CERIANNA™
(FLUOROESTRADIOL F 18) INJECTION

Cerianna (FES) PET

GE HealthCare

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).

CONTRAINDICATIONS
None.

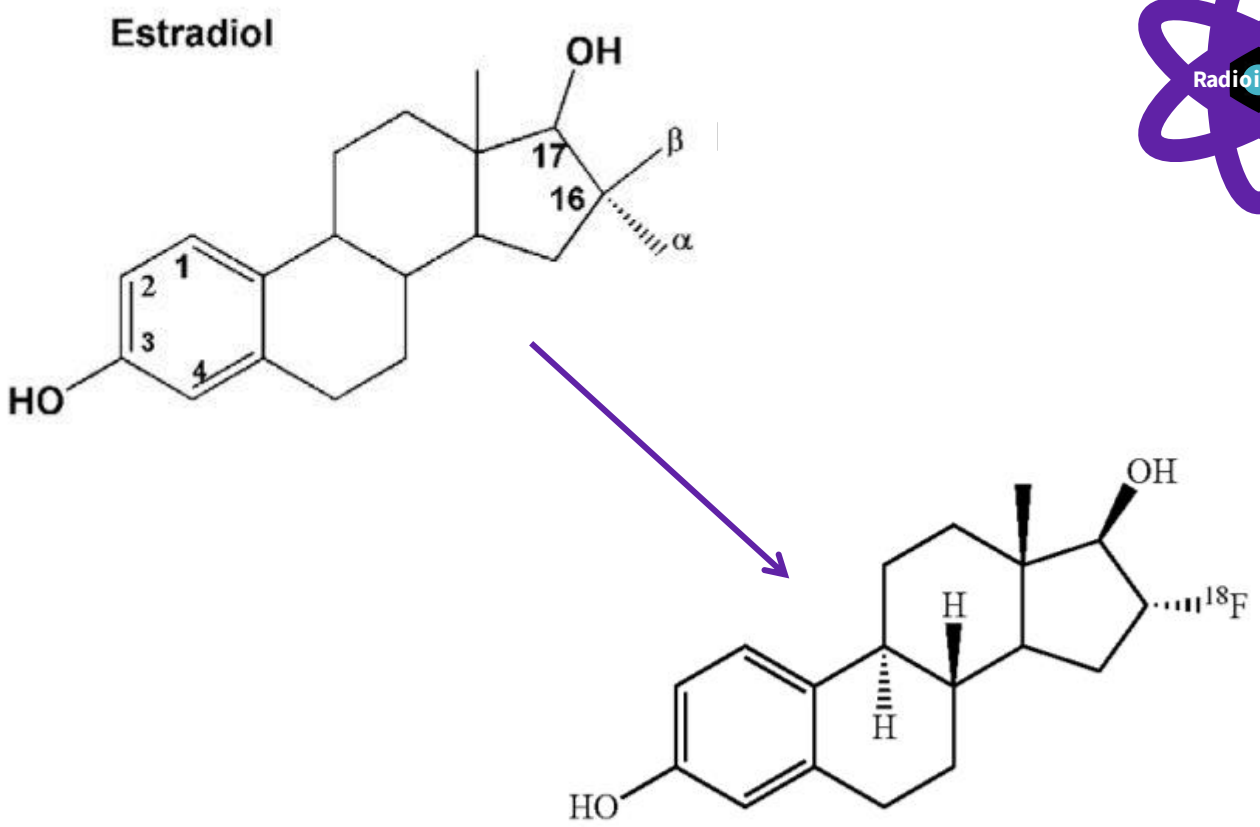
WARNINGS AND PRECAUTIONS
Risk of Misdiagnosis

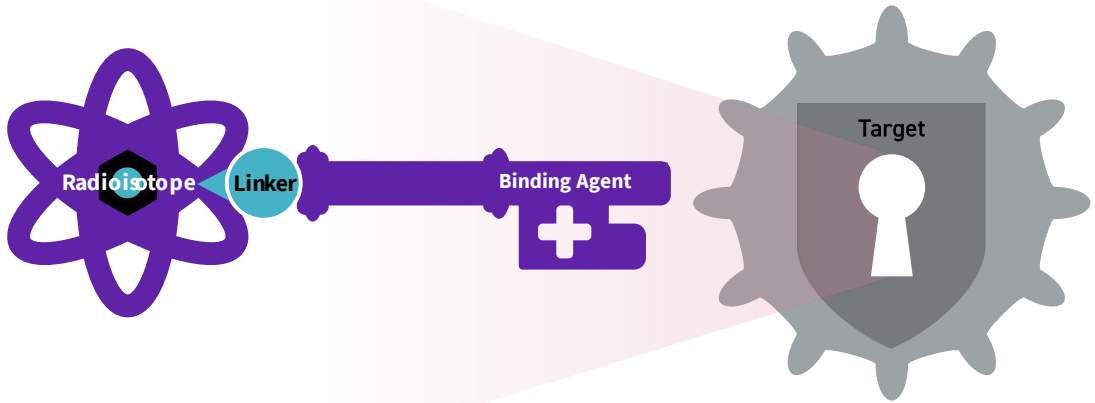
Inadequate Tumor Characterization and Other ER-Positive Pathology: Breast cancer may be heterogeneous within patients and across time. CERIANNA images ER and is not useful for imaging other receptors such as HER2 and PR. The uptake of fluoroestradiol F 18 is not specific for breast cancer and may occur 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.

