CIGNA MEDICAL COVERAGE POLICIES - RADIOLOGY

Breast Imaging Guidelines

Effective Date: July 1, 2025

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

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Abbreviations for Breast Guidelines	
BI-RADS™	Breast Imaging Reporting and Database System
BRCA	tumor suppressor gene
CAD	computer-aided detection
CT	computed tomography
CTA	computed tomography angiography
CTV	computed tomography venography
DCIS	ductal carcinoma in situ
FDA	Food and Drug Administration
FDG	fluorodeoxyglucose
FNA	fine needle aspiration
HRCT	high resolution computed tomography
LCIS	lobular carcinoma in situ
MRA	magnetic resonance angiography
MRI	magnetic resonance imaging
PEM	positron-emission mammography
PET	positron emission tomography

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General Guidelines (BR-Preface 1.0)

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- A current clinical evaluation since the onset or change in symptoms is usually required prior to considering advanced imaging.
  - A clinical evaluation should include the following:
    - A relevant history and physical examination since the onset or change in symptoms
    - Appropriate laboratory studies and non-advanced imaging modalities, such as mammogram and/or ultrasound
    - Other meaningful contact (telephone call, electronic mail or messaging) since the onset or change in symptoms by an established individual can substitute for a face-to-face clinical evaluation
- Current clinical evaluation is not required prior to screening studies.
- Throughout this guideline, when MRI Breast is indicated any **ONE** of the following codes is supported:
  - CPT® 77049 MRI Breast Bilateral, including CAD, with and without contrast
  - HCPCS C8908 MRI Breast Bilateral, with and without contrast
- If the individual has breast implants, the following code is supported when MRI Breast is requested to assess integrity of breast implants **AND** is also indicated in the guidelines:
  - CPT® 77047 MRI Breast Bilateral, without contrast

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BI-RADS™ Categories Chart (BR-Preface 1.1)

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BI-RADS™ Categories Chart	
Category	**Description**
Category 0: Incomplete	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.
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.

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BI-RADS™ Categories Chart	
Category	**Description**
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 (BR-Preface 1.2)

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

Breast Ultrasound (BR-1)

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Breast Ultrasound (BR-1.1)

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- Routine performance of breast ultrasound as stand-alone screening or with screening mammography is not indicated.
  - Breast ultrasound is a supplemental screening alternative for high-risk females (as described in **MRI Breast Indications [BR-5]**) with dense breasts on mammography, when MRI Breast without and with contrast cannot be performed. The inability to perform MRI Breast may be because it cannot be tolerated (i.e., insurmountable claustrophobia or body habitus), or there exists a contraindication (i.e., non-MRI compatible implantable devices or an inability to receive MRI contrast). When a MRI Breast has not been performed in the past year for high-risk screening, then a bilateral breast ultrasound requested for supplemental screening in high-risk females with dense breasts on mammography is supported.
  - 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) can be used to further evaluate abnormalities found on mammogram, especially in differentiating cysts from solid lesions.
  - A clinical office visit is not necessary prior to breast ultrasound when an abnormality has been identified on a 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).
  - 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.
- For breast implant imaging, please see **Breast Implant Evaluation (BR-5.2)**.
- Axilla ultrasound (CPT® 76882)
  - For females with clinically suspicious lymph nodes, pre-operative axillary ultrasound with a FNA or biopsy can help identify individuals who have positive nodes.
    - See **Axillary Lymphadenopathy (and Mass) (CH-2.2)** in the Chest Imaging Guidelines.

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  - Bilateral should be coded CPT® 76882 x 2.
- US-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 US-directed breast biopsy to document successful lesion sampling if histology is benign and non-specific, 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.

MRI Breast Coding (BR-2)

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MRI Breast Coding (BR-2.1)

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- 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 **NOT** necessary with these procedures.
  - The use of CAD has little influence on the sensitivity and specificity of MRI Breast interpretation.
  - 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 MRI Breast.
- MRI-guided breast biopsy (CPT® 19085) includes the imaging component and the needle placement under MR guidance; CPT® 77021 MR guidance for needle placement is **NOT** an appropriate code to bill for a breast biopsy.
  - Additional lesions should be billed using CPT® 19086.
  - This program does not manage codes CPT® 19085 or CPT® 19086.

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.”

