

# Cigna Medical Coverage Policies – Radiology Breast Imaging

October 1, 2021



---

## Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the [Cigna CPT code list](#) for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2021 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

<b>Breast Imaging Guidelines</b>	
<b>Abbreviations for Breast Guidelines</b>	<b>3</b>
<b>BR-Preface1: General Considerations</b>	<b>5</b>
<b>BR-1: Breast Ultrasound</b>	<b>8</b>
<b>BR-2: MRI Breast</b>	<b>9</b>
<b>BR-3: Breast Reconstruction</b>	<b>11</b>
<b>BR-4: MRI Breast is NOT Indicated</b>	<b>12</b>
<b>BR-5: MRI Breast Indications</b>	<b>13</b>
<b>BR-6: Nipple Discharge/Galactorrhea</b>	<b>16</b>
<b>BR-7: Breast Pain (Mastodynia)</b>	<b>17</b>
<b>BR-8: Alternative Breast Imaging Approaches</b>	<b>18</b>
<b>BR-9: Suspected Breast Cancer in Males</b>	<b>19</b>
<b>BR-10: Breast Evaluation in Pregnant or Lactating Females</b>	<b>20</b>
<b>BR-11: Digital Breast Tomosynthesis</b>	<b>21</b>

## Abbreviations for Breast Guidelines

<b>AAA</b>	abdominal aortic aneurysm		
<b>ACE</b>	angiotensin-converting enzyme		
<b>AVM</b>	arteriovenous malformation		
<b>BI-RADS</b>	Breast Imaging Reporting and Database System		
<b>BP</b>	blood pressure	<b>BRCA</b>	tumor suppressor gene
<b>CAD</b>	computer-aided detection	<b>CBC</b>	Complete blood count
<b>COPD</b>	chronic obstructive pulmonary disease		
<b>CT</b>	computed tomography		
<b>CTA</b>	computed tomography angiography		
<b>CTV</b>	computed tomography venography		
<b>DCIS</b>	ductal carcinoma in situ	<b>DVT</b>	deep venous thrombosis
<b>ECG</b>	electrocardiogram	<b>EM</b>	electromagnetic
<b>EMG</b>	electromyogram	<b>FDA</b>	Food and Drug Administration
<b>FDG</b>	fluorodeoxyglucose	<b>FNA</b>	fine needle aspiration
<b>GERD</b>	gastroesophageal reflux disease		
<b>GI</b>	gastrointestinal		
<b>HRCT</b>	high resolution computed tomography		
<b>IPF</b>	idiopathic pulmonary fibrosis		
<b>LCIS</b>	lobular carcinoma in situ		
<b>LFTP</b>	localized fibrous tumor of the pleura		
<b>MRA</b>	magnetic resonance angiography		
<b>MRI</b>	magnetic resonance imaging		
<b>MRV</b>	magnetic resonance venography		
<b>NCV</b>	nerve conduction velocity		
<b>PE</b>	pulmonary embolus		
<b>PEM</b>	positron-emission mammography		
<b>PET</b>	positron emission tomography		
<b>PFT</b>	pulmonary function tests		
<b>PPD</b>	purified protein derivative of tuberculin		

<b>RODEO</b>	Rotating Delivery of Excitation Off-resonance MRI
<b>SPN</b>	solitary pulmonary nodule
<b>SVC</b>	superior vena cava

## BR-Preface1: General Considerations

<b>BR-Preface1.0: General Guidelines</b>	<b>6</b>
<b>BR-Preface1.1: BI-RADS™ Categories Chart</b>	<b>6</b>
<b>BR-Preface1.2: BI-RADS™ Breast Density Categories</b>	<b>7</b>

## **BR-Preface1.0: General Guidelines**

- A current clinical evaluation (within 60 days) is usually required prior to considering advanced imaging.
  - ◆ A clinical evaluation should include the following:
    - A relevant history and physical examination
    - Appropriate laboratory studies and non-advanced imaging modalities, such as mammogram and/or ultrasound
    - Other meaningful contact (telephone call, electronic mail or messaging) by an established individual can substitute for a face-to-face clinical evaluation
- Current clinical evaluation is not required prior to screening studies.