Mechanism of action

Estrogen receptor (ER) targeted imaging





F 18 Fluoroestradiol PET

ER, estrogen receptor; **PET,** positron emission tomography.

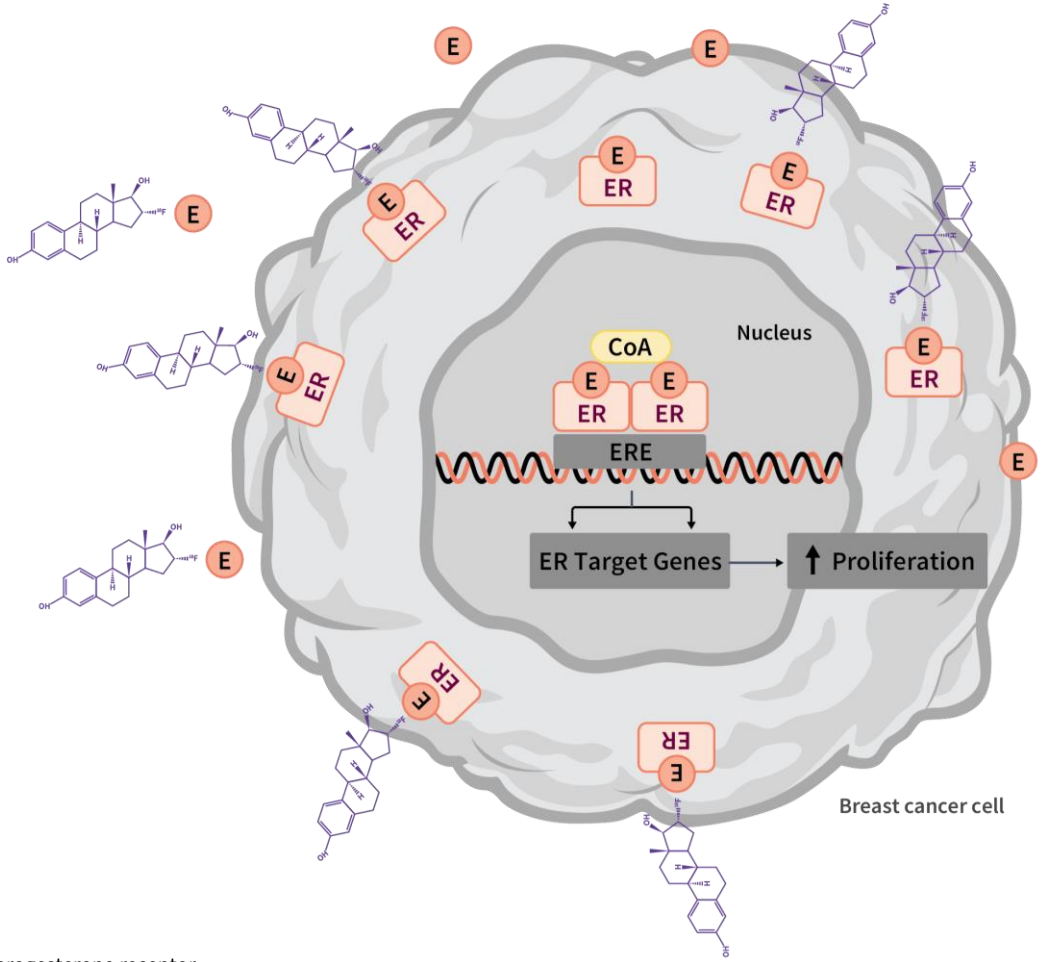
Image credit: Dr. Gary Ulaner, Hoag Family Cancer Institute.

Important Safety Information and a link to the full prescribing information can be found on slides 21-23

Unique mechanism of action that detects ER+ lesions

F18 fluoroestradiol (FES) mechanism of action[1]

- FES is a radiolabeled estrogen analog that binds to functioning estrogen receptors with relatively high (60-100%) affinity[1,2]
- The labeling of fluoroestradiol with F 18, a radioactive isotope, enables PET imaging of lesions with functioning estrogen receptor imaging[1,2]
- FES uptake measured by PET in BC tumors is directly proportional to tumor ER expression measured by in vitro assays[1]
- FES is not useful for imaging other receptors, such as HER2 and PR, or for assessing regions with high activity due to hepatobiliary and urinary excretion[1,3]



*__CoA,__ coenzyme A; __E,__ estradiol; __ER,__ estrogen receptor; __ERE,__ estrogen response element, __HER2,__ human epidermal growth factor receptor 2; __PR,__ progesterone receptor

1. Cerianna (FES) PET Prescribing Information. Arlington Heights, IL: GE HealthCare, 2024. **2.** van Kruchten M, de Vries EFJ, Glaudemans AWJM, et al. PET imaging of oestrogen receptors in patients with breast cancer. Lancet Oncol. 2013;14(11):e465-e475. doi:10.1016/S1470-2045(13)70374-7. **3.** van Kruchten M, Glaudemans AWJM, de Vries EFJ, et al. Assessment of estrogen receptor expression in epithelial ovarian cancer patients using 16α-[18F]-fluoro-17β-estradiol PET/CT. J Nucl Med. 2012;53(2):182-190. doi:10.2967/jnumed.111.094243

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Note difference from 18F-FDG normal distribution

