Austin Radiological Association

ILLUCCIX PROSTATE STUDY
(Ga-68 Gozetotide a.k.a. PSMA-11)

Overview

- Illuccix Ga-68 gozetotide 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

- Illuccix Ga-68 gozetotide 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:

- **Traditional Medicare or Self-Pay initially. Anticipate July 2022 HCPCS code.**

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 Illuccix 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. 18 - 40 minutes acquisition

Patient Preparation

- Adequately hydrate prior to administration of Illuccix 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 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: Ga-68 gozetotide (a.k.a. PSMA-11)
- Dosing:

	Siemens	**GE**
Average Adult	5 mCi (370 MBq)	5 mCi (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.
- The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of < 1%.

Patient Positioning & Imaging Field

- Patient position: Supine, arms up
- Imaging field of view: Scan mid thighs to vertex of skull; scanning caudocranially.

Acquisition Protocol

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

Siemens Horizon

- Emission data acquisition: 3 minutes per bed for patients <250lbs.
  4 minutes per bed for patients 250 ≥
- scanning caudal-cranial

GE Discovery ST

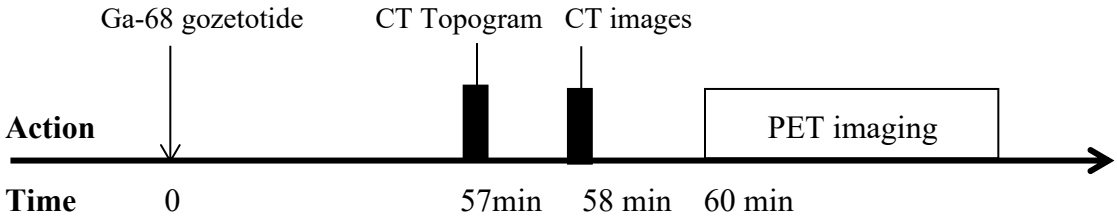
- Emission data acquisition: 4 minutes per bed

- Have the patient void frequently 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, 110-130 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 – Ga-68

- Physical half-life = 68 minutes.

Radiation	Mean % per disintegration	Mean energy (keV)
Beta +	88.0	836.0
Beta +	1.1	352.6
Gamma (Positron)	178.0	511.0
Gamma	3.0	1077.0
X-ray	2.8	8.6
X-ray	1.4	8.6

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 259 MBq (7 mCi) of Illuccix is 4.4 mSv. For an administered activity of 259 MBq (7 mCi), the highest-magnitude radiation doses are delivered to the kidneys, urinary bladder and spleen: 96.2 mGy, 25.4 mGy, and 16.8 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 Illuccix (Ga68 Gozetotide)

Organ/Tissue	**Mean Absorbed Dose per Unit Administered Activity (mGy/MBq)**
Adrenal glands	0.0156
Brain	0.0104
Breasts	0.0103
Gallbladder wall	0.0157
Lower large intestine wall	0.0134
Small intestine wall	0.014
Stomach wall	0.0129
Upper large intestine wall	n/a
Heart wall	0.012
Kidneys	0.3714
Liver	0.0409
Lungs	0.0111
Muscle	0.0103
Ovaries	n/a
Pancreas	0.0147
Red bone marrow	0.0114
Osteogenic cells	n/a
Skin	0.0091
Spleen	0.065
Testes	0.0111
Thymus gland	0.0105
Thyroid	0.0104
Urinary bladder wall	0.0982
Uterus	n/a
Total body	0.0143
Effective dose	**0.0169 (mSv/MBq)**