CERIANNA ACCESS SUPPORT℠

# Reimbursement Guide

cERianna™
(FLUOROESTRADIOL F 18) INJECTION

# Introduction

Thank you for choosing Cerianna, radiolabeled 18F-Fluoroestradiol indicated for use with positron emission tomography (PET) imaging for detection of estrogen receptor-positive (ER+) lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.

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The information provided by this document and the GE Healthcare Cerianna Access Support team are presented for illustrative and/or informational purposes only. Many factors affect third-party reimbursement and it's always the provider's responsibility to determine medical necessity and submit appropriate codes, modifiers, and charges for services rendered. Any information or assistance provided does not constitute reimbursement, medical, or legal advice.

GE Healthcare's Cerianna Access Support does not promise nor guarantee coverage, levels of reimbursement, or payment. Payment of benefits are subject to all terms, conditions, limitations, and exclusions of the member's contract at time of service.

***We highly recommend you consult the payer organization for its reimbursement policies.***

## 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 s can 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 Target Estrogen Receptors**

Certain classes of systemic endocrine therapies, including ER modulators and ER down-regulators, block ER, reduce the uptake of fluoroestradiol F 18, and may reduce detection of ER-positive lesions after administration of CERIANNA. Drugs from these classes such as tamoxifen and fulvestrant may block ER for up to 8 and 28 weeks, respectively. Do not delay indicated therapy in order to administer CERIANNA. Administer CERIANNA prior to starting systemic endocrine therapies that block ER.

**To report SUSPECTED ADVERSE REACTIONS, contact Zionexa US Corp, a GE Healthcare Company at +1.800.654.0118 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

**GE Healthcare provides a range of**

# Reimbursement services and support

CERIANNA **ACCESS SUPPORT**℠ *can assist you with:*

- **Benefit Investigations—**aid in determining a patient's health insurance coverage
- **Billing and Coding Assistance—**guidance for billing and coding requirements
- **Claims Assistance—**help in navigating through the claims process
- **Pre-Service and Post-Service Appeals—** Assistance with expediting these appeals
- **Prior Authorizations Support and Status Monitoring—**Guidance with submitting Prior Authorization Requests from insurance companies (prefill request on your behalf)
- **Medical Necessity Support—**Guidance in how to navigate the Medical Necessity process
- **Peer-to-Peer Preparation—**Provide training for HCP engagement for upcoming Payer Peer-to-Peer discussions

To request assistance with any of the following, a **Cerianna Access Support** Consent form is required and must be signed by the physician or provider. To get a copy of the consent form, you may call Cerianna Access Support at (833) 946-6392, your assigned team member of the Market Access Team, or visit **www.cerianna.com/reimbursement.**

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**Cerianna Access Support** *is staffed with individuals knowledgeable in Cerianna reimbursement and diagnostic agents, who are available at:*

***(833)-946-6392***

**www.cerianna.com/reimbursement**

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**At GE Healthcare, you are also assigned a member of the Market Access Team to deliver personalized customer service on all of the above, plus:**

- Reimbursement Consultation
- Consent Forms
- Account Management
- Payer Coverages
- Potential Patient Out-of-Pocket Cost
- Cerianna Access Support Education

# Billing and coding information

GE Healthcare can help with billing questions you may have.  Please contact the Cerianna Access Support line at 1-833-946-6392.

Submitting accurate codes and claims is important to ensure proper reimbursement of services. It is important to note that the codes identified below are the assigned codes provided to Cerianna. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. Remember the use of the following codes does not guarantee reimbursement.

## Product details

**Brand Name:** Cerianna™

**Generic Name:** Fluoroestradiol F 18

**NDC:** 72874-0001-01

## Healthcare Common Procedure Coding System (HCPCS) coding

CMS has granted Cerianna pass-through status and issued a permanent HCPCS code for Cerianna.

| HCPCS Code | Description |
|---|---|
| **A9591*†** | Fluoroestradiol F18, diagnostic, 1 mCi |

The standard patient dose is 6 mCi. When requesting a prior authorization (PA) and submitting a claim, ensure the correct number of units are reflected on the initial authorization request and claim form.

*Effective January 1, 2021.
†When billing in the Hospital Outpatient Prospective Payment System (HOPPS) setting, use the appropriate revenue code.

## Suggested revenue codes

| Revenue Codes | Description |
|---|---|
| **404** | Imaging services, positron emission tomography (PET) |
| **343** | Nuclear medicine, diagnostic radiopharmaceuticals |

Please verify that these codes are valid for your Medicare intermediary.

## ICD-10 codes most frequently associated with ER+ tumor imaging

The following table provides the ICD-10 coding for the primary indication—malignant neoplasm of breast:

| Code | Description |
|---|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |

*This is not a comprehensive list of all appropriate diagnosis codes. Providers are responsible for ensuring that all coding is accurate and documented in a patient's medical record based on the patient's condition.

*Some payers may require family and/or individual history diagnosis codes when requesting a prior authorization. Confirm requirements with the patient's insurer

**Z17.0 Add on Code: Estrogen receptor positive status (ER+)**
Make sure to indicate add-on code on your claim form and prior authorization request form.

**Z**** Payer may require additional ICD-10 codes for family and individual history**
Some insurance payers require the family and/or individual history diagnosis code when requesting prior authorization. It is important to conduct a benefit investigation for verification.