	FES	FDG
Hepatobiliary system	Physiological tracer uptake seen in liver with biliary excretion into the bowels	Modest uptake, but significantly lower than FES
Urinary system	Physiological tracer excretion seen in renal PCS and bladder	Similar uptake
Background	Low background uptake in brain, muscles and blood pool	High uptake in brain and heart. Minimal to modest uptake in muscles

FES
(detects ER+ lesions)

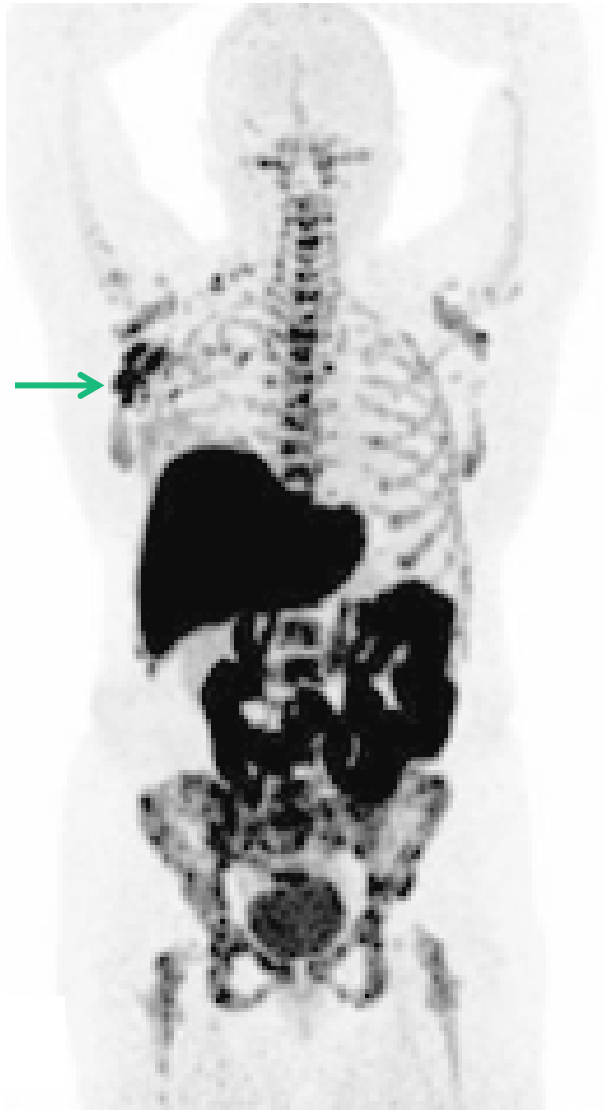
FDG
(demonstrates glucose metabolism)

FES, Fluoroestradiol; **FDG,** fluorodeoxyglucose; **PCS,** pelvicalyceal system; **ER+,** estrogen receptor positive

1. Boers J, de Vries EFJ, Glaudemans AWJM, et al. Analyzing the estrogen receptor status of liver metastases with [18F]-FES-PET in patients with breast cancer. Eur J Cancer. 2020;126:11-20. doi:10.1016/j.ejca.2020.07.021

Lesions greater than background are considered positive

- Uptake depends on **ER density** and **function** in tumors and physiologic tissue, including in liver, ovary, and uterus[1]
- 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[1]
- There are nuances within interpreting Cerianna (FES) PET SUV values[2]
  - Avoid Cerianna (FES) PET scan interpretations based solely on SUV



ER, estrogen receptor; **FES,** fluoroestradiol; **PET,** positron emission tomography; **SUV,** standardized uptake value.

1. Cerianna (FES) PET Prescribing Information. Arlington Heights, IL: GE HealthCare, 2024. **2.** Chae SY, Ahn SH, Kim SB, et al. Diagnostic accuracy and safety of 16α-[18F]fluoro-17β-oestradiol PET-CT for the assessment of oestrogen receptor status in recurrent or metastatic lesions in patients with breast cancer: a prospective cohort study. Lancet Oncol. 2019;20(4):546-555. doi:10.1016/S1470-2045(18)30908-6

Image credit: Boers et. Al., Eur J Cancer 2020.

Diagnostic accuracy

IMPACT-MBC study: diagnostic accuracy analysis[1]

Diagnostic accuracy for whole-body ER status assessment in MBC

Agreement between whole-body FES PET/CT assessment and IHC assay

Qualitative FES PET/CT assessment predicted ER expression in the biopsied metastasis with good accuracy†

*The F18 fluoroestradiol administered in this study was not equivalent to the FDA-approved formulation of Cerianna (FES) PET.

MBC, metastatic breast cancer; **ER,** estrogen receptor; **FES,** fluoroestradiol; **PET,** positron emission tomography; **CT,** computed tomography; **IHC,** immunohistochemistry; **PPV,** positive predictive value; **NPV,** negative predictive value.