## **BR-Preface1.1: BI-RADS™ Categories Chart**

<b>BI-RADS™ Categories Chart</b>	
<b>Category</b>	<b>Description</b>
<b><i>Category 0: Incomplete</i></b>	Need additional imaging evaluation or prior mammograms for comparison. Category 0 classification requires that additional imaging study be specified, e.g. ultrasound, additional mammogram view, MRI.
<b><i>Category 1: Negative</i></b>	There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.
<b><i>Category 2: Benign Finding</i></b>	This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions (such as oil cysts, lipomas, galactoceles, and mixed density hamartomas) all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.
<b><i>Category 3: Probably Benign Finding – Short Interval Follow-up Suggested</i></b>	A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data is becoming available that sheds light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

<b>BI-RADS™ Categories Chart</b>	
<b>Category</b>	<b>Description</b>
<b>Category 4: Suspicious Abnormality – Biopsy Should Be Considered</b>	There are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant possibilities should be cited so that the individual and her physician can make the decision on the ultimate course of action.
<b>Category 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken</b>	These lesions have a high probability of being cancer and should be biopsied or treated surgically.
<b>Category 6: Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken</b>	These lesions have been biopsied and are known to be malignant.

### **BR-Preface1.2: BI-RADS™ Breast Density Categories**

<b>BI-RADS™ Breast Density Categories</b>
<b>Category A: Almost entire fatty</b>
<b>Category B: Scattered fibroglandular densities</b>
<b>Category C: Heterogeneously dense</b>
<b>Category D: Extremely dense</b>

## BR-1: Breast Ultrasound

- Routine performance of breast ultrasound as stand-alone screening or with screening mammography is inappropriate.<sup>1,2,3</sup>
  - ◆ Ultrasound screening for females whose only indication is dense breast tissue is not indicated.<sup>1,2,3</sup>
  - ◆ Equivocal or Occult Findings:
    - Breast ultrasound (CPT® 76641 or CPT® 76642): Radiologist Report recommendation and inconclusive or conflicting findings on mammography or MRI Breast
- Breast ultrasound (CPT® 76641: unilateral, complete OR CPT® 76642: unilateral, limited) further evaluate abnormalities found on mammogram, especially in differentiating cysts from solid lesions.<sup>1</sup>
  - ◆ A clinical office visit is not necessary prior to breast ultrasound when an abnormality has been identified on recent (within the last 60 days) mammogram.
- BI-RADS™ Cat 3 ultrasound follow up imaging for stable findings at 6 months
  - ◆ If repeat imaging remains BI-RADS™ 3, repeat at 12 months, 18 months and 24 months from the date of the initial imaging. After 2 years of stability, the finding should be assessed as benign (Cat 2).<sup>16</sup>
  - ◆ If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- Mammography and breast ultrasound, in any order, regardless of age for palpable breast masses or other clinical abnormalities (such as skin change, pain, nipple inversion). Ultrasound can enhance biopsy.<sup>3</sup>
- Axilla ultrasound (CPT® 76882)
  - ◆ For females with clinically suspicious lymph nodes, preoperative axillary ultrasound with a FNA or biopsy can help identify individuals who have positive nodes.<sup>3</sup>
    - See **CH-2.2: Axillary Lymphadenopathy (and Mass)** in the Chest Imaging Guidelines
  - ◆ Bilateral should be coded CPT® 76882 x 2
- Ultrasound guided breast biopsy (CPT® 19083) includes the imaging component
  - ◆ Additional lesions should be billed using CPT® 19084
- Ultrasound Breast can be repeated at least 6 months after an ultrasound directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.
- 3D Reconstruction (CPT® 76377) is not considered medically necessary for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.



## BR-2: MRI Breast

- The use of gadolinium contrast is required for the evaluation of breast parenchyma.
- The use of gadolinium contrast is not necessary for the evaluation of implant integrity in asymptomatic, average-risk individuals.
- Computer-aided detection (CAD) is included with the MRI Breast CPT® 77049 and CPT® 77048 procedures. The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is unnecessary with these procedures.
  - ◆ The use of CAD has little influence on the sensitivity and specificity of MRI Breast interpretation.<sup>9</sup>
  - ◆ The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is currently considered investigational, experimental, and/or unproven.
  - ◆ Since the CAD software automatically performs 3D imaging, CPT® 76376 or CPT® 76377 should not be used in conjunction with CPT® 77049, CPT® 77048 or HCPCS code C8937.
- Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral (CPT® 77049) is preferred in most individuals for the evaluation of breast parenchyma.
- Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral (CPT® 77048) may be preferred in some individuals after mastectomy, per physician request.
- Magnetic resonance imaging, breast, without contrast material; bilateral (CPT® 77047) or Magnetic resonance imaging, breast, without contrast material; unilateral (CPT® 77046) may be performed if there are clinical reasons or concerns regarding the use of gadolinium contrast.
- MRI guided breast biopsy (CPT® 19085) includes the imaging component.
  - ◆ Additional lesions should be billed using CPT® 19086.
- MRI Breast can be repeated at least 6 months after an MRI directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific, equivocal or uncertain.<sup>5</sup>