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Breast Reconstruction (BR-3)

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Breast Reconstruction (BR-3.1)

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- CTA or MRA of the body part from which the free-tissue transfer flap is being taken, can be performed for breast reconstruction pre-operative planning.
  - 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.
- Routine use of CTA Chest (CPT® 71275) to evaluate recipient vessels is **NOT** indicated.
  - **Criteria exception**: In circumstances where there has been previous cardiac/vascular surgery and/or known vascular anomalies in the chest, it may be warranted.
- 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.

Evidence Discussion

The American College of Radiology (ACR) Appropriateness Criteria state that either MRA abdomen and pelvis with and without IV contrast and CTA abdomen and pelvis with IV contrast are usually appropriate for preoperative planning in patients undergoing DIEP flap breast reconstruction.[2] Studies have found CTA mapping results in a shorter operative time when compared with no mapping in cases of breast reconstruction with free-tissue flap transfer (e.g., with Deep Inferior Epigastric Perforator (DIEP) flaps).[1]

In contrast, routine use of CTA chest to evaluate for recipient vessels (often the internal mammary vessels) is not indicated. This is because a number of studies have found that the anatomy and course of these vessels is largely consistent, and that there is good concordance between surgical and radiological findings – either with ultrasound or CTA.[3] CTA, however, carries with it significant risks, including contrast nephrotoxicity and allergic reactions, and the significantly higher risk of radiation exposure in the chest than in the abdomen.[4] As such, many surgeons will use hand-held Doppler ultrasound either pre- and/or intra-operatively to evaluate recipient vessels. In certain circumstances, such as with previous surgery and/or radiation that would be expected affect the candidacy of potential recipient vessels, preoperative CTA of the chest may be considered.

As pedicled flaps, by definition, do not require a microvascular anastomosis and are not disconnected from their blood supply, there is no current evidence to support routine preoperative imaging in these patients. A recent study evaluating the use of preoperative CTA in patients undergoing pedicled TRAM flap reconstruction found that

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there was no significant difference in terms of operative time nor flap loss in patients who had a preoperative CTA compared those who did not.[5]

MRI Breast Indications (BR-5)

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MRI Breast Indications (BR-5.1)

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Breast MRI Considerations

- When MRI Breast imaging is clinically indicated (per the criteria listed in the sections below), an MRI Breast Bilateral with and without contrast is supported.
- MRI Breast Unilateral is **NOT** clinically supported.
- See **Breast Ultrasound (BR-1)** when there is a contraindication to MRI contrast.
- See **MRI Breast Coding (BR-2)** for MRI-guided breast biopsy.
- See **Breast Cancer (ONC-11)** in the Oncology Imaging Guidelines for imaging indications related to breast cancer as follows:
  - Breast Cancer - Initial work-up/Staging
  - Breast Cancer - Restaging/Recurrence
  - Breast Cancer - Surveillance/Follow-up
  - Annual screening with prior history of breast cancer

Malignant Phyllodes Tumor (Cystosarcoma Phyllodes)

- MRI Breast is indicated pre-operatively to establish extent of disease where a diagnosis of malignant phyllodes tumor has previously been established by tissue diagnosis.

Mammogram and/or US with Equivocal or Occult Findings

- MRI Breast is **NOT** indicated 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.
- MRI Breast is indicated for **EITHER** of the following:
  - Radiologist Report Recommendation for MRI Breast to assess inconclusive or conflicting findings on mammography or ultrasound with **EITHER** of the following:
    - Findings that are not associated with a discrete palpable mass.
    - Inconclusive findings of fat necrosis (most commonly due to trauma or surgery) in an individual with a history of breast cancer treated with surgery (lumpectomy or mastectomy with or without reconstruction).
  - Documented histopathologic discordance between core-needle biopsy findings and imaging findings. MRI Breast is indicated for further evaluation **after** the discordant biopsy (before consideration for surgical management vs. observation).
    - Discordance exists when the biopsy result does not adequately explain the abnormal (BI-RADS™ 4 or 5) findings on mammogram and/or ultrasound.
- See **MRI BI-RADS™ 3** section for lesions categorized as BI-RADS™ 3 on MRI.