1. van Geel JJL, de Vries EFJ, Glaudemans AWJM, et al. Clinical validity of 16α-[18F] fluoro-17β-estradiol positron emission tomography/computed tomography to assess estrogen receptor status in newly diagnosed metastatic breast cancer. J Clin Oncol. 2022;40(31):3642-3652. doi:10.1200/JCO.22.00400

Diagnostic Accuracy of FES PET/CT in ER+ Breast Cancer

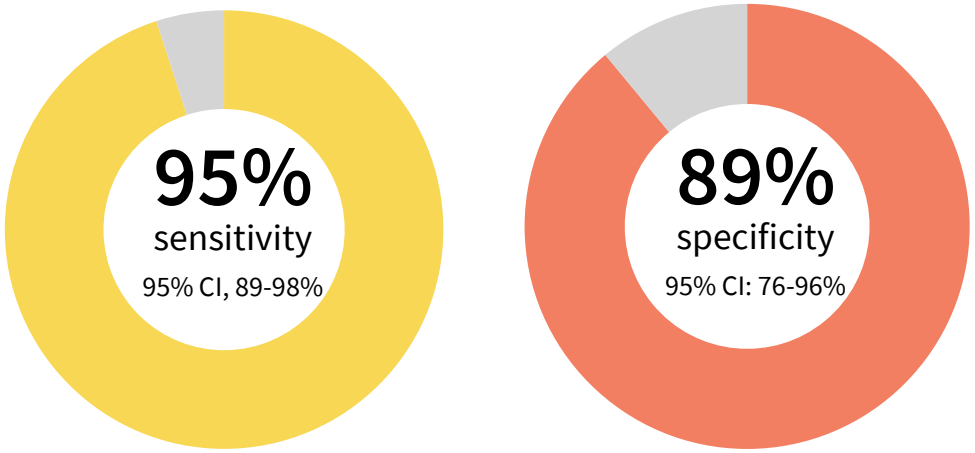
Scan to review publication abstract

FES PET/CT was evaluated for its ability to detect recurrence or de novo metastasis in 162 ER+ breast cancer patients

- Compared FES PET/CT to standard-of-care imaging across patient and region levels

FES PET/CT demonstrated high diagnostic accuracy and outperformed standard imaging in key anatomical regions.

- **Detection rate:** 92% (95% CI, 89%-94%) for FES vs. 83% (95% CI, 79%-87%) for standard-of-care imaging (P < 0.001)



Study Limitations[1]:

Majority of reference standards based on imaging follow-up (81%) rather than biopsy (19%)

The standard-of-care imaging varied from patient to patient

This is a retrospective analysis of a prospective study

SOC imaging included: mammography, breast ultrasound, chest CT, abdominopelvic CT, bone scintigraphy, regional MRI, and FDG PET/CT

*The F18 fluoroestradiol administered in this study was not equivalent to the FDA-approved formulation of Cerianna (FES) PET.

FES, fluoroestradiol; **PET,** positron emission tomography; **CT,** computed tomography; **ER,** estrogen receptor.

1. Shin E et al. Diagnostic Accuracy of 18F-FES PET/CT for the Detection of Recurrent and Metastatic Breast Cancer. Clinical Nuclear Medicine. 2024;00(00):1–7. doi:10.1097/RLU.0000000000005447

Important Safety Information and a link to the full prescribing information can be found on slides 21-23

High diagnostic accuracy[2]

Case details[1]

- Patient is a female in her 50s with history of invasive lobular carcinoma
- She presented with a suspected recurrence and underwent FDG PET/CT and Cerianna (FES) PET/CT as part of a clinical trial

Cerianna (FES) PET scan was ordered to assess presence of ER and its ability to bind to estrogen.

FDG, fluorodeoxyglucose; **PET,** positron emission tomography; **CT,** computed tomography; **FES,** fluoroestradiol; **ER,** estrogen receptor.

1. Ulaner GA, Lin K, Toriihara A, et al. ER-targeted PET for initial staging and suspected recurrence in ER-positive breast cancer. JAMA Netw Open. 2024;7(7):e2423435. doi:10.1001/jamanetworkopen.2024.23435 **2.** van Geel JJL, de Vries EFJ, Glaudemans AWJM, et al. Clinical validity of 16α-[18F] fluoro-17β-estradiol positron emission tomography/computed tomography to assess estrogen receptor status in newly diagnosed metastatic breast cancer. J Clin Oncol. 2022;40(31):3642-3652. doi:10.1200/JCO.22.00400

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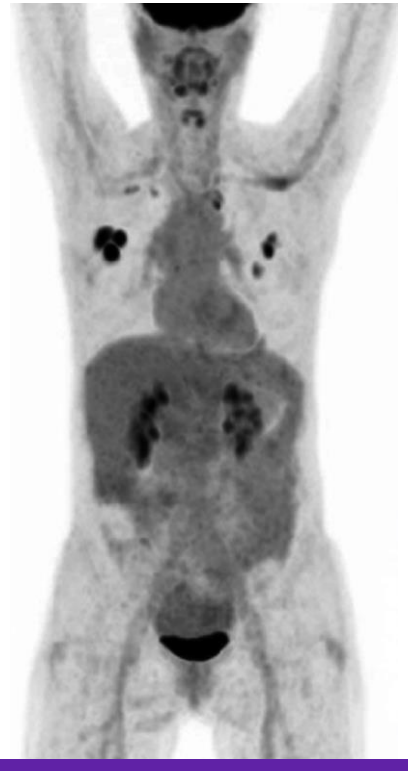
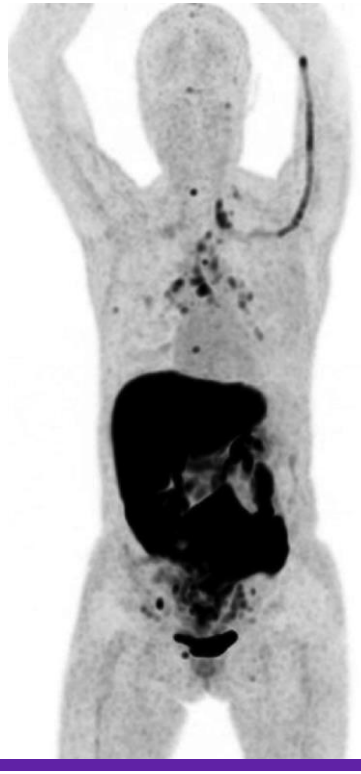
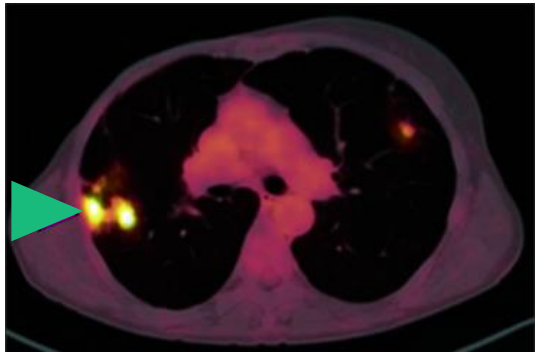
FDG PET/CT: MIP



