BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 6.01.62 Oncologic Applications of Positron Emission Tomography Scanning (Breast and Gynecologic)

### Annual Effective Policy Date: April 1, 2026

### Original Policy Date: September 2024

### Related Policies:

6.01.06 - Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography
6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning
6.01.51 - Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment
6.01.63 - Oncologic Applications of Positron Emission Tomography Scanning (Bone Sarcoma and Soft Tissue Sarcoma)
6.01.64 - Oncologic Applications of Positron Emission Tomography Scanning (Hematologic)
6.01.65 - Oncologic Applications of Positron Emission Tomography Scanning (Lung)
6.01.66 - Oncologic Applications of Positron Emission Tomography Scanning (Thyroid, Neuroendocrine, Head and Neck)
6.01.67 - Oncologic Applications of Positron Emission Tomography Scanning (Brain, Melanoma, Unknown Primary)

# Oncologic Applications of Positron Emission Tomography Scanning (Breast and Gynecologic)

## Description

## Description

Positron emission tomography (PET) is a nuclear imaging technique that uses positron-emitting tracers attached to molecules like glucose or water to create 3D images of metabolic activity. In cancer care, tracer choice depends on tumor type and cancer stage under evaluation.

## OBJECTIVE

The objective of this evidence review is to examine whether the use of PET for diagnosis, staging and restaging, and/or surveillance improves the net health outcome in individuals with breast or gynecologic cancers.

# POLICY STATEMENT

## Breast Cancer

PET scanning using $^{18}$F-FDG isotope may be considered **medically necessary** in the staging or restaging of breast cancer for the following application:

- Detecting locoregional or distant recurrence or metastasis (except axillary lymph nodes) when suspicion of disease is high and other imaging is inconclusive.

PET scanning using $^{18}$F-FDG isotope is considered **investigational** in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in individuals with suspicious breast lesions or an indeterminate or low suspicion finding on mammography
- Staging axillary lymph nodes.
- Predicting pathologic response to neoadjuvant therapy for locally advanced disease.

PET scanning using fluoroestradiol F18 (FES) is considered **investigational** in individuals with breast cancer (see Policy Guidelines for exceptions).

## Cervical Cancer

PET scanning using $^{18}$F-FDG isotope may be considered **medically necessary** in the initial staging of individuals with locally advanced cervical cancer.

PET scanning using $^{18}$F-FDG isotope may be considered **medically necessary** in the evaluation of known or suspected recurrence.

## Endometrial Cancer

PET scanning using $^{18}$F-FDG isotope is considered **medically necessary** in the:

- Detection of lymph node metastases, and
- Assessment of endometrial cancer recurrence.

## Ovarian Cancer

PET scanning using $^{18}$F-FDG isotope may be considered **medically necessary** in the evaluation of individuals with signs and/or symptoms of suspected ovarian cancer recurrence (restaging) when standard imaging, including CT scan, is inconclusive.

PET scanning using $^{18}$F-FDG isotope is considered **investigational** in the initial evaluation of known or suspected ovarian cancer in all situations.

# POLICY GUIDELINES

None

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA REGULATORY STATUS

As of October 2025 , the following radiopharmaceuticals have been granted approval by the U.S. Food and Drug Administration, to be used with PET for breast and gynecologic cancer-related indications (see Table 1).[1,]

Cerianna™ is indicated for use with PET for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in individuals with recurrent or metastatic breast cancer. It's limitation of use states that "tissue biopsy should be used to confirm recurrence of breast cancer and to verify ER status by pathology."

**Table 1. Radiopharmaceuticals Approved for Use With PET for Breast and Gynecologic Cancer Applications**

| Radiopharmaceutical | Manufacturer | Name | Carcinoma-Related Indication With PET |
|---|---|---|---|
| Fluorine-18 fluorodeoxyglucose (FDG) | Various | | Suspected or existing diagnosis of cancer, all types |
| Fluorine-18 fluoroestradiol (FES) | Zionexa USA | Cerianna™ | Detection of ER-positive lesions as an adjunct to biopsy in individuals with recurrent or metastatic breast cancer |

ER: estrogen receptor.