### ***Background and Supporting Information***

- Although MRI Breast has superior sensitivity in identifying new unknown malignancies, it carries a significant false positive risk when compared to mammogram and ultrasound. Incidental lesions are seen on 15% of MRI Breast and increase with younger age. The percentage of incidental lesions that turn out to be malignant varies from 3% to 20% depending on the individual population. Cancer is identified by MRI Breast in only 0.7% of those with “inconclusive mammographic lesions”.<sup>6,7</sup>

## BR-3: Breast Reconstruction

- CTA or MRA of the body part from which the free tissue transfer flap is being taken, can be performed for breast reconstruction preoperative planning.<sup>2,3</sup>
  - ◆ For example, CTA Abdomen and/or Pelvis (CPT<sup>®</sup> 74175 or CPT<sup>®</sup> 72191 or CPT<sup>®</sup> 74174) or MRA Abdomen and/or Pelvis (CPT<sup>®</sup> 74185 and/or CPT<sup>®</sup> 72198) for Deep Inferior Epigastric Perforators (DIEP) flap.<sup>8</sup>
- There is currently insufficient evidence-based data to support the need for routine advanced imaging for TRAM flaps or other flaps performed on a vascular pedicle.<sup>8</sup>

## BR-4: MRI Breast is NOT Indicated

- MRI Breast should not be used to determine biopsy recommendations for suspicious or indeterminate lesion(s) that can be readily biopsied, either using imaging guidance or physical exam, such as palpable masses and microcalcifications.<sup>3,6</sup>
- Individuals with dense breasts as determined by mammogram
  - ◆ To date, evidence does not suggest improved outcomes for females whose only risk factor is breast density [See “Equivocal or Occult Findings” (Radiologist Report) in **BR-5: MRI Breast Indications**.<sup>13,14,15</sup>
- Low risk, probably benign (BI-RADS™ 3) lesions
  - ◆ Repeat the original type study (mammogram, US, or MRI) in 6 months
    - If repeat imaging remains BI-RADS™ 3, repeat original study at 12 months, 18 months, and 24 months from the date of the initial imaging. After 2 years of stability, the finding should be assessed as benign (Cat 2).<sup>16</sup>
    - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- Suspicious (BI-RADS™ 4 or 5) lesion on mammogram and/or ultrasound.
  - ◆ A lesion categorized as BI-RADS™ 4 or 5 should be biopsied.<sup>16</sup>
- Surveillance MRI for silent/asymptomatic rupture of silicone implants is considered investigational, as there is no evidence basis that surveillance reduces morbidity and/or mortality.
- Cigna does not cover surveillance MRI for breast implants if they were placed as part of purely cosmetic surgery
- Routine surveillance MRI Breast following bilateral mastectomy is not indicated<sup>45</sup>