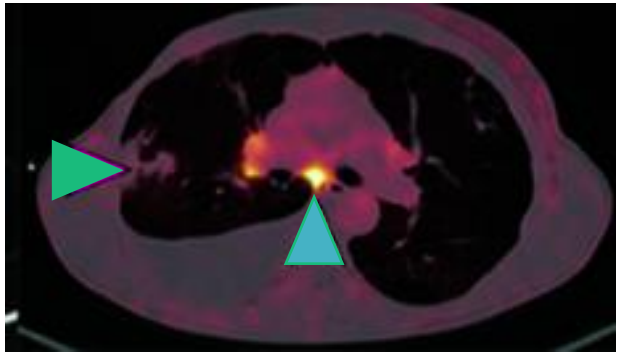
Cerianna (FES) PET/CT: MIP



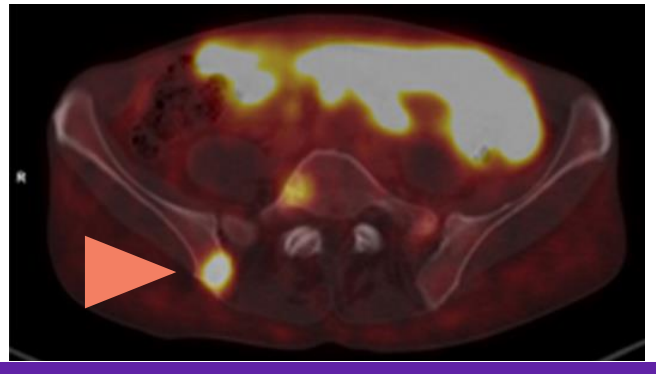
FDG–avid lung nodules



Cerianna (FES) negative lung nodules, positive lymph node



True positive osseous lesion on Cerianna (FES) PET/CT



Interpretation:

- FDG PET/CT showed avid lung nodules which were suspicious for malignancy
- Cerianna (FES) PET/CT demonstrated no avidity in the lung nodules but showed avid lymph nodes, gastric, and osseous foci which were suspicious for ER+ malignancy

Importance:

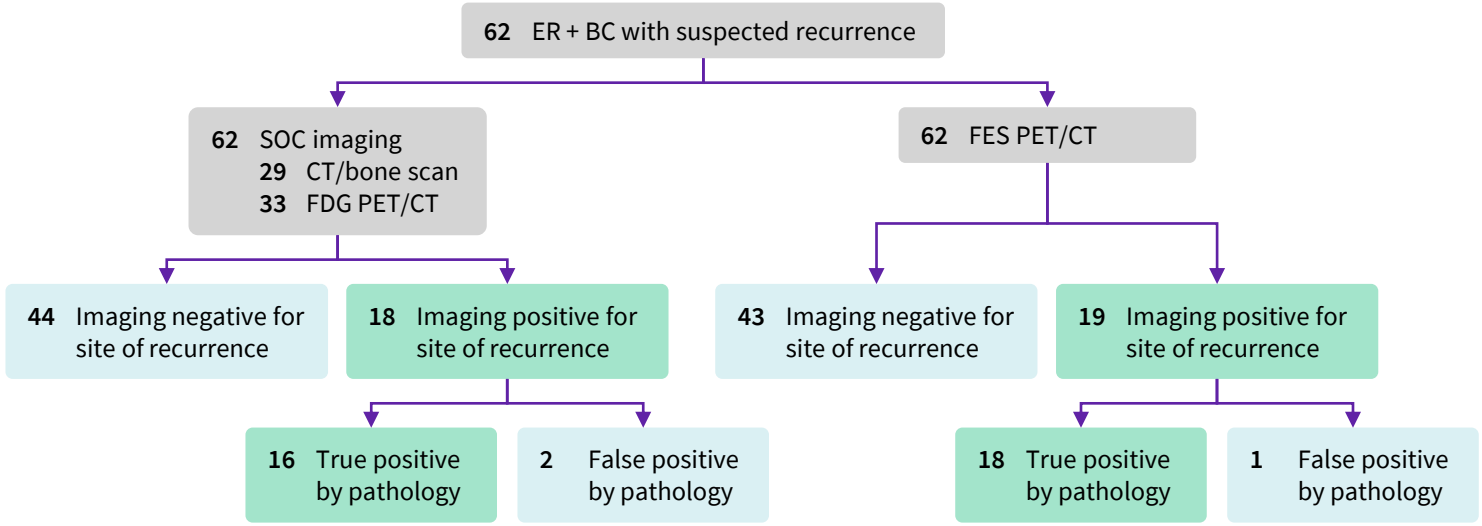
- The lung nodule was biopsied but found to represent benign granulomatous inflammation and thus a false positive on FDG PET/CT and true negative on Cerianna (FES) PET/CT
- Osseous focus was subsequently biopsied and proved to be an osseous metastasis and thus true positive on Cerianna (FES) PET and false negative of FDG PET/CT
- **Cerianna (FES) PET binds to the estrogen receptor with high affinity[1]**

