Guidelines for using FES PET/CT

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

FES PET/CT is included as an imaging option for systemic staging of ER+ recurrent / stage IV (M1) disease in the NCCN Guidelines® for Breast Cancer

Recurrent/stage IV (M1) disease

Clinical stage

Stage IV (M1) or recurrent ›

Workup

History and physical exam

Discuss goals of therapy, adopt shared decision-making, and document course of care

CBC

Comprehensive metabolic panel, including liver function tests and alkaline phosphatase

Imaging for systemic staging:
- Chest diagnostics CT ± contrast
- Abdomen ± pelvis diagnostic CT with contrast or MRI with contrast
- Brain MRI with contrast if suspicious CNS symptoms
- Spine MRI with contrast if back pain or symptoms of cord compression
- Bone scan or sodium fluoride PET/CT (NCCN Category 2B)
- Useful in certain circumstances: FDG PET/CT **(consider FES PET/CT for ER-positive disease and lobular histology)**
- X-rays of symptomatic bones and long and weight-bearing bones abnormal on bone scan

Biomarker testing
- Biopsy of at least first recurrence of disease (consider re-biopsy if progression)
- Evaluation of ER/PR and HER2 status
- Comprehensive germline and somatic profiling to identify candidates for targeted therapies

Genetic counseling if patient is at risk for hereditary breast cancer

Assess for distress

NCCN Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

SNMMI appropriate use criteria[1]

4 scenarios for appropriate use

Assessing ER status in lesions that are difficult to biopsy, or when biopsy is nondiagnostic

After progression of metastatic disease, for considering second line of endocrine therapy

At initial diagnosis of metastatic disease, for considering endocrine therapy

Detecting ER status when other imaging tests are equivocal or suggestive

1. Ulaner GA, Lin K, Toriihara A, et al. Summary: Appropriate use criteria for estrogen receptor–targeted PET imaging with 16α-[18F]-fluoro-17β-fluoroestradiol. J Nucl Med. 2023;64(3):351-354. doi:10.2967/jnumed.122.265847.

CERIANNA™
(FLUOROESTRADIOL F 18) INJECTION

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.

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).

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

Acronym definitions
ER, estrogen receptor; **FES,** fluoroestradiol; **FDG,** fluorodeoxyglucose; **PET**, positron emission tomography; **CT**, computed tomography; **MBC**, metastatic breast cancer; **MRI**, magnetic resonance imaging; **NCCN**, National Comprehensive Cancer Network; **M1**, metastasis one; **CBC**, complete blood count; **CNS**, central nervous system; **SNMMI**, Society of Nuclear Medicine and Molecular Imaging

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