

Cigna Medical Coverage Policies – Radiology Breast Imaging

Effective February 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.

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Breast Imaging Guidelines

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Abbreviations for Breast Guidelines

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

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

BR-Preface1: General Considerations

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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

BI-RADS™ Categories Chart	
Category	Description
<i>Category 0: Incomplete</i>	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.
<i>Category 1: Negative</i>	There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.
<i>Category 2: Benign Finding</i>	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.
<i>Category 3: Probably Benign Finding – Short Interval Follow-up Suggested</i>	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.

BI-RADS™ Categories Chart	
Category	Description
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.

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

BI-RADS™ Breast Density Categories
Category A: Almost entire 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.^{1,2,3}
 - ◆ Ultrasound screening for women whose only indication is dense breast tissue is not indicated.^{1,2,3}
 - ◆ 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.¹
 - ◆ 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).¹⁶
 - ◆ 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.³
- 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.³
 - 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.⁹
 - ◆ 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.⁵

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”.^{6,7}

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.^{2,3}
 - ◆ 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.⁸
- 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.⁸

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.^{3,6}
- 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**.^{13,14,15}
- 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).¹⁶
 - 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.¹⁶
- 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 indicated⁴⁵

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.¹
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.^{18,19,20}
- 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.
 - ◆ 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.
 - ◆ 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).¹⁶
 - 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.⁵
- Newly Diagnosed Breast Cancer⁴ (including DCIS).^{1,6,24,25,26}
- Newly Diagnosed Paget's Disease⁵ (thereafter treat as DCIS according to these guidelines).^{26,28}
- 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.²⁹
 - ◆ 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.²⁹

➤ 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"> ◆ Atypical ductal hyperplasia (ADH) ◆ Atypical lobular hyperplasia (ALH) ◆ Lobular carcinoma in situ (LCIS)²¹
<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"> ◆ BARD1, MSH2, MLH1, MSH6, PMS2, EPCAM, RAD51C, Genetic variants of unknown significance, genetic variants favoring polymorphism, genetic variants of intermediate penetrance.⁴¹
<i>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.^{4,12,22,30,42,43}</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.

Additional Risks:	
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"> ◆ Chest (thorax) ◆ Whole lung ◆ Mediastinal ◆ Axilla ◆ Mini-mantle, mantle, or extended mantle ◆ Total (TLI) or subtotal (SLTI) lymphoid irradiation ◆ Total body irradiation (TBI)
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. ^{2,3}
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. ³⁹
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. ³⁹

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.^{31,32,33,34}

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.^{31,32,33,34}
- 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.³⁹
- 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)).³⁹
 - ◆ 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%.³⁹

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 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.

Background and Supporting Information

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

BR-10: Evaluation in Pregnant or Lactating Women

- Breast US is first-line imaging in pregnant and lactating women.
- 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 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.

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