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- Lesions that are categorized as BI-RADS™ 3 (low risk, probably benign) **on mammogram and/or ultrasound** are not considered equivocal. MRI Breast is **NOT** indicated for these lesions.
  - Repeat the original study type (mammogram or US) in 6 months
    - if repeat imaging remains BI-RADS™ 3, repeat original study type 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).
    - if repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile. See **Risk Factors** section.
- MRI Breast is **NOT** indicated for suspicious (BI-RADS™ 4 or 5) lesion on mammogram and/or ultrasound.
  - A lesion categorized as BI-RADS™ 4 or 5 should be biopsied.

MRI BI-RADS™ 3

- A probably benign lesion on **MRI** (MRI BI-RADS™ 3) should undergo repeat MRI in 6 months.
  - if repeat imaging remains MRI BI-RADS™ 3, then 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).
  - if repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile. See **Risk Factors** section.

Post Biopsy Imaging

- For lesions initially seen on MRI Breast **and** that have benign and non-specific, equivocal or uncertain histology (based on a stereotactic, MRI-guided, or US-directed breast biopsy), an MRI Breast can be repeated at least 6 months after the biopsy to document successful lesion sampling.

Risk Factors

- To date, evidence does not suggest improved outcomes for individuals whose only risk factor is breast density. Therefore, MRI Breast is **NOT** indicated for individuals whose only risk factor is dense breasts as determined by mammogram.
  - See **Mammogram and/or US with Equivocal or Occult Findings** section.
- Routine MRI Breast following bilateral mastectomy is **NOT** indicated (even if high-risk screening criteria may otherwise be met).
- Annual MRI Breast screening is indicated for individuals meeting the high-risk criteria in the table below:

High-Risk Indications	Age at which screening can start**
Genetic Mutations:*	

High-Risk Indications	Age at which screening can start**
Li Fraumeni (p53)	20
BRCA 1 or 2	25
STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2, ATM, CHEK2	30**
BARD1, RAD51C, RAD51D	40**
Personal history of atypia/LCIS:	
ADH, ALH, LCIS	At diagnosis but not prior to age 25
Family history:	
If the individual has **NOT** been tested for BRCA mutation **and** there is a first-degree relative (parent, sibling, child; half siblings are considered second-degree relatives) with BRCA 1 or BRCA 2 mutation. Annual screening is **NOT** indicated if the individual has been tested and is negative for BRCA 1 or BRCA 2 mutation unless they meet other criteria.	40**
Two or more first-degree relatives with breast or ovarian cancer	40**
One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤ age 50	40**
One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer	40**
A first- or second-degree male relative (father, brother/half-brother, uncle, grandfather) diagnosed with breast cancer	40**
Risk by Gail (NCI), Claus, Tyrer-Cuzick (IBIS), or BRCAPRO Model:	
Clinical lifetime-risk estimated at greater than or equal to 20%	40**
Personal history of radiation therapy when younger than age 30:	

High-Risk Indications	Age at which screening can start**
Radiation to chest, whole lung, mediastinum, axilla, mantle (including mini mantle or extended mantle), total or subtotal lymphoid irradiation or total body irradiation (TBI)	25 or 8 years after completion of radiation therapy *whichever comes later*

*The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is NOT indicated at this time: MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, genetic variants of unknown significance, genetic variants favoring polymorphism, and genetic variants of intermediate penetrance.

OR 10 years prior to the age of diagnosis of the earliest relative with breast cancer (regardless of degree of relativity) *whichever comes first*, **but not before age 25

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 biopsy of mammographically, clinically, and/or sonographically suspicious findings (ACR Practice Guidelines).

Evidence Discussion

High Risk Indications

Li Fraumeni Syndrome is associated with an increased incidence of premenopausal breast cancer, with the median age of diagnosis being in the early 30s.[10] Accordingly, the National Institute for Health and Care Excellence[9] recommends annual MRI screening beginning at age 20.[9]

While the American Cancer Society has found that there's not enough evidence to make a recommendation for or against screening MRI in these populations,6 the NCCN has recommended annual breast MRI for those with ADH, ALH or LCIS who have at least a 20% residual lifetime risk of developing breast cancer. Screening could begin at the age of diagnosis of ADH or lobular neoplasia, but not before the age of 25. They further note that the residual lifetime risk calculation depends on the age at diagnosis.[7]

