

2024 Magnetic Resonance Imaging (MRI) Breast

Diagnostic Imaging

 $$\operatorname{MRI-Breast-HH}$$ Copyright © 2024 WNS (Holdings) Ltd.

Last Review Date: 10/28/2024 Previous Review Date: 01/11/2024 Guideline Initiated: 06/30/2019



Table of Contents

Magnetic Resonance Imaging (MRI) Breast	. 3
MRI General Contraindications	. 3
Preamble: Pediatric Diagnostic Imaging	. 3
MRI Breast Guideline	. 3
Chest Cancer Surveillance	. 7
Bone Cancer Surveillance	. 7
Breast Cancer Surveillance	. 9
Esophageal and Esophagogastric Junction Cancer Surveillance	. 9
Mesothelioma: Pleural Surveillance	10
Non-Small Cell Lung Cancer Surveillance	10
Occult Primary Cancer Surveillance	11
Small Cell Lung Cancer Surveillance	11
Soft Tissue Sarcoma Surveillance	11
MRI Breast Procedure Codes	12
MRI Breast Summary of Changes	13
MRI Breast Definitions	14
MRI Breast References	17
Disclaimer section	19
Purpose	19
Clinician Review	19
Payment	20
Registered Trademarks (®/™) and Copyright (©)	20
National and Local Coverage Determination (NCD and LCD)	
Background	
Medical Necessity Codes	21



Magnetic Resonance Imaging (MRI) Breast



NCD 220.2

See also, **NCD 220.2**: Magnetic Resonance Imaging at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

MRI General Contraindications

MRI may be contraindicated for **ANY** of the following:

- Safety, related to clinical status (body mass index exceeds MRI capability, intravascular stents within recent 6 weeks)
- Safety, related to implanted devices (aneurysm clips, cochlear implant, insulin pump, spinal cord stimulator)¹

References: [21] [7] [10]

Preamble: Pediatric Diagnostic Imaging

HealthHelp's clinical guidelines for the Diagnostic Imaging program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

MRI Breast Guideline

Magnetic resonance imaging (MRI) of the breast is considered medically appropriate when the documentation demonstrates **ANY** of the following:

- 1. Breast cancer detection <u>screening</u> when there is **NO** history of breast cancer and **ANY** of the following:
 - a. Breast cancer risk assessment (by validated tool [eg, Gail model, Tyrer-Cuzik risk model]) identifies a lifetime breast cancer development risk of 20% or more, begin annual screening 10 years earlier than youngest family member's age at diagnosis or age 40 years and **NOT** before age 25 years.
 - b. Cancer gene mutation risk is known for **ANY** of the following:

¹Some implanted devices that were once absolute contraindications to a MRI may now be accepted, including if the specific MRI is able to accommodate the device or the device itself is deemed safe for MRI.



- i. Breast cancer (BRCA) 1/2 mutation is known, begin annual screening at age 25 years.
- ii. BRCA mutation is known in first degree relative (child, parent, sibling), but **NOT** yet tested for BRCA gene, begin annual screening at age 25 years.
- iii. Germline mutations (known to be predisposed to a high risk of breast cancer) are known, including **ANY** of the following:
 - A. Ataxia telangiectasia (ATM), begin screening at age 40 years
 - B. BRCA1 associated RING domain 1 (BARD1), begin screening at age 40 years
 - C. Bannayan-Riley-Ruvalcaba syndrome (BRRS), begin screening at age 35 years or 10 years before the earliest age of family member diagnosed with breast cancer
 - D. Cadherin 1 (CDH1), begin screening at age 30 years
 - E. Checkpoint kinase 2 (CHEK2), begin screening at age 40 years
 - F. Cowden syndrome (PTEN), begin screening at age 35 years or 10 years before earliest breast cancer diagnosis in family
 - G. Li-Fraumeni syndrome (TP53 mutation), begin screening between ages 20 years to 29 years or age of earliest diagnosed breast cancer in family
 - H. Neurofibromatosis 1 (NF1), begin screening at age 30 years and stop at age 50 years
 - I. Partner and localizer of BRCA2 (PALB2), begin screening at age 30 years
 - J. Peutz-jeghers syndrome (STK11), begin screening at age 25 years
- c. Chest irradiation with extensive history (eg, lymphoma treatments between ages 10 years to 30 years), begin screening 8 years after radiation and **NOT** before age 25 years
- d. Lobular neoplasia (atypical ductal hyperplasia [ADH], atypical lobular hyperplasia [ALH], lobular carcinoma in situ [LCIS]) is known, with high lifetime risk of 20% or greater; annual screening beginning at age of diagnosis but **NOT** before age 25 years.
- e. Lobular neoplasia (ADH, ALH, LCIS) is known, with intermediate lifetime risk of 15% to 20% **AND** dense breast tissue is present on mammography; annual screening beginning at age of diagnosis but **NOT** before to age 25 years.



