

# Cigna Medical Coverage Policies – Radiology Breast Imaging

Effective July 31, 2020



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## 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.

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## 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

## BI-RADS™ Categories Chart

### **Category 0: Incomplete**

Need additional imaging evaluation or prior mammograms for comparison.

### **Category 1: Negative**

There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.

### **Category 2: Benign Finding**

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.

### **Category 3: Probably Benign Finding – Short Interval Follow-up Suggested**

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.

### **Category 4: Suspicious Abnormality – Biopsy Should Be Considered**

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.

### **Category 5: Highly Suggestive of Malignancy-Appropriate Action Should Be Taken**

These lesions have a high probability of being cancer and should be biopsied or treated surgically

### **Category 6: Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken**

These lesions have been biopsied and are known to be malignant.

## BI-RADS™ Breast Density Categories

**Category A: Almost entirely fatty**

**Category B: Scattered fibroglandular densities**

**Category C: Heterogeneously dense**

**Category D: Extremely dense**

## 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 women 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 women 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>



### ***MRI Breast – 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® 74175 or CPT® 72191 or CPT® 74174) or MRA Abdomen and/or Pelvis (CPT® 74185 and/or CPT® 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 women 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 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 and inconclusive or conflicting findings on mammography or ultrasound of a finding that is not a discrete palpable mass.
  - ◆ 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

*MRI screening to begin at age 20:*

- |    |  |
|----|--|
| 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. |
|----|--|

*MRI screening to begin at diagnosis but not prior to age 25:*

- |    |   |
|----|---|
| 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> |
|----|---|

*MRI screening to begin at age determined by gene mutation:*

- |    |   |
|----|---|
| 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> |

*MRI screening begins at age 40, or 10 years before the age of relative when first diagnosed with breast cancer, but not prior to the age of 25.<sup>4,12,22,30,42,43</sup>*

- |     |  |
|-----|--|
| 7.  | First-degree relative (parent, sibling, child) 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 or BRCAPRO models.  |

### Additional Risks:

- |     |  |
|-----|--|
| 13. | Women with history of radiation to the chest between ages 10 and 30; breast screening should start 8 to 10 years post-therapy, or at age 25, whichever comes first. <sup>4,12,30</sup> |
|-----|--|

Personal History of Breast Cancer	
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 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 diagnosed before age 50. <sup>39</sup>

### *MRI Breast Indications - Background and Supporting Information*

- 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
  - ◆ Mammogram and ultrasound (CPT® 76641: unilateral, complete or CPT® 76642: unilateral, limited) should be obtained as initial imaging, with clinical pathway determined by results.
  - ◆ MRI Breast if BOTH of the following:
    - Mammogram and ultrasound are negative, AND
    - No palpable mass
  - ◆ Ductography is an alternative imaging study, if available
- 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>

### *Nipple Discharge/Galactorrhea - 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**

### *Breast Pain – 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
  - ◆ 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.

### *Alternative Breast Imaging Approaches - Background and Supporting Information*

- 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 men <25 years of age with an indeterminate palpable mass.
- Mammography is recommended initially followed by ultrasound if mammography is inconclusive or suspicious for men ≥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.

### *Suspected Breast Cancer in Males – Background and Supporting Information*

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

## BR-10: 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.

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