BRCA1 and *2* are associated with a risk of developing breast cancer > 60%.8 The NCCN guidelines recommend starting MRI screening at the age of 25.[8] *STK11* mutations are associated with a 32-54% risk of developing primary breast cancer. *CDH1* and *PALB2* mutations each confer a risk of 41-60% of developing breast cancer. NCCN guidelines recommend starting MRI screening in these patients at age 30. For patients with NF1, the risk of developing breast cancer is 20-40%. NCCN guidelines recommend considering annual MRI screening from ages 30-50. *ATM* mutations are associated

with a 20-30% risk of developing breast cancer, and *CHEK2* mutations similarly are associated with a 20-40% risk. NCCN guidelines suggest consideration of annual breast MRI starting at age 30-35 in both of these groups. *PTEN* mutations are associated with a 40-60% risk of developing breast cancer. While NCCN guidelines are silent on breast cancer screening for this population, ESMO guidelines recommend starting annual MRI at the age of 30.[8,11]

BARD1, RAD51C and *RAD51D* are each associated with a 17-30% risk of developing breast cancer. The NCCN guidelines recommend considering an annual breast MRI starting at age 40.[8]

However, mutations and variants with a < 15% absolute risk of developing breast cancer lack sufficient evidence to suggest that screening MRI would be beneficial. Therefore, the NCCN does not recommend screening MRI for these patients unless other risks are present.[8]

The American Cancer Society considers individuals who have a first-degree relative with a BRCA 1 or 2 gene mutation and who have not been tested themselves to be at high risk. They recommend an annual MRI screening starting at age 30.[6] On the other hand, NCCN guidelines suggest that untested individuals with a first-degree relative with a BRCA 1 or 2 mutation should start screening either 10 years before the youngest family member was diagnosed with breast cancer, but not before age 25, or at age 40, whichever comes first.[7]

MRI utilizes a magnetic field and radio waves with computer processing to produce detailed images whereas CT uses ionizing radiation. Radiation dosages vary based on many factors and can be harmful to tissues. Thus, from radiation safety perspective MRI should be utilized when appropriate and supported by existing literature; however, the NCCN also acknowledges potential harms of MRI use, such as increased false positives, increased recall, and increased benign biopsies.[7]

Phyllodes Tumor

Phyllodes tumors of the breast are usually benign, fibroepithelial lesions that have a range of biologic behaviors. Diagnosis is made by percutaneous core biopsy or excisional biopsy. MRI breast has not been shown to be of value in distinguishing phyllodes tumor from fibroadenoma. However, malignant phyllodes have the propensity to metastasize. Thus, MRI is supported in malignant phyllodes to determine the extent of disease and resectability.[12]

Breast Implant Evaluation (BR-5.2)

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Suspected Rupture of Breast Implants

- Routine surveillance imaging for asymptomatic individuals to assess the integrity of breast implants (silicone or saline) is **NOT** supported.
- Cigna does **NOT** cover surveillance MRI for breast implants if they were placed as part of purely cosmetic surgery.
- Breast MRI is **NOT** indicated for evaluation of capsular contracture.
- For suspected rupture of breast implants (saline or silicone), with a relevant equivocal clinical examination and/or conventional imaging, the imaging for further evaluation is indicated in the table below:

SALINE

Evaluation of Suspected Rupture of Breast Implant		
Saline Implants (in females or transfeminine)	**Asymptomatic**	**Exam Equivocal For Rupture**
<30	No routine imaging supported.	Ultrasound
30-39	No routine imaging supported.	Ultrasound or Diagnostic Mammogram
≥40	No routine imaging supported.	Ultrasound or Diagnostic Mammogram

If ultrasound or diagnostic mammogram results are indeterminate for saline implant rupture, additional imaging with Breast MRI without contrast (CPT® 77047) is supported for further evaluation.

SILICONE

Evaluation of Suspected Rupture of Breast Implant			
Silicone Implants (in females or transfeminine)	**Asymptomatic (< 5 years after implant placement)**	**Asymptomatic (initial imaging at > 5 years after implant placement and follow-up imaging every 2 to 3 years after initial negative imaging)**	**Exam Equivocal For Rupture**
All ages	No routine advanced imaging supported.	Ultrasound (further evaluation with Breast MRI without contrast (CPT® 77047) if ultrasound is indeterminate	Ultrasound OR Breast MRI without contrast (CPT® 77047)