## BR-5: MRI Breast Indications

- MRI Breast is indicated for silicone breast implants to:
  - ◆ Evaluate or confirm breast implant rupture when mammography or ultrasound is uninterpretable.<sup>1</sup>  
Note: If implants were placed for cosmetic reasons, coverage is not indicated
- Phyllodes Tumor (Cystosarcoma Phyllodes)
  - ◆ MRI Breast is indicated preoperatively to establish extent of disease where a diagnosis of malignant phyllodes tumor has previously been established by tissue diagnosis.<sup>18,19,20</sup>
- Equivocal or Occult Findings
  - ◆ Radiologist Report Recommendation for MRI Breast to assess inconclusive or conflicting findings on mammography or ultrasound that are not associated with a discrete palpable mass. This would include possible fat necrosis which is most commonly due to trauma or surgery.
  - ◆ Discordance between imaging findings and core needle biopsy findings. Biopsy result does not adequately explain the abnormal findings on mammogram and/or ultrasound (BI-RADS™ 4 or 5). MRI Breast can be used for further evaluation after the discordant biopsy, before consideration for surgical management vs. observation, when there is documentation provided of histopathologic discordance.
  - ◆ Fat Necrosis (most commonly due to trauma or surgery)
    - May evaluate with MRI if Ultrasound or mammogram reports inconclusive findings of fat necrosis in a woman with a history of breast cancer treated with surgery (lumpectomy or mastectomy with or without reconstruction)
  - ◆ A probably benign lesion on MRI (MRI BI-RADS™ 3) should undergo repeat MRI in 6 months
    - If repeat imaging remains BI-RADS™ 3, repeat at 12 months, 18 months and 24 months from the date of the initial imaging. After 2 years of stability, the finding should be assessed as benign (Cat 2).<sup>16</sup>
    - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individuals risk profile.
- MRI Breast can be repeated at least 6 months after an MRI directed breast biopsy to document successful lesion sampling if histology is benign and nonspecific equivocal or uncertain.<sup>5</sup>
- Newly Diagnosed Breast Cancer<sup>4</sup> (including DCIS).<sup>1,6,24,25,26</sup>
- Newly Diagnosed Paget's Disease<sup>5</sup> (thereafter treat as DCIS according to these guidelines).<sup>26,28</sup>
- Residual or Recurrent Malignancy
  - ◆ Assessment of residual tumor in individuals who have undergone lumpectomy and have close or positive margins, when the findings may indicate a significant change in surgical management.<sup>29</sup>
  - ◆ Evaluate clinical suspicion of recurrence, following evaluations with mammography and/or ultrasound, if those evaluations are inconclusive or conflict

with physical examination or other clinical indicators. This applies to intact breasts, reconstructed breasts, and possible chest wall recurrences following mastectomy.<sup>29</sup>

➤ Indications for annual MRI Breast screening, See table below:

High Risk Indications	
<i>MRI screening to begin at age 20:</i>	
1.	Li-Fraumeni Syndrome (TP53 mutation) should start annual breast screening MRI starting at age 20 or at the age of the earliest diagnosed breast cancer in the family, whichever comes first.
<i>MRI screening to begin at diagnosis but not prior to age 25:</i>	
2.	<i>Individuals with a history of :</i> <ul style="list-style-type: none"> <li>◆ Atypical ductal hyperplasia (ADH)</li> <li>◆ Atypical lobular hyperplasia (ALH)</li> <li>◆ Lobular carcinoma in situ (LCIS)<sup>21</sup></li> </ul>
<i>MRI screening to begin at age determined by gene mutation:</i>	
3.	BRCA 1 or BRCA 2, Peutz-Jehgers Syndrome (STK11/LKB1 gene variations) begin age 25
4.	PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2 begin age 30
5.	ATM, CHEK2, NBN begin age 40
6.	The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is not indicated at this time: <ul style="list-style-type: none"> <li>◆ BARD1, MSH2, MLH1, MSH6, PMS2, EPCAM, RAD51C, Genetic variants of unknown significance, genetic variants favoring polymorphism, genetic variants of intermediate penetrance.<sup>41</sup></li> </ul>
<i>MRI screening begins at age 40, or 10 years before the age of relative (lineage as described below) when first diagnosed with breast cancer, but not prior to the age of 25.<sup>4,12,22,30,42,43</sup></i>	
7.	First-degree relative (parent, sibling, child. Half siblings are considered second degree relatives) with BRCA 1 or BRCA 2, if individual has not been tested for BRCA mutation. (If individual has been tested and negative for mutation then annual screening is not indicated.)
8.	Two or more first-degree relatives with breast or ovarian cancer.
9.	One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤age 50.
10.	One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer.
11.	A first or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer.

12.	Clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator such as Gail, Claus, Tyrer-Cuzick (also known as IBIS) or BRCAPRO models.
<b>Additional Risks:</b>	
13.	Annual MRI Breast is recommended beginning at age 25 or 8 years after completion of radiotherapy (whichever occurs later) for individuals receiving therapeutic radiation exposure in the following fields for any pediatric cancer. <ul style="list-style-type: none"> <li>◆ Chest (thorax)</li> <li>◆ Whole lung</li> <li>◆ Mediastinal</li> <li>◆ Axilla</li> <li>◆ Mini-mantle, mantle, or extended mantle</li> <li>◆ Total (TLI) or subtotal (SLTI) lymphoid irradiation</li> <li>◆ Total body irradiation (TBI)</li> </ul>
<b>Personal History of Breast Cancer</b>	
14.	MRI Breast surveillance (annual) is indicated for individuals with a personal history of breast cancer (not treated with bilateral mastectomy) who had a clinical lifetime risk estimated at greater than or equal to 20% using genetic risk or clinical risk estimator such as Gail, Claus, Tyrer-Cuzick or BRCAPRO models prior to initial diagnosis of breast cancer. <sup>2,3</sup>
15.	MRI Breast surveillance (annual) is indicated for individuals with a personal history of breast cancer (not treated with bilateral mastectomy) and extremely dense breast tissue (Breast Density Category D) on mammography. <sup>39</sup>
16.	MRI Breast surveillance (annual) is indicated for individuals with a personal history of breast cancer (not treated with bilateral mastectomy) diagnosed before age 50. <sup>39</sup>