# RATIONALE

## Summary of Evidence

### Breast Cancer

For individuals who have diagnosed breast cancer and inconclusive results from other imaging techniques who receive adjunctive FDG-PET or FDG-PET/CT for staging or restaging, the evidence includes meta-analyses. Relevant outcome is test validity. While studies included in the meta-analyses reported variability in estimates of sensitivity and specificity, FDG-PET or FDG-PET/CT may be helpful in situations in which standard staging results are equivocal or suspicious, particularly in individuals with locally advanced or metastatic disease. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected or diagnosed breast cancer and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes a TEC Assessment, several systematic reviews, and meta-analyses. Relevant outcome is test validity. There is no evidence supporting the use of PET in diagnosing breast cancer. The false-negative rates (5.5% to 8.5%) using PET in individuals with breast cancer can be considered unacceptable, given that breast biopsy can provide more definitive results. Use of PET/CT may be considered for the detection of metastases only when results from other imaging techniques are inconclusive. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic after completing breast cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with recurrent or metastatic breast cancer and in need of estrogen receptor status information to make decisions about endocrine therapy who undergo adjunctive $^{18}$F-FES-PET, the evidence includes 1 randomized controlled trial, nonrandomized clinical trials, and 1 systematic review and meta-analysis. Relevant outcome is test validity. Studies on the clinical utility of the technology are still ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Cervical Cancer

For individuals who have diagnosed cervical cancer and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) report and meta-analyses. Relevant outcome is test validity. Pooled results have shown that PET can be used for staging or restaging and for detecting recurrent disease. Clinical guidelines include PET and CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected cervical cancer or who are asymptomatic after completing cervical cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcomes are test accuracy and test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Endometrial Cancer

For individuals who have diagnosed endometrial cancer in need of staging or restaging information or who are asymptomatic after completing endometrial cancer treatment who receive FDG-PET or FDG-PET/CT, the evidence includes a systematic review and meta-analysis. Relevant outcome is test validity. Pooled estimates from the meta-analysis showed high sensitivities and specificities for FDG-PET/CT in detecting lymph node metastases and endometrial cancer recurrence following treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### Ovarian Cancer

For individuals who have diagnosed ovarian cancer and in need of staging or restaging information who receive FDG-PET or FDG-PET/CT, the evidence includes an AHRQ systematic review and several meta-analyses. Relevant outcome is test validity. Pooled sensitivities and specificities have supported the use of PET and PET/CT for the detection of recurrent ovarian cancer. Clinical guidelines include PET/CT to inform management decisions that may offer clinical benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected ovarian cancer or who are asymptomatic after completing ovarian cancer treatment who receive FDG-PET or FDG-PET/CT, there is no evidence. Relevant outcome is test validity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Current National Comprehensive Cancer Network, American College of Radiology, and other relevant U.S.-based guidelines are summarized in each section of the Rationale.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

The Medicare coverage policy on positron emission tomography scans, effective for claims with dates of service on and after June 11, 2013, is summarized in Table 1.[41,]

**Table 1. National FDG PET Coverage for Oncologic Conditions**

| FDG PET for Cancers by Tumor Type | Initial Treatment Strategy (formerly "diagnosis" & "staging") | Subsequent Treatment Strategy (formerly "restaging" & "monitoring response to treatment") |
|---|---|---|
| Colorectal | Cover | Cover |
| Esophagus | Cover | Cover |
| Head and Neck (not thyroid, CNS) | Cover | Cover |
| Lymphoma | Cover | Cover |
| Non-small cell lung | Cover | Cover |
| Ovary | Cover | Cover |
| Brain | Cover | Cover |
| Cervix | Cover with exceptions * | Cover |
| Small cell lung | Cover | Cover |
| Soft tissue sarcoma | Cover | Cover |
| Pancreas | Cover | Cover |
| Testes | Cover | Cover |
| Prostate | **Non-cover** | Cover |
| Thyroid | Cover | Cover |
| Breast (male and female) | Cover with exceptions * | Cover |
| Melanoma | Cover with exceptions * | Cover |
| All other solid tumors | Cover | Cover |
| Myeloma | Cover | Cover |
| All other cancers not listed | Cover | Cover |

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.
*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.
*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| September 2024 | New policy- Add to Radiology/Interventional Radiology section | Policy created by separating out breast and gynecologic cancer indications from policy 6.01.26. Policy revised with literature review through October 13, 2023. No references added. No changes to policy statements. |
| September 2025 | Replace policy | Policy updated with literature review through September 30, 2024. References added. New PICO on the use of adjunctive 18F-FES-PET in individuals with recurrent or metastatic breast cancer and in need of estrogen receptor status information to make decisions about endocrine therapy added with an investigational policy statement. All other policy statements unchanged. |
| March 2026 | Replace policy | Policy updated with literature review through October 15, 2025. References added. Editorial revision throughout policy related to use of guidelines. Intent of policy statements unchanged.. |