Evidence Discussion

Breast Implant Evaluation

The two types of breast implants include saline and silicone. Saline implant rupture is more clinically apparent, since the body readily resorbs the leaking saline and the implant shell appears deflated on exam.[13] Thus, there is no role for MRI breast(s) in asymptomatic women with saline implants.[14] However, if the exam is equivocal for rupture, initial imaging supported by the American College of Radiology includes diagnostic mammogram and/or ultrasound in individuals >30 years old. In those <30 years of age, diagnostic mammogram is not typically performed and ultrasound is the initial imaging of choice.[14]

An exam is not as reliable for detecting the rupture of silicone implants as it is for saline implants. Therefore, if an exam is equivocal for rupture, imaging with a combination of ultrasound, mammogram, and/or MRI of the breast (with the choice of mammogram depending upon age) is appropriate.[15]

The initial evaluation of individuals who present with a suspicious finding on breast imaging or a palpable mass upon examination involves a biopsy (percutaneous or surgical if percutaneous is not feasible). If the biopsy results are discordant with the imaging findings, an MRI for further evaluation is supported.[16]

Imaging with BI-RADS assessment of category 4 require biopsy. MRI is not supported prior to biopsy.[17]

Imaging with BI-RADS assessment of category 3 require short-term follow up imaging: at 6, 12, and 24 months.[18]

Nipple Discharge/ Galactorrhea (BR-6)

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Nipple Discharge/Galactorrhea (BR-6.1)

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- 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 Breast is the next appropriate imaging study.
- 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.

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.
- 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.

Evidence Discussion

No specific breast imaging is used for evaluation of physiologic discharge, other than usual screening mammogram in the appropriate age group. Otherwise, the evaluation is medical, including lab studies to rule out endocrine etiology. In a study of 13,443 women with nipple discharge, 316 (2.3%) had nonspontaneous discharge, only 1 (0.3%) of whom had carcinoma.[19] Similarly, a retrospective review of 273 women who underwent diagnostic and therapeutic surgery for nipple discharge found no malignancies in those presenting with physiologic nipple discharge.[20]

The evaluation of pathologic nipple discharge is aimed at determining if there is an underlying intraductal papilloma, high-risk lesion, or a malignancy. Larger studies estimate the rate of malignancy or high-risk histopathologic lesions to be 11% to 16% of patients with pathologic nipple discharge.[22] Initial radiographic evaluation includes both diagnostic mammography and targeted breast ultrasound. If both are non-diagnostic, then MRI is the next imaging modality used for evaluation. Contrast-enhanced MRI has demonstrated sensitivities of 93 to 100 percent for invasive cancers as well as benign papillary lesions.[23]

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Breast Pain (Mastodynia) (BR-7)

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Breast Pain (Mastodynia) (BR-7.1)

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- Evaluation of breast pain requires a history and physical exam.
- Mammogram and ultrasound are the initial imaging for breast pain.
- Advanced imaging is **NOT** routinely indicated in individuals with breast pain and negative mammogram and ultrasound (CPT® 76641: unilateral, complete; or, CPT® 76642: unilateral, limited).
  - If mammogram and ultrasound are not negative, see **MRI Breast Indications (BR-5)**.

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%.

Evidence Discussion

In a recent study of 2820 patients presenting with breast pain, the cancer detection rate in those who underwent breast imaging was found to be 0.09%, 1% and 1.4% in patients under the age of 40, 40-49 and 50 years of age or older, respectively.[24] Similarly, in a case control study comparing 987 women with painful breasts and 987 controls, the prevalence of breast cancer was similar between the two groups (0.8% vs. 0.7%, respectively).[25] Given these data, in the absence of other factors, the American College of Radiology recommends against the use of MRI in patients with breast pain.[26]

Alternative Breast Imaging Approaches (BR-8)

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Alternative Breast Imaging Approaches (BR-8.1)

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Molecular Breast Imaging (MBI)

- Molecular Breast Imaging (CPT® 78800) is supported in individuals who meet criteria for breast cancer screening with MRI (per **BR-5**) but for whom MRI is contraindicated.
  - See **Risk Factors** below.