### **Background and Supporting Information**

- myRisk® Hereditary Cancer (Myriad Genetics, Inc.) is not accepted as a risk calculator to determine high risk for breast cancer
- MRI should not be used in lieu of mammographically, clinically, and/or sonographically suspicious findings (ACR Practice Guidelines).

## BR-6: Nipple Discharge/Galactorrhea

- Pathologic nipple discharge
  - ◆ Initial imaging should include diagnostic mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited). If these are negative or inconclusive, MRI Breasts with and without contrast (CPT® 77049) is the next appropriate imaging study.<sup>31,32,33,34</sup>
- Physiologic nipple discharge
  - ◆ If nipple discharge is physiologic, there are no suspicious findings on clinical exam, and mammogram and ultrasound are negative, no additional imaging is necessary, and the individual can be reassured.<sup>31,32,33,34</sup>

### *Background and Supporting Information*

- Physiologic nipple discharge is predominantly bilateral, but may be unilateral. It is commonly multi-duct. It is predominantly milky, but may be white or a variety of colors including serous, yellow, green, brown, or gray. Evaluation for hyperprolactinemia can be considered.<sup>31,32,33,34</sup>
- For milky discharge, prolactin and TSH levels are recommended to diagnose prolactinoma; pituitary imaging is not needed if normal serum Prolactin.
- Pathologic nipple discharge is defined as unilateral, bloody or serous, arising from a single duct, persistent, and spontaneous.



## BR-7: Breast Pain (Mastodynia)

- Mammogram and ultrasound are the initial imaging for breast pain.<sup>39</sup>
- Advanced imaging is NOT routinely indicated in individuals with breast pain and negative evaluation (evaluation includes individual history and physical exam, pregnancy test, mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited)).<sup>39</sup>
  - ◆ If evaluation is not negative, See **BR-5: MRI Breast Indications**

### *Background and Supporting Information*

- The risk of malignancy following a negative clinical examination (clinical breast exam, mammogram, ultrasound) has been estimated to be only 0.5%.<sup>39</sup>

## BR-8: Alternative Breast Imaging Approaches

- New and/or alternative breast imaging techniques include:
  - ◆ Nuclear breast imaging, including:
    - Scintimammography
    - Molecular breast imaging (MBI)
    - Breast specific gamma imaging (BSGI)
  - ◆ PET Mammography (PEM)
  - ◆ Thermography
  - ◆ Impedance Mammography
  - ◆ Other techniques to detect oxygen consumption, light absorption, microwave transmission, nitrous oxide production
  - ◆ CT Breast (CPT® 0633T, CPT® 0634T, CPT® 0635T, CPT® 0636T, CPT® 0637T, or CPT® 0638T)
  - ◆ Cone Beam CT Breast
- While alternative breast imaging techniques may have FDA approval, they remain investigational with respect to both screening and diagnosis of breast cancer.

### *Background and Supporting Information*

- CT Breast
  - ◆ CT Breast is evolving and currently being studied as a mode of breast cancer detection. It remains under investigation, and is not to be used in lieu of conventional breast imaging modalities.
- Positron Emission Mammography
  - ◆ There is currently insufficient data available to generate appropriateness criteria for this modality, and this procedure should be considered investigational at this time.
  - ◆ High-resolution positron-emission mammography (PEM) by Naviscan™ PET Systems, also referred to as Naviscan™ or PET mammography, performs high-resolution metabolic imaging for breast cancer using an FDG tracer. The PEM detectors are integrated into a conventional mammography system, allowing acquisition of the emission images immediately after the mammogram.
  - ◆ Requesting providers often ask for PEM as CPT® 78811 or “PET scan of the breast”.