FDG, fluorodeoxyglucose; **PET,** positron emission tomography; **CT,** computed tomography; **FES,** fluoroestradiol; **ER+,** estrogen receptor positive; **MIP**, Maximum intensity projection.

1. Katzenellenbogen JA. The quest for improving the management of breast cancer by functional imaging: the discovery and development of 16α-[18F]fluoroestradiol (FES), a PET radiotracer for the estrogen receptor, an historical review. Nucl Med Biol. 2021;92:24-37. doi:10.1016/j.nucmedbio.2020.02.007. **2.** Ulaner GA, Lin K, Toriihara A, et al. ER-targeted PET for initial staging and suspected recurrence in ER-positive breast cancer. JAMA Netw Open. 2024;7(7):e2423435. doi:10.1001/jamanetworkopen.2024.23435

Cerianna performs similar to standard of care imaging[1]

ER-targeted PET for suspected recurrence in ER-positive breast cancer



Inclusion criteria for cohort 2 were women aged 18 years or older with BC and suspected recurrent disease due to symptom, abnormal tumor marker, or equivocal imaging finding.

*Note: Cohort 1 included initial staging evaluation and is considered off-label. It is not discussed here.

ER, estrogen receptor; **PET,** positron emission tomography; **BC,** breast cancer; **LABC,** locally advanced breast cancer; **ER+,** estrogen receptor positive; **SOC,** standard of care; **CT,** computed tomography; **FDG,** fluorodeoxyglucose; **FES,** fluoroestradiol.

1. Ulaner GA, Lin K, Toriihara A, et al. ER-targeted PET for initial staging and suspected recurrence in ER-positive breast cancer. JAMA Netw Open. 2024;7(7):e2423435. doi:10.1001/jamanetworkopen.2024.23435

Discussion

This study provides comparative effectiveness research for FES PET/CT and suggests FES PET/CT may be considered in patients with ER-positive BC for evaluation of suspected recurrences.[1]

This study provides evidence that FES PET/CT performs comparably with current SOC imaging methods for evaluating suspected recurrences.[1]

This diagnostic study using pathological findings as the reference standard found no significant difference between FES PET/CT and current SOC imaging methods for the detection rate of distant metastases in patients with LABC or recurrences in patients with suspected recurrence.[1]

Limitations:

- Single-center design
- The patients included in the study had a lower disease rate than assumed during the study design, affecting the power for the primary aims; subgroup analyses were not powered to show differences

FES, fluoroestradiol; **PET,** positron emission tomography; **CT,** computed tomography; **SOC,** standard of care; **ER,** estrogen receptor; **BC,** breast cancer; **LABC,** locally advanced breast cancer.

1. Ulaner GA, Lin K, Toriihara A, et al. ER-targeted PET for initial staging and suspected recurrence in ER-positive breast cancer. JAMA Netw Open. 2024;7(7):e2423435. doi:10.1001/jamanetworkopen.2024.23435

Beyond Detection

Changing the diagnostic landscape for ER+ recurrent and metastatic breast cancer patients

Moving beyond "Where is it?" to "Is it ER+?"

	CT scan	FDG PET	FES PET
Mechanism of action	Uses X-rays[1]	Taken up by metabolically active cells[2]	Binds to estrogen receptors (ERs)[3]
What the image shows	Shape and size of tumor[2]	Metabolic activity[2]	ER+ tumor presence and the potential binding ability of ER[3]
Relevance to treatment	Evaluates solid tumor treatment response[2]	Provides information about treatment response[2]	May enable tailored treatment planning for breast cancer[3]

- In a study by Ryu et al., it was shown that the addition of FES PET in managing ER+ recurrent and metastatic breast cancers changes patient management 35% of the time.[3]
- Cerianna (FES) PET allows for more specific diagnostic insights, redefining and expanding the capabilities of imaging for breast cancer patients.

Access the publication to learn more

The F18 fluoroestradiol administered in this study was not equivalent to the FDA-approved formulation of Cerianna (FES) PET.

ER+, estrogen receptor-positive; **FES,** fluoroestradiol; **PET,** positron emission tomography; **MOA,** mechanism of action; **ET,** endocrine therapy

1. Johnson, T. R. C. (2012). Dual-energy CT: General principles. American Journal of Roentgenology, 199(Supplement), S3–S8. https://doi.org/10.2214/AJR.12.9116 **2.** Riedl CC, Weng AM, Wangerin K, et al. Comparison of FDG-PET/CT and contrast-enhanced CT for monitoring therapy response in patients with metastatic breast cancer. Eur J Nucl Med Mol Imaging. 2017;44(9):1428-1437. doi:10.1007/s00259-017-3703-7. **3.** Ryu J, Han S, Shin E, et al. Impact of 18F-FES PET/CT on clinical decisions in the management of recurrent or metastatic breast cancer. J Nucl Med. 2024;65(11):1689-1694. doi:10.2967/jnumed.124.267913.