Risk Factors

- To date, evidence does not suggest improved outcomes for individuals whose only risk factor is breast density. Therefore, MRI Breast is **NOT** indicated for individuals whose only risk factor is dense breasts as determined by mammogram.
  - See **Mammogram and/or US with Equivocal or Occult Findings** section.
- Routine MRI Breast following bilateral mastectomy is **NOT** indicated (even if high-risk screening criteria may otherwise be met).
- Annual MRI Breast screening is indicated for individuals meeting the high-risk criteria in the table below:

High-Risk Indications	Age at which screening can start**
Genetic Mutations:*	
Li Fraumeni (p53)	20
BRCA 1 or 2	25
STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2, ATM, CHEK2	30**
BARD1, RAD51C, RAD51D	40**
Personal history of atypia/LCIS:	
ADH, ALH, LCIS	At diagnosis but not prior to age 25
Family history:	

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High-Risk Indications	Age at which screening can start**
If the individual has **NOT** been tested for BRCA mutation **and** there is a first-degree relative (parent, sibling, child; half siblings are considered second-degree relatives) with BRCA 1 or BRCA 2 mutation. Annual screening is **NOT** indicated if the individual has been tested and is negative for BRCA 1 or BRCA 2 mutation unless they meet other criteria.	40**
Two or more first-degree relatives with breast or ovarian cancer	40**
One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤ age 50	40**
One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer	40**
A first- or second-degree male relative (father, brother/half-brother, uncle, grandfather) diagnosed with breast cancer	40**
Risk by Gail (NCI), Claus, Tyrer-Cuzick (IBIS), or BRCAPRO Model:	
Clinical lifetime-risk estimated at greater than or equal to 20%	40**
Personal history of radiation therapy when younger than age 30:	
Radiation to chest, whole lung, mediastinum, axilla, mantle (including mini mantle or extended mantle), total or subtotal lymphoid irradiation or total body irradiation (TBI)	25 or 8 years after completion of radiation therapy *whichever comes later*

*The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is NOT indicated at this time: MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, genetic variants of unknown significance, genetic variants favoring polymorphism, and genetic variants of intermediate penetrance.

OR 10 years prior to the age of diagnosis of the earliest relative with breast cancer (regardless of degree of relativity) *whichever comes first*, **but not before age 25

Other Alternative Breast Imaging Techniques

Other alternative breast imaging techniques may have FDA approval, but they remain investigational with respect to **BOTH** screening and diagnosis of breast cancer. These include the following:

- Nuclear breast imaging, including:
  - Scintimammography
  - 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

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.”

Evidence Discussion

There is limited data regarding the use of MBI in individuals of average breast cancer risk. However, in those classified as high risk (lifetime risk ≥ 20%), the NCCN does support MBI for those who meet criteria for supplemental breast MRI, but who cannot undergo MRI.[7]

There is no data to support other alternative breast imaging techniques. They are not supported for screening by the ACR, NCCN, or other breast society guidelines. As more data becomes available, the guidelines will be updated accordingly.

The American Cancer Society considers individuals who have a first-degree relative with a BRCA 1 or 2 gene mutation and who have not been tested themselves to be at high risk. They recommend an annual MRI screening starting at age 30.[6] On the other hand, NCCN guidelines suggest that untested individuals with a first-degree relative with a BRCA 1 or 2 mutation should start screening either 10 years before the youngest family member was diagnosed with breast cancer, but not before age 25, or at age 40, whichever comes first.[7]

Suspected Breast Cancer in Males (BR-9)

Guideline Page

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Suspected Breast Cancer in Males (BR-9.1)

BR.MA.0009.1.A
v2.1.2025

See **Breast Ultrasound (BR-1)**

- 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.

Evidence Discussion

Breast cancer management in cis-gender males is similar to females. NCCN guidelines recommend that, for male patients presenting with bilateral breast enlargement consistent with gynecomastia or pseudogynecomastia, reassurance with clinical management of the presumed cause (e.g., drug induced, hypogonadism, hyperthyroidism, etc) is all that is needed. For male patients presenting with palpable symptoms not explained by gynecomastia, or for those presenting with bloody nipple discharge, work up should include mammography and ultrasound, followed by core needle biopsy if these studies should be found to be BIRADS category 4-5.[7] Mammography has been found to be accurate in distinguishing benign from malignant lesions in men, and has a sensitivity and specificity of 92% and 90%, respectively, such that more advanced imaging is generally not required.[27]

Breast Evaluation in Pregnant or Lactating Females (BR-10)

Guideline Page

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Breast Evaluation in Pregnant or Lactating Females (BR-10.1)

BR.PR.0010.1.A

v2.1.2025

- Breast US (CPT® 76641 or CPT® 76642) is first-line imaging in pregnant and lactating females.
- If pregnant/lactating female 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.
- Breast MRI without and with contrast (CPT® 77049) is supported for evaluation in lactating women if criteria are met otherwise (see **BR-5.1**).

