This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address diagnostic breast imaging utilized when there are signs and/or symptoms suggestive of breast cancer or a history of breast cancer exists. A variety of techniques may be utilized.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Mammography: most widely used imaging modality for the detection of breast cancer that uses a specialized x-ray that is transmitted through breast and surrounding tissue and produces two dimensional images. Images may be recorded using digital detectors known as full field digital mammography (FFDM).
Contrast Enhanced Mammogram: uses intravenous administration of contrast dye containing iodine to enhance visibility of breast lesions and highlight areas with unusual blood flow. May also be referred to as contrast enhanced spectral mammography or contrast enhanced digital mammography.
Digital Breast Tomosynthesis (DBT): three-dimensional breast imaging technique based on two dimensional FFDM mammography that is similar to computed tomography (CT) scan that only contain images of the breast(s).
Magnetic Resonance Imaging (MRI): creates images of the breast(s) by measuring changes in the movement of protons in fat and water with the application of changing magnetic fields.
Computer-aided Detection (CAD): software systems, CADe [detection] and CADx [diagnosis] assess images for patters that may represent microcalcifications or masses indicative of breast cancer. This method is intended a second examination of images and does not replace a radiologist.
Positron Emission Tomography (PET): generates three-dimensional images of tissue metabolism by using a radioactive tracer that is thought to accumulate in rapidly dividing and metabolizing tissue, such as tumors.
Ultrasonography (Ultrasound): uses high energy sound waves to create echoes that form images of tissues or organs.
Optoacoustic Ultrasound: non-invasive scan that combines the use of light and conventional ultrasound to produce high-resolution images that purportedly identify submillimeter vascular structures and tumors as small as 3 mm.
Tactile Breast Imaging: uses a hand-held device which integrates ultrasound shear-wave elastography with computer-aided sensors to produce a map of abnormal breast tissues and masses.
Three-Dimensional Computed Tomography (3D CT): uses x-ray and computers to produce thin cross-sectional views or slices of the body.
Artificial Intelligence (AI) Software: alleged to automatically detect and characterize suspicious soft tissue

lesions and calcifications from mammography/DBT or compare fibroglandular volume calculations from ultrasound images to assess the likelihood of malignance.
Electrical Impedance Tomography (EIT): involves the transmission of electrical currents into the body via a handheld device and electrode placed on the arm.
Molecular Breast Imaging (MBI): nuclear medicine scan that may be performed following abnormal or inconclusive mammography to determine the need for biopsy.
Optical Imaging: non-invasive test conducted by shining high intensity infrared light through the breast or reflecting such light off the breast.
Thermography (digital infrared thermal imaging): uses an infrared camera to detect temperature differences within breast tissue.

POLICY

Diagnostic Mammography

SECUR Health Plan will consider diagnostic mammography with or without the use of CAD, contrast enhancement, or DBT as medically necessary when the following are met:

1. Breast abnormality as indicated by one or more of the following:
   - Abnormal findings identified on ultrasound or mammography, or
   - Abnormal nipple and/or areolar symptoms, or
   - Axillary lymphadenopathy of undetermined origin, or
   - Benign, biopsy proven, breast disease, or
   - Breast abnormality on clinical exam, or
   - Breast implant rupture, known or suspected, or
   - Short interval (6 months or less) follow up necessary for unresolved clinical/radiographic concern(s), or
   - Suspected inflammatory breast cancer (IBC), or
2. Known breast cancer and one or more of the following:
   - Assessment of tumor response to preoperative chemotherapy to determine appropriateness of breast conserving surgery, or
   - Following initial treatment for breast cancer, or
   - Post-excision to determine adequacy of excision, or
   - Post radiation therapy, or
3. Occult breast cancer suspected as indicated by diagnosis of adenocarcinoma or carcinoma not otherwise specified and no palpable breast mass suitable for biopsy, or
4. Repeat evaluation indicated by a change in clinical status or following a core needle biopsy of nonmalignant breast mass or re-imaging prior to or following an invasive procedure.

Diagnostic MRI

SECUR Health Plan will consider breast MRI, with or without the use of CAD, medically necessary when the following is met:

1. Breast abnormality evaluation is needed, indicated by one or more of the following:
   - Anatomic guidance during biopsy of a breast lesion, or
   - Breast implant complication suspected, or
   - Nipple discharge present and etiology was indeterminate on mammography or ultrasound, or
   - Positive axillary nodes without a known primary cancer source, or
   - Suspected Paget disease of the breast and negative mammogram, or
   - Equivocal mammogram results and the member is a candidate for MRI-directed needle biopsy,

nonpalpable breast lesion not visible on ultrasound and not amenable to fine needle biopsy, and ultrasound findings are indeterminate

2. Known breast cancer and one or more of the following:
   - Assessment of tumor response to preoperative chemotherapy to determine appropriateness of breast conserving surgery, or
   - Confirmed diagnosis of Paget disease to define, extend, or identify additional disease, or
   - Evaluation for suspected cancer recurrence, or
   - Evaluation of newly diagnosed member with a negative or indeterminate mammogram result for contralateral breast involvement, or
   - Further evaluation of invasive breast cancer, or
   - Locoregional staging when there is a high risk or suspicion of occult disease, or
   - Postsurgical follow up as indicated by assessment for residual disease with close or positive margins following lumpectomy, or surveillance in contralateral breast in a member at high risk, or suspected tumor recurrence at lumpectomy site with negative or equivocal mammogram, or
3. Occult breast cancer suspected as indicated by all the following:
   - Diagnosis of adenocarcinoma or carcinoma, not otherwise specified, and
   - Mammogram and breast ultrasound show no evidence of cancer, and
   - No palpable breast mass suitable for biopsy, or
4. Repeat evaluation required as indicated by one or more of the following:
   - Change in clinical status, or
   - Following a core needle biopsy, or
   - Re-imaging prior to or following an invasive procedure

Screening MRI

SECUR Health Plan considers breast MRI, with or without the use of CAD, medically necessary when the following is met:

1. Absence of prior breast or ovarian cancer and one or more of the following:
   - Carrier of pathogenic or likely pathogenic variant high risk breast cancer gene, or
   - Individual has a diagnosis of or has a first degree relative with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, hereditary diffuse gastric cancer with pathogenic or likely pathogenic variant of CDH1 gene, or Li-Fraumeni syndrome and/or Peutz-Jeghers syndrome, or
   - Lifetime risk estimated at greater than or equal to 20% based on familial risk stratification tool, or
   - Other high risk family history indicated by at least one first, second, or third degree relative with male breast cancer, or member has a first degree relative who is a carrier of pathogenic or likely pathogenic variant high risk breast cancer gene BRCA1 or BRCA2, or previous radiation to the chest between ages 10-30.

PET Scan

SECUR Health Plan considers PET scan of the breast medically necessary when the following is met:

1. Additional imaging information is required for one or more of the following:
   - Equivocal or suspicious findings on MRI, or
   - Locally advanced breast cancer, or
   - Planned invasive diagnostic or therapeutic procedures for breast cancer where assessment is needed for identifying appropriateness or anatomic location, or
   - Subsequent staging/restaging is needed for diagnosed breast cancer or for monitoring treatment response

SECUR Health Plan considers the following as not medically necessary for any member:

1. 3D CT
2. AI software used in conjunction with mammography, DBT, or ultrasound
3. CAD for breast ultrasonography
4. Electrical impedance tomography (EIT)
5. Molecular breast imaging
6. Optoacoustic ultrasound
7. Tactile breast imaging

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