- f. Supplemental breast cancer <u>screening</u> for **ANY** of the following:
 - Average risk (less than 15% lifetime risk of breast cancer) with dense breasts
 - ii. High risk (eg, 20% or greater lifetime risk of breast cancer, first degree relative with genetic disposition to breast cancer if **NOT** tested, genetic predisposition to breast cancer, history of chest irradiation between ages 10 years and 30 years old), regardless of breast density
 - iii. Intermediate risk (eg, 15% to 20% lifetime risk of breast cancer, family history of breast cancer WITHOUT known genetic mutations such as BRCA 1/2, personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia) with dense breasts
- g. Transmasculine (female to male) with reduction mammoplasty or **NO** chest surgery, 30 years of age or older with **EITHER** of the following risks:
 - i. High risk (eg, genetic predisposition to breast cancer, first degree relative with genetic disposition to breast cancer if **NOT** tested, history of chest irradiation between ages 10 years and 30 years old, 20% or greater lifetime risk of breast cancer) and age 25 years or older
 - ii. Intermediate risk (eg, personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia or 15% to 20% lifetime risk of breast cancer) and 30 years of age or older

References: [24] [27] [4] [18] [2] [5] [18] [31] [23] [29] [19] [3] [6] [28]

- 2. Cancer is known with **ANY** of the following:
 - a. Axillary nodal adenocarcinoma, with unidentified primary tumor
 - b. Breast cancer is known in a transmasculine (female to male) person, prior to neoadjuvant chemotherapy, to determine tumor size and extent within the breast.
 - c. Initial staging, when prior imaging is non-diagnostic or indeterminate.
 - d. Lobular carcinoma is invasive and <u>physical exam</u>, <u>mammography</u> **OR** <u>ultrasound</u> are non-diagnostic or indeterminate.
 - e. Lobular neoplasia is biopsy proven.
 - f. Surveillance <u>annually</u> for **ANY** of the following:
 - i. Breast cancer history **AND** diagnosis was prior to age 50 years.
 - ii. Breast cancer history **AND** mammography shows dense breast tissue
 - iii. Risk of new cancer or recurrence is high due to risk factors (eg, genetic, life-style, personal history of cancer).



- g. Treatment response monitoring at baseline, during and after cancer treatments **References:** [24] [15] [9] [2] [12] [1] [11]
- 3. Cancer is suspected and **ANY** of the following:
 - a. Breast imaging-reporting and data system (BI-RADS) 3 lesion is probably benign **AND** seen <u>only</u> on prior MRI, for follow-up. (***NOTE**: when prior mammogram and ultrasound did **NOT** show abnormality)
 - b. Breast cancer is suspected and **ALL** of the following:
 - i. Biopsy could **NOT** be performed (eg, single view on mammogram without ultrasound correlation).
 - ii. <u>Physical examination is non-diagnostic or indeterminate</u> (includes skin changes of suspected inflammatory breast cancer).
 - iii. <u>Prior imaging (eg, ultrasound, mammography) is non-diagnostic or</u> indeterminate.
 - c. Lobular neoplasia (ADH, ALH, LCIS) is evident from biopsy.