## Procedure coding

The following table summarizes the key codes for Cerianna. Using the KX modifier, patients may be able to get 3 or more PET scans approved by the payer.

| CPT® Codes and Modifiers Associated with PET Imaging* | | |
|---|---|---|
| **Code Type** | **Code** | **Description** |
| **HCPCS** | A9591 | Fluoroestradiol F18, diagnostic, 1 mCi |
| **CPT** | 78813 | Positron emission tomography (PET) imaging; whole body |
| | 78812 | Positron emission tomography (PET) imaging; skull base to mid-thigh |
| | 78811 | Positron emission tomography (PET) imaging; limited area (eg. chest, head/neck) |
| | 78816 | Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body |
| | 78815 | Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh |
| **Modifiers** | PI | Positron emission tomography (PET) or PET/computed tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing |
| | PS | Positron emission tomography (PET) or PET/computed tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent antitumor strategy |
| | ***Consider the KX modifier to indicate that the patient has had more than 3 oncologic PET scans.*** This modifier currently anticipates the use of multiple FDG scans per patient; its application to the use of Cerianna in addition to FDG scans limits will depend on individual carrier policies. Also note that the use of the KX modifier requires that justification is documented in the patient's medical record. | |

*Providers must determine which of the above codes best reflects the imaging procedure performed. It is recommended that the imaging procedure is performed from the top of the skull to below the knees.

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GE Healthcare provides a range of reimbursement support services and solutions for Cerianna through

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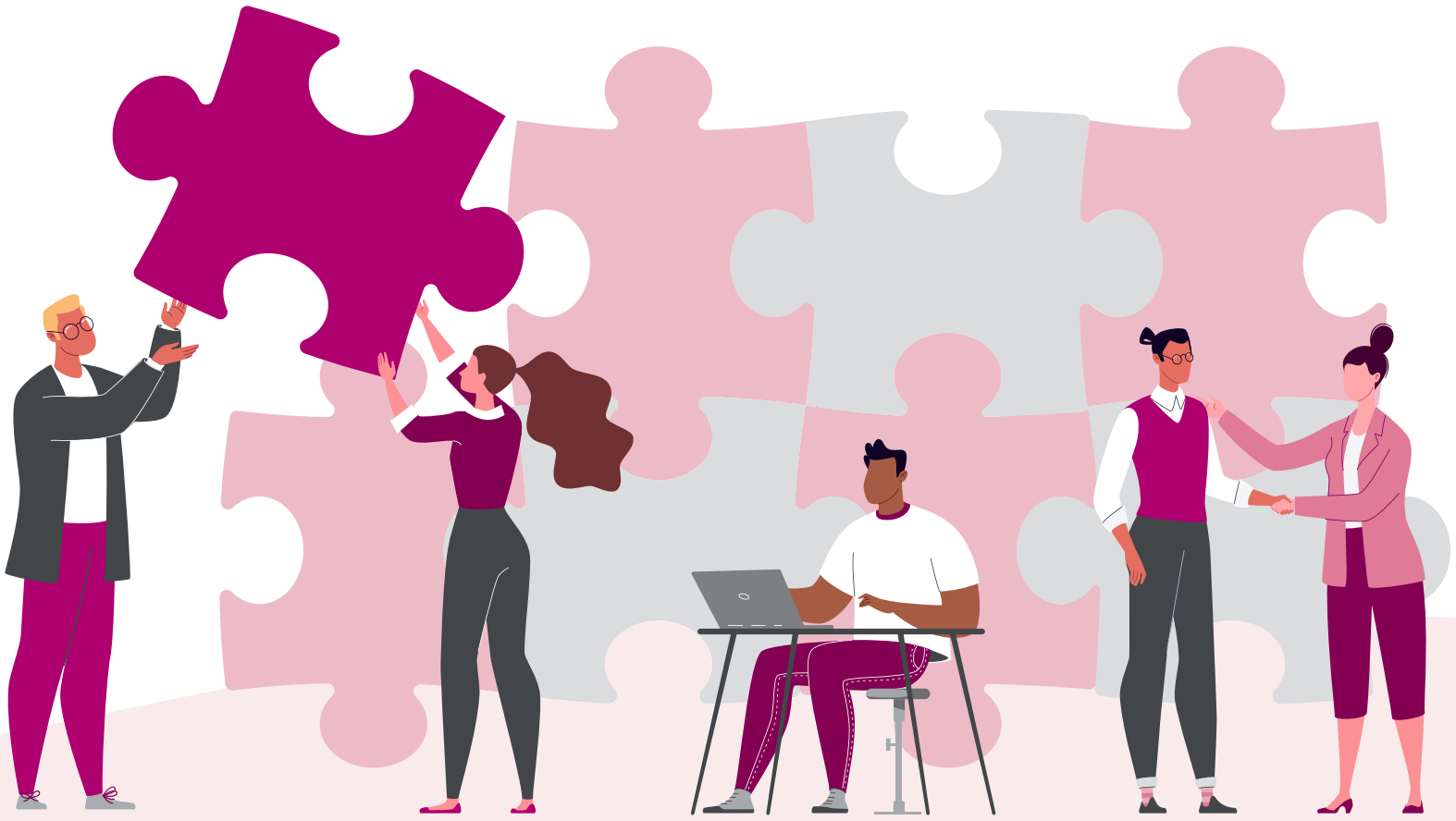

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