Supporting guidelines

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

Useful in certain circumstances: Consider FES PET/CT for ER-positive disease and lobular histology

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

FES, fluoroestradiol; **PET,** positron emission tomography; **CT,** computed tomography; **ER,** estrogen receptor.

SNMMI AUC: 16α-^{18}F-Fluoro-17β-Fluoroestradiol (^{18}F-FES)[1]

Scan to review AUC summary

Scenario #	Description	Appropriateness	Score
8	Assessing ER status in lesions that are difficult to biopsy, or when biopsy is nondiagnostic	Appropriate	8
9	After progression of metastatic disease, for considering second line of endocrine therapy	Appropriate	8
10	At initial diagnosis of metastatic disease, for considering endocrine therapy	Appropriate	8
14	Detecting ER status when other imaging tests are equivocal or suspicious	Appropriate	8

SNMMI, Society of Nuclear Medicine and Molecular Imaging; **FES,** fluoroestradiol; **ER,** estrogen receptor; **PET**, positron emission tomography; **AUC,** appropriate use criteria.

1. Ulaner 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.

Product Information

Cerianna (FES) PET drug interactions[1]

Scan to review medications sheet

- Drugs that bind to the estrogen receptor (ER) may compete with the binding of fluoroestradiol F 18 and may reduce the detection of ER-positive lesions with Cerianna (FES) PET
- Before administering Cerianna (FES) PET, **discontinue** drugs that bind to the ER, such as SERMs and SERDs, for at least **five biological half-lives**

Approximate duration that therapy may reduce Cerianna (FES) PET uptake

	Five half-lives
tamoxifen	8 weeks
fulvestrant	28 weeks
elacestrant	11 days
imlunestrant	6.25 days

AIs and CDK 4/6 inhibitors do not need to be withdrawn. These agents deplete estrogen, but do not interfere with the ER or Cerianna (FES) PET binding[2,3]

FES, fluoroestradiol; **PET,** positron emission tomography; **ER,** estrogen receptor; **SERM,** selective estrogen receptor modulator; **SERD,** selective estrogen receptor degrader; **AI,** aromatase inhibitor; **CDK 4/6,** cyclin dependent kinase.

1. Cerianna (FES) PET Prescribing Information. Arlington Heights, IL: GE HealthCare, 2024. **2.** Linden, et al. Clin Cancer Res. 2011; 10.1158/1078-0432. **3**. Tenzin A, et al, RSC Adv., 2021, 11, 29227–29246.

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).

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.

Important Safety Information (cont'd)

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.

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.

Important Safety Information (cont'd)

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).

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

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.

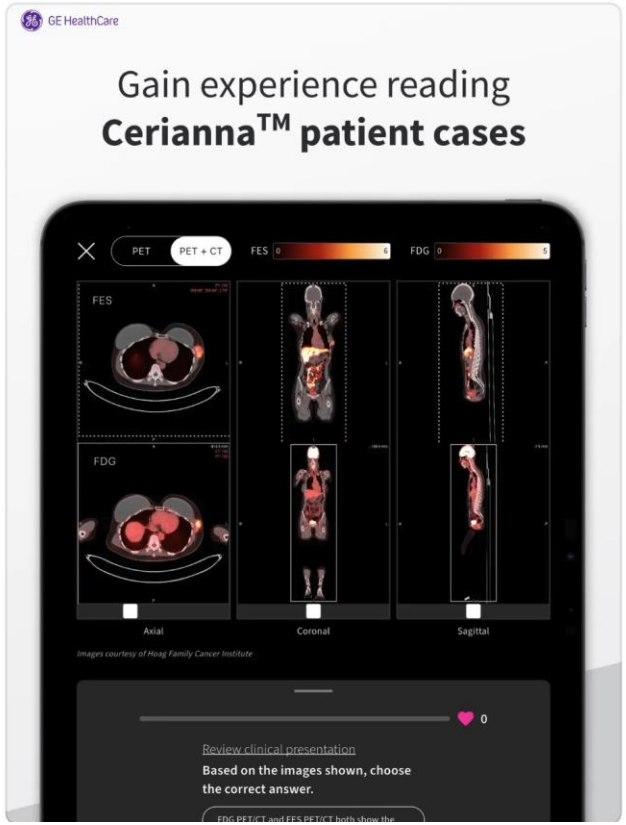
RESOURCES
Customer Service: 800-292-8514
Cerianna Support Center: 833-946-6392
Medical Affairs for Clinical and Scientific Support: 800-654-0118. (option 2, then option 3) or medical.affairs@gehealthcare.com
gehealthcare.com