References: [24] [9] [2]

- 4. Mass, lesion or abnormality in breast for **ANY** of the following:
 - a. <u>Diagnostic mammogram or ultrasound is non-diagnostic or indeterminate</u> **OR** findings are conflicting, when the finding is **NOT** a palpable or discrete mass.
 - b. Mass, lesion, distortion or abnormality of the breast is <u>known</u>, with history of breast cancer **AND** <u>prior imaging is non-diagnostic or indeterminate</u>.
 - c. Nipple discharge (bloody or serous) is unilateral and spontaneous, with **NO** palpable mass **AND** conventional imaging (eg, breast ultrasound, diagnostic mammography) is non-diagnostic or indeterminate.
 - d. Nipple inversion is new, when <u>prior mammogram and ultrasound are non-diagnostic or indeterminate</u> **AND** biopsy **CANNOT** be performed.
 - e. Paget's disease of the breast, with **NO** palpable mass and <u>prior imaging is non-diagnostic or indeterminate</u>.
 - f. Phyllodes tumor is known, diagnosed by biopsy to determine extent of disease, AND for surgical planning.

References: [24] [14] [8] [20] [26] [16] [13] [25]

- 5. Peri-procedural for **EITHER** of the following:
 - a. Pre-procedure evaluation within 30 days of planned breast surgery, to guide treatment plan or monitor neoadjuvant chemotherapy response prior to surgery



Post-procedural follow-up

References: [24] [17] [22]

- 6. Silicone breast implant complication assessment for **ANY** of the following: (***NOTE**: *MRI is* **NOT** indicated for evaluation of saline implant complications **OR** for asymptomatic silicone implants)
 - a. Post-operative complications are suspected **AND** <u>prior imaging is non-diagnostic or</u> indeterminate.
 - b. Rupture is suspected, asymptomatic **AND** <u>mammogram **OR** breast ultrasound is abnormal, non-diagnostic or indeterminate</u>.
 - Symptomatic (eg, capsular contracture, breast lumps, changes in breast shape),
 for silicone implant rupture detection

References: [24] [17]



LCD 33585

See also, LCD 33585: Breast Imaging:Breast Echography (sonography)/Breast MRI/Ductography at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.



LCD 33950

See also, **LCD 33950**: Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography at https://www.cms.gov/medicare-coverage-database/search.aspx if applicable to individual's healthplan membership.

Chest Cancer Surveillance

Surveillance imaging (after cancer treatment) of the chest is considered medically appropriate when the documentation demonstrates **ANY** of the following:

Bone Cancer Surveillance

NCCN Bone Cancer Version 1.2025

Bone cancer surveillance includes **ANY** of the following:

- 1. Chondrosarcoma surveillance for **ANY** of the following:
 - a. Atypical cartilaginous tumor surveillance with **ALL** of the following:



- i. Chest imaging every 6 to 12 months for 2 years, then annually as clinically indicated
- ii. Primary site X-rays and/or cross-sectional imaging magnetic resonance imaging (MRI) (with and without contrast) or computed tomography (CT) (with contrast) every 6 to 12 months for 2 years, then annually as clinically indicated
- Low-grade, extracompartmental appendicular tumor, grade I axial tumors or highgrade (grade II or III, clear cell or extracompartmental) tumors surveillance with ALL of the following:
 - Chest imaging every 3 to 6 months, may include CT at least every 6 months for 5 years, then annually for at least 10 years, as clinically indicated
 - ii. Primary site X-rays and/or cross-sectional imaging MRI (with and without contrast) or CT (with contrast) as clinically indicated.
- 2. Chordoma surveillance with **ALL** of the following:
 - a. Chest imaging every 6 months, with CT included, annually for 5 years, then annually thereafter as clinically indicated
 - Imaging of primary site, timing and modality (eg, MRI ± CT [both with contrast],
 X-ray) as clinically indicated up to 10 years
- 3. Ewing Sarcoma after primary treatment completed and stable/improved disease, surveillance with **ALL** of the following:
 - a. Chest imaging with X-ray or CT: every 3 months
 - b. Primary site imaging with MRI ± CT (both with contrast) and