## BR-9: Suspected Breast Cancer in Males

- Ultrasound is recommended as initial imaging followed by mammography if ultrasound is inconclusive or suspicious for males <25 years of age with an indeterminate palpable mass.
- Mammography is recommended initially followed by ultrasound if mammography is inconclusive or suspicious for males ≥25 years of age with an indeterminate palpable mass or with a concerning physical examination.
- There is limited evidence on the use of MRI in the evaluation of male breast disease.
- Further diagnostic pathway for suspicious clinical or imaging findings usually requires tissue diagnosis.

### *Background and Supporting Information*

Breast cancer in males presents as a mass, skin/nipple change, or pathologic nipple discharge

## BR-10: Breast Evaluation in Pregnant or Lactating Females

- Breast US (CPT® 76641 or CPT® 76642) is first-line imaging in pregnant and lactating females.
- If pregnant/lactating woman has a palpable mass OR has persistent unilateral bloody nipple discharge and US is negative or suspicious, follow with diagnostic mammogram (with lead abdominal shielding).
- IV Gadolinium is required with MRI to evaluate breast parenchyma, but is contraindicated in pregnancy. Biopsy, rather than advanced imaging, is recommended after inconclusive mammogram and US.

## BR-11: Digital Breast Tomosynthesis

Cigna considers digital breast tomosynthesis (DBT), also called 3D mammography, a medically appropriate imaging option in the screening of breast cancer.

➤ Coding Notes:

- ◆ CPT® 77061: Digital breast tomosynthesis; unilateral
- ◆ CPT® 77062: Digital breast tomosynthesis; bilateral
- ◆ CPT® +77063: Screening digital breast tomosynthesis (used in conjunction only with screening bilateral mammography code CPT® 77057)
- ◆ 3D rendering (CPT® 76376 or CPT® 76377) should not be assigned with any 3-D mammography code.

## References

1. Final Recommendation Statement: Breast Cancer: Screening. U.S. Preventive Services Task Force. November 2016.  
<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening>.
2. Mainiero MB, Lourenco A, Mahoney MC, et al. ACR Appropriateness Criteria® Breast cancer screening. *Journal of the American College of Radiology*. 2013; 10(1):11-14.
3. Sprague BL, Stout NK, Schechter C, et al. Benefits, harms, and cost-effectiveness of supplemental ultrasonography screening for women with dense breasts. *Ann Intern Med*. 2015; 162(3):157-166.
4. Mendelson EB, Böhm-Vélez M, Berg WA, et al. ACR BI-RADS® Ultrasound. In: ACR BI-RADS® Atlas, Breast imaging reporting and data system. Reston, VA, American College of Radiology. 2013.
5. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017 – May 17, 2017. Thyroid Carcinoma. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer Screening and Diagnosis 2.2017. ©2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
6. Peters NHG, Borel Rinkes IHM, Zuithoff NPA, et al. Meta-analysis of MR imaging in the diagnosis of breast lesions. *Radiology* 2008; 246(1).
7. Moy L, Elias K, Patel V, et al. Is Breast MRI helpful in the evaluation of inconclusive mammographic findings? *American Journal of Roentgenology*. 2009; 193(4):986-993.
8. Pinel-Giroux FM, El Khoury MM, Trop I, et al. Continuing medical education: breast reconstruction: review of surgical methods and spectrum of imaging findings. *Radiographics*. 2013; 33(2):435-453.
9. Dorrius MD, Van der Weide MCJ, van Ooijen PMA, et al. Computer-Aided Detection in Breast MRI: A systematic review and meta-analysis. *Eur Radiol*. August 2011; 21(8):1600–1608.
10. Lehman CD, Blume JD, DeMartini WB, et al. Accuracy and interpretation time of computer-aided detection among novice and experienced breast MRI readers. *American Journal of Roentgenology* 2013; 200(6):W683–W689.
11. NCCN Guidelines Version 2.2017. Invasive Breast Cancer: Principles of Dedicated Breast MRI Testing. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
12. Saslow D, Boetes C, Burke W, et al. American Cancer Society Guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin* 2007; 57(2):75-89.
13. Emaus MJ, Bakker MF, Peeters PHM, et al. MR Imaging as an additional screening modality for the detection of breast cancer in women aged 50-75 years with extremely dense breasts: The DENSE trial study design. *Radiology*. 2015; 277(2).
14. American College of Obstetricians and Gynecologists. Management of women with dense breasts diagnosed by mammography. Committee Opinion No. 625 American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2015; 125. <https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Management-of-Women-With-Dense-Breasts-Diagnosed-by-Mammography#here>.
15. Siu AL. Screening for breast cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2016; 164(4):279-296.
16. Sickles EA and D'Orsi CJ. ACR BI-RADS® Follow-up and Outcome Monitoring. In: ACR BI-RADS® atlas, breast imaging reporting and data system. American College of Radiology. 2013.
17. McCarthy CM, Pusic A, and Kerrigan CL. Silicone breast implants and magnetic resonance imaging screening for rupture: do U.S. food and drug administration recommendations reflect an evidence-based practice approach to patient care? *Plastic & Reconstructive Surgery*: April 2008; 121(4):1127-1134.
18. Holmich LR, Vejborg I, Conrad C, et al. Untreated Silicone Breast Implant Rupture, *Plastic & Reconstructive Surgery*: July 2004; 114(1):204-214.

