GE HealthCare

cERianna™
(FLUOROESTRADIOL F 18) INJECTION

We are dedicated to providing comprehensive coverage and access support for your patient

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Support starts with the Cerianna Patient Referral Form. Available from:

- Your Account Manager
- Via the Cerianna website, **here**
- Call the Cerianna Support Center at 833-946-6392
- Email the Cerianna Support Center at gehealthcare@pharmacord.com

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The Cerianna Support Center supports the entire reimbursement journey
Live support 833-946-6392 (Mon-Fri, 8AM to 6PM ET)

Benefit Investigations
- Verifing a patients's in-network 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
- Help with initiating and monitoring prior authorization requests from insurance companies (prefilled patient and physician demographics)

Medical Necessity Assistance
- Guidance on how to navigate the Medical necessity requirements for the Payor

Peer-to-Peer Preparation
- Provide training for HCP engagement for upcoming Payer Peer-to-Peer discussions

Cerianna Imaging Center Locator
- Support in finding in-network imaging center(s)

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A dedicated Field Reimbursement Manager (FRM) available to your office:
- Can provide onboarding when preparing your office to prescribe Cerianna
- Can provide your billing staff with inservice reimbursement training
- Can provide payor-specific answers on Cerianna coding and billing questions
- Can engage the GE HealthCare Managed Market Payor Executives for payor-specific challenges

Please see Important Safety Information About Cerianna on next page, and full Prescribing Information, here.

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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 F18 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 F18 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 F18 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 F18 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 F18, 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.

Please see full Prescribing Information here for additional important safety information.

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@ge.com

gehealthcare.com

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