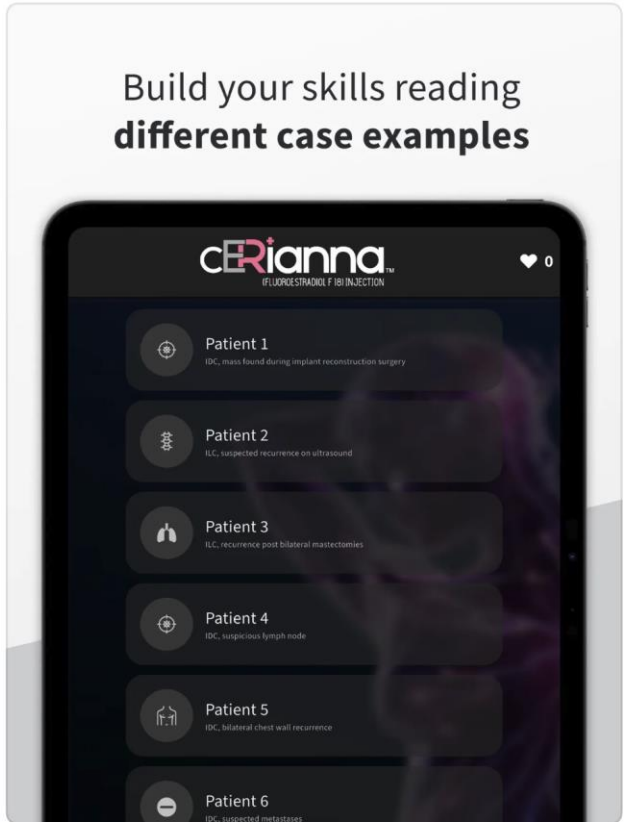
For full Prescribing Information, please scan the QR Code

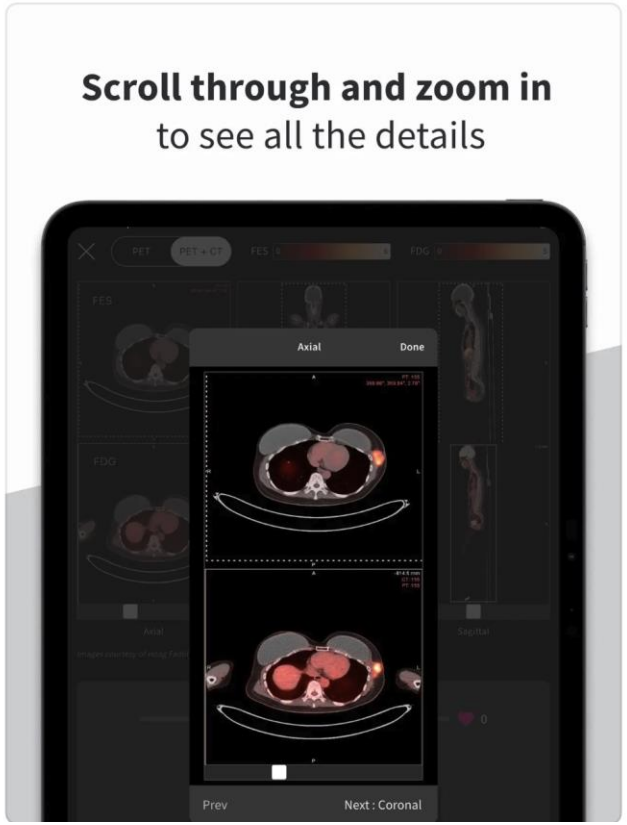
Tools and resources

CeriannaView mobile app

CeriannaView is an innovative educational app designed for oncologists and nuclear medicine physicians to enhance their understanding of Cerianna (FES) PET imaging and its applications in ER+ breast cancer patients. The app provides a comprehensive platform to explore and learn from a curated collection of interesting Cerianna (FES) PET patient exams, alongside their corresponding standard of care images.







Apple App Store

Google Play Store

FES, fluoroestradiol; **PET,** positron emission tomography; **ER+,** estrogen receptor positive.

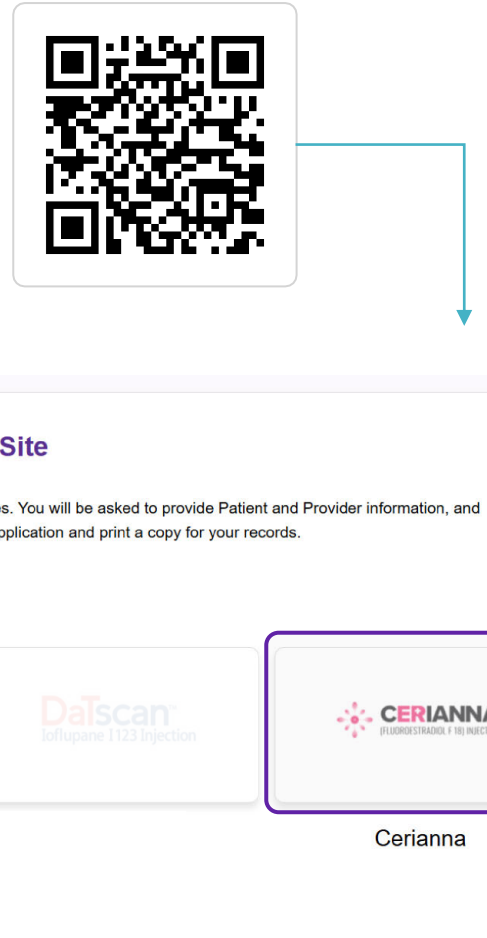
Insurance support services

The Cerianna (FES) PET Support Center supports the entire reimbursement journey

Services the Support Center provides:

- Benefit investigations
- Billing and coding guidance
- Claims support
- Assistance with prior authorizations, appeals, and medical necessity documentation
- Locating in-network imaging centers to ensure seamless patient access

Scan the QR code to access support through the online portal



FES, fluoroestradiol; **PET,** positron emission tomography.

Thank you

November 2025 | JB08072US