19. Grau AM, Bapsi C, Chugh R, et al. Phyllodes tumors of the breast. UpToDate, 6/2017.
20. Tan H, Zhang S, Liu H, et al, Imaging findings in phyllodes tumors of the breast. Eur J Radiol. Jan 2012; 81(1):e62-69.
21. NCCN Guidelines Version 2.2017: Phyllodes Tumor National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
22. NCCN Guidelines Version 1.1017: Breast Cancer Risk Reduction National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
23. Morris EA, Comstock CE, Lee CH, et al. ACR BI-RADS® Magnetic Resonance Imaging. In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology. 2013.
24. Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jan. 45 p.
25. NCCN Guidelines Version 2.2017: Ductal Carcinoma in Situ. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
26. NCCN Guidelines Version 2.2017: Invasive Breast Cancer National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
27. Lehman CD, Gatsonis C, Kuhl CK, et al. MRI evaluation of the contralateral breast in women with recently diagnosed breast cancer. N Engl J Med. 2007 March; 356(13):1295-1303.
28. NCCN Guidelines Version 2.2017: Paget's Disease. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 2.2017 ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
29. Lim HS et al. Paget Disease of the breast: mammographic, US, and MR imaging findings with pathologic correlation. Radiographics. 2011; 31(7); 1973-1987.
30. Moy L, Newell MS, Mahoney MC, et al. ACR Appropriateness criteria stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women. Journal of the American College of Radiology. 2016; 13(11):43-52.

31. NCCN Guidelines Version 3.2019. Genetic/Familial High-Risk Assessment: Breast and Ovarian. National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2019: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 3.2019 ©2019 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
32. Lee SJ, Trikha S, Moy L, et al. ACR Appropriateness Criteria® Evaluation of Nipple Discharge. *Journal of the American College of Radiology*. 2017; 14(5):138-153.
33. Berger N, Luparia A, Di G, et al. Diagnostic Performance of MRI versus galactography in women with pathologic nipple discharge: a systematic review and meta-analysis. *AJR. American Journal of Roentgenology*. August 2017; 209(2):465-471.
34. Bahl M, Gadd MA, Lehman CD. Diagnostic utility of MRI after negative or inconclusive mammography for the evaluation of pathologic nipple discharge. *American Journal of Roentgenology*. 2017; 209(6):1404-1410.
35. Morrogh M, Morris EA, Liberman L, et al. The predictive value of ductography and magnetic resonance imaging in the management of nipple discharge. *Ann Surg Oncol*. 2007; 14; 3369.
36. Expert Im, Mainiero MB, Moy L, et al. ACR Appropriateness Criteria® Breast Cancer Screening. *American College of Radiology*. 14(11s):s383-s390.
37. Berg WA. Current status of dedicated nuclear breast imaging. *Society of breast imaging white paper. Journal of Nuclear Medicine*. 2016 Feb; 57(Supplement 1):46S-52S.
38. Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. *J Am Coll Radiol*. 2010; 7(1):18-27.
39. Expert Im, Jokich PM, Bailey L, et al. ACR Appropriateness Criteria® Breast Pain. *American College of Radiology*. 2014(5S).
40. Monticciolo DL, Newell MS, Moy L, Niell B, Monsees B, Sickles EA. Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR. *Journal of the American College of Radiology*. 2018;15(3):408-414.
41. <https://www.cdc.gov/genomics/gtesting/file/print/fbr/BCAnaVal.pdf>.
42. NCCN Guidelines Version 3.2018, Breast Cancer Screening and Diagnosis. National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2018: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 3.2018 ©2018 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
43. NCCN Guidelines Version 3.2019, Genetic/Familial High Risk Assessment: Breast and Ovarian. National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2019: Breast Cancer. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Breast Cancer 3.2019 ©2019 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
44. Koning Breast CT. Koning Corporation. <http://koninghealth.com/en/kbct/>. Accessed March 18, 2019.
45. Golan O, Amitai Y, Barnea Y, Menes TS. Yield of surveillance magnetic resonance imaging after bilateral mastectomy and reconstruction: a retrospective cohort study. *Breast Cancer Research and Treatment*. 2018;174(2):463-468. doi:10.1007/s10549-018-05077-9.
46. Sanders LM, El-Madany M, Persing A, Mehta A. Use of Contrast-Enhanced MRI in Management of Discordant Core Biopsy Results. *American Journal of Roentgenology*. 2019;212(5):1157-1165. doi:10.2214/ajr.18.20157
47. Sanders LM. Breast MRI in the management of the discordant-benign core biopsy. *Diagnostic Imaging Europe*. 2019;35(5). 13-16.



