

Cerianna (FES) PET/CT Dictation guide



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

Intended to help guide you through your Cerianna (FES) interpretations.

Clinical history:

- Relevant clinical history
- Stage, histology, receptor status (ER, PR, HER2)
- Type/duration of current therapy
 - Indicate if recent treatment with SERM/SERD and duration of medication withdrawal
 - Before administering Cerianna, discontinue drugs that bind to the ER, such as SERMs and SERDs, for at least five biological half-lives
- Indicate clinical scenario: Why is scan being performed?

Comparison:

- Baseline comparison/correlative studies (if applicable): MRI, bone scan, CT, FDG, Cerianna (FES)
 - Identify concordance and discordance between images

Radiopharmaceutical:

- Administered activity ([3-6]mCi F-18 FES) and site of injection of Cerianna (FES)
- Cerianna (FES) uptake time (20-80 min) — indicate imaging start time post injection

Scanner type:

- Camera make/model [PET/CT scanner]

Technique:

- Following intravenous administration of radiotracer and after a standard delay (20-80 min acceptable), PET data was acquired from top of the skull through the proximal thighs (or to knee) and reconstructed in sagittal, axial, and coronal planes. CT scan done according to ALARA.

Findings:

- Normal biodistribution is identified in the liver, bowel, kidneys, and bladder
- Identify any infiltration of dose
- Report visual assessment in comparison to blood pool and liver
- Note any other normal or abnormal areas of uptake such as endometrial, ovarian, or diffuse pulmonary
- Lesion by lesion analysis

Impression:

- ER+ disease identified: Please note any Cerianna avid lesions/areas.
 - Uptake is considered positive when based in comparison with tissue background outside of organs with high physiologic uptake.
 - *Please remember that there is low sensitivity of Cerianna to characterize metastatic liver lesions¹*
- ER+ disease NOT identified: No Cerianna avid lesions/areas noted.
- Note any discordance observed in comparison to other imaging modalities

Please refer to the SNMMI Procedure Standard/EANM Practice Guideline for Estrogen Receptor Imaging of Patients with Breast Cancer Using 16a-[18F]Fluoro-17b-Estradiol PET for additional information.²

References: 1. Boers et al. *Diagnostics*. 2021;11: 2019. 2. Mankoff D, Balogová S, Dunnwald L, et al. Summary: SNMMI Procedure Standard/EANM Practice Guideline for Estrogen Receptor Imaging of Patients with Breast Cancer Using 16a-[18F]Fluoro-17β-Estradiol PET. *J Nucl Med*. 2024;65(2):221-223. Published 2024 Feb 1. doi:10.2967/jnumed.123.266938.

Important Safety Information and a link to the full prescribing information can be found on page 3.

Cerianna (FES) PET/CT dictation template



The molecular imaging diagnostic agent that helps support clinical evaluation and confidence in diagnosis for patients with ER+ recurrent or metastatic breast cancer.

Replace anything in the brackets with patient information, scan details, and your image interpretation.

Clinical history: *[Input patient clinical history, including pathology and reason for scan.]*

Comparison: *[Input any previous image findings.]*

Radiopharmaceutical: *[]mCi F-18 FES.*

Scanner type: *Camera make/model [PET/CT scanner]*

Technique: Following intravenous administration of radiotracer and after a standard delay of *[20-80 mins]*, PET data was acquired from the skull vertex through the proximal thighs *[or the knee]* and **reconstructed in sagittal, axial, and coronal planes. CT scan done according to ALARA.**

Findings:

Brain: *[No suspicious foci.]*

Neck: *[No suspicious foci.]*

Chest: *[No suspicious foci.]*

Abdomen/Pelvis: *[No suspicious foci.]* Physiologic radiotracer accumulation is seen in the liver, bowel, kidneys, ureters, and bladder.

Bones: *[No suspicious foci.]*

Impression: *[Insert scan impression here.]*

Important Safety Information

INDICATIONS AND USAGE

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

Limitations of Use:

Tissue biopsy should be used to confirm recurrence of breast cancer and to verify ER status by pathology. CERIANNA is not useful for imaging other receptors, such as human epidermal growth factor receptor 2 (HER2) and the progesterone receptor (PR).

Important Safety Information

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

Risk of Misdiagnosis

Inadequate Tumor Characterization and Other ER-Positive Pathology

- Breast cancer may be heterogeneous within patients and across time. CERIANNA images ER and is not useful for imaging other receptors such as HER2 and PR. The uptake of fluoroestradiol F 18 is not specific for breast cancer and may occur in a variety of ER-positive tumors that arise outside of the breast, including from the uterus and ovaries. Do not use CERIANNA in lieu of biopsy when biopsy is indicated in patients with recurrent or metastatic breast cancer.

False Negative CERIANNA Scan

- A negative CERIANNA scan does not rule out ER-positive breast cancer. Pathology or clinical characteristics that suggest a patient may benefit from systemic hormone therapy should take precedence over a discordant negative CERIANNA scan.

Radiation Risks

- Diagnostic radiopharmaceuticals, including CERIANNA, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe drug handling and patient preparation procedures (including adequate hydration and voiding) to protect patients and health care providers from unintentional radiation exposure.

Pregnancy Status

- Assessment of pregnancy status is recommended in females of reproductive potential before administering CERIANNA.

ADVERSE REACTIONS

- In Clinical Trials (n=1207) the most common adverse reactions seen occurred at a rate < 1% were injection-site pain and dysgeusia.

Please see full Prescribing Information [here](#), for additional important safety information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

- All radiopharmaceuticals, including CERIANNA, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of radiation dose. Advise a pregnant woman of the potential risks of fetal exposure to radiation from administration of CERIANNA.
- There are no available data on CERIANNA use in pregnant women. No animal reproduction studies using fluoroestradiol F 18 have been conducted to evaluate its effect on female reproduction and embryo-fetal development.
- The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Lactation

Risk Summary

- There are no data on the presence of fluoroestradiol F 18 in human milk, or its effects on the breastfed infant or milk production. Lactation studies have not been conducted in animals. Advise a lactating woman to avoid breastfeeding for 4 hours after CERIANNA administration in order to minimize radiation exposure to a breastfed infant.

Pediatric Use

- The safety and effectiveness of CERIANNA in pediatric patients have not been established.

Geriatric Use

- Clinical studies of fluoroestradiol F 18 injection did not reveal any difference in pharmacokinetics or biodistribution in patients aged 65 and over.

DRUG INTERACTIONS

Systemic Endocrine Therapies that Bind to ER

- Drugs that bind to the ER, including SERMs and SERDs, may compete with the binding of fluoroestradiol F18 and may reduce detection of ER-positive lesions with CERIANNA.
- Before administration of CERIANNA, discontinue drugs that bind to the ER, such as SERMs and SERDs, for at least 5 biological half-lives: (e.g., elacestrant for 11 days, tamoxifen for 8 weeks and fulvestrant for 28 weeks).