Evidence Discussion

Pregnancy-associated breast cancer (PABC) is defined as breast cancer diagnosed during pregnancy, throughout the first postpartum year, or during lactation.

The most common presentation of PABC is a palpable mass, but >80% of palpable masses that are biopsied in pregnant and breastfeeding women are benign.[82]

Given the difficulty examining the pregnant and lactating individual, diagnostic breast imaging is crucial in characterizing the features of a palpable mass. In up to 20% of lactating women, isolated bloody nipple discharge without an associated mass can occur, most commonly due to benign etiologies. However, if persistent, bloody nipple discharge can also be a sign of breast cancer. Diagnostic imaging is also recommended in these women.

Ultrasound has the highest sensitivity for the diagnosis of PABC.[83,84] Additionally, both pregnant and lactating woman are predominantly young and have dense breast tissue. Therefore the sensitivity of mammography decreases in these women. For that reason, ultrasound is the first-line imaging in pregnant and lactating women.[84]

Advanced imaging with breast MRI has a limited role in pregnant women. The IV administration of gadolinium is contraindicated. If there is clinical suspicion of malignancy, a biopsy is the next step in evaluation.[61,85]

Digital Breast Tomosynthesis (BR-11)

Digital Breast Tomosynthesis (BR-11.1)

BR.BT.0011.1.C
v2.1.2025

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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Transgender Breast Cancer Supplemental Screening (BR-12)

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Transgender Breast Cancer Supplemental Screening (BR-12.1)

BR.TS.0012.1.A

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- Annual supplemental Ultrasound **AND/OR** MRI Breast screening is indicated for the following:
  - Transmasculine (female-to-male) with **ALL** of the following risk factors:
    - Reduction mammoplasty or no chest surgery
    - Age ≥25
    - High-risk (≥20% lifetime risk)
- Annual Ultrasound and/or MRI Breast, in addition to mammogram, for breast cancer screening is **NOT** indicated in any other scenarios, including **ANY** of the following:
  - Transfeminine (male-to-female)
  - Transmasculine (female-to-male), who have had bilateral mastectomies
  - Transmasculine (female-to-male), who have **NOT** had mastectomies **AND** are at average risk or intermediate risk
- Acceptable models of calculating clinical lifetime-risk include the following: Gail (NCI), Claus, Tyrer-Cuzick (IBIS), or BRCAPRO.

Evidence Discussion

A number of studies have found that transgender patients who have transitioned from female to male have the same risk of developing breast cancer as their cis-gendered female counterparts.[28-30] As such, those who still have breast tissue (i.e., have only undergone reduction mammoplasty or no chest surgery), should be screened similarly to cis-gendered women.

The American College of Radiology Appropriateness criteria recommend the use of ultrasound and/or MRI for patients who are at intermediate to high risk based on either having a lifetime risk ≥ 20%, a personal history of breast cancer, lobular neoplasia or atypia, chest wall irradiation, or have a genetic predisposition to developing breast cancer.[30] The ACR, does however, recommend transmasculine (female-to-male) patients start screening earlier than their cis-gendered counterparts (starting at 25-30 years of age).[30]

For transmasculine patients who are at low to average risk, mammography alone is sufficient.[28-30] Patients who have had bilateral mastectomies have minimal residual breast tissue, such that breast cancer screening using imaging is not indicated.[28-30]

The ACR found insufficient evidence to support the use of routine MRI screening in transfeminine (male-to-female) patients, regardless of duration of hormone use and/or genetic factors. Transfeminine patients who would otherwise be considered "high risk" based on personal or family history may consider annual mammography. Similaraly, mammography may be appropriate in transfeminine patients who have taken feminizing hormones for more than 5 years.[30]

3D Rendering (BR-13)

3D Rendering (BR-13.1)

BR.TD.0013.1.A

v2.1.2025

- 3D rendering (CPT® 76376 or CPT® 76377) should **NOT** be used in conjunction with **ANY** 3D mammography code.
- 3D rendering (CPT® 76376 or CPT® 76377) is **NOT** indicated for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.
- 3D rendering (CPT® 76376 or CPT® 76377) should **NOT** be used in conjunction with MRI Breast.

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References (BR)

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