48. ACR Practice Parameter for the Performance of Contrast-Enhanced Magnetic Resonance Imaging (MRI) of the Breast. Revised 2018. (Resolution 34). <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-contrast-breast.pdf>.
49. Difflorio-Alexander RM, Slanetz PJ, Moy L, et al. ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women. *Journal of the American College of Radiology*. 2018;15(11). doi:10.1016/j.jacr.2018.09.013.
50. Children's Oncology Group. Long-term follow up guidelines for survivors of childhood, adolescent and young adult cancers, version 5.0. Monrovia, CA: Children's Oncology Group; pg 90. October 2018. [http://www.survivorshipguidelines.org/pdf/2018/COG\\_LTFU\\_Guidelines\\_v5.pdf](http://www.survivorshipguidelines.org/pdf/2018/COG_LTFU_Guidelines_v5.pdf).
51. Boone JM, Kwan ALC, Yang K, Burkett GW, Lindfors KK, Nelson TR. Computed Tomography for Imaging the Breast. *Journal of Mammary Gland Biology and Neoplasia*. 2006;11(2):103-111. doi:10.1007/s10911-006-9017-1.
52. Boone JM, Nelson TR, Lindfors KK, Seibert JA. Dedicated Breast CT: Radiation Dose and Image Quality Evaluation. *Radiology*. 2001;221(3):657-667. doi:10.1148/radiol.2213010334.
53. Diekmann F. Contrast-enhanced Dedicated Breast CT. *Radiology*. 2011;258(2):650-650. doi:10.1148/radiol.101761.
54. Glick SJ. Breast CT. *Annual Review of Biomedical Engineering*. 2007;9(1):501-526. doi:10.1146/annurev.bioeng.9.060906.151924.
55. Hendrick RE. Radiation Doses and Cancer Risks from Breast Imaging Studies. *Radiology*. 2010;257(1):246-253. doi:10.1148/radiol.10100570.
56. The Future of Breast Imaging is Here. Koning Corporation. <http://koninghealth.com/en/>.
57. Lindfors KK, Boone JM, Nelson TR, Yang K, Kwan ALC, Miller DF. Dedicated Breast CT: Initial Clinical Experience. *Radiology* 2008; 246: 725- 733.
58. Prionas ND, Lindfors KK, Ray S, et al. Contrast-enhanced Dedicated Breast CT: Initial Clinical Experience. *Radiology*. 2010;256(3):714-723. doi:10.1148/radiol.10092311.
59. Aminololama-Shakeri S, Abbey CK, Gazi P, et al. Differentiation of ductal carcinoma in-situ from benign micro-calcifications by dedicated breast computed tomography. *European Journal of Radiology*. 2016;85(1):297-303. doi:10.1016/j.ejrad.2015.09.020.
60. Aminololama-Shakeri S, Abbey CK, López JE, et al. Conspicuity of suspicious breast lesions on contrast enhanced breast CT compared to digital breast tomosynthesis and mammography. *The British Journal of Radiology*. 2019;92(1097):20181034. doi:10.1259/bjr.20181034.
61. Aminololama-Shakeri S, Hargreaves JB, Boone JM, Lindfors KK. Dedicated Breast CT: Screening Technique of the Future. *Current Breast Cancer Reports*. 2016;8(4):242-247. doi:10.1007/s12609-016-0227-2.
62. SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED). [https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/P130022b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf). Accessed November 5, 2020.