to imaging.
- Recommend no Tamoxifen for 8 weeks
- Recommend no Fulvestrant for 28 days.
- Advise pregnant patients of the potential risks of fetal exposure to radiation.
- Advise lactating patients to avoid breastfeeding for 4 hours after dose administration in order to minimize radiation exposure to a breastfed infant.

Patient Uptake Phase

- 60 min uptake (20-to-80-minute window)

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-fluoroestradiol

- Dosing:

	Siemens	**GE**
Average Adult	6 mCi (222 MBq)	6mCi (222MBq)
Pediatric Patients – not applicable		

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

- Technique of administration: over 1 – 2 minutes via standard intravenous injection or through an existing intravenous line. May QS dose up in volume.

Patient Positioning & Imaging Field

- Patient position: Supine, arms up

- Imaging field of view: Scan craniocaudal. Top of skull to close to knees.

Acquisition Protocol

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

- Begin image acquisition 60 minutes

- Imaging times:
    ### Siemens Horizon
    ➢ Emission data acquisition: 2-3 minutes per bed unless system has variable time option. Scanning craniocaudal:

    - 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: 3 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.
   c. Siemens Care Dose may be utilized if available.

Protocol Summary Diagram

	F-18-Cerianna		CT Topogram	CT images	
Action					PET imaging
Time	0		56 min	58 min	60 min
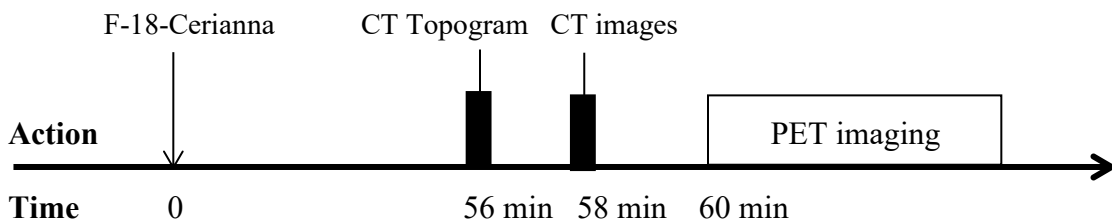
Data Processing

- The PET images are reconstructed using iterative reconstruction. Siemens settings include: matrix 180, 4 iterations, 10 subsets, Gaussian filter, filter FWHM 5.0, 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 222 MBq of Cerianna is 4.9 mSv. For an administered activity of 222 MBq (6 mCi), the highest-magnitude radiation doses are delivered to the liver, gallbladder and uterus: 24.9 mGy, 20.2 mGy, and 7.7 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 2. Principal Radiation Produced From Decay of Fluorine 18 Radiation

Radiation	Energy Level (keV)	% Abundance Positron
Positron	249.8	96.9
Gamma	511	193.5

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	0.023
Brain	0.01
Breasts	0.009
Gallbladder wall	0.102
Lower large intestine wall	0.012
Small intestine wall	0.027
Stomach wall	0.014
Upper large intestine wall	0.03
Heart wall	0.026
Kidneys	0.035
Liver	0.126
Lungs	0.017
Muscle	0.021
Ovaries	0.018
Pancreas	0.023
Red bone marrow	0.013
Osteogenic cells	0.014
Skin	0.005
Spleen	0.015
Testes	0.012
Thymus gland	0.014
Thyroid	0.012
Urinary bladder wall	0.05
Uterus	0.039
Lens	0.009
Effective dose	**0.022 (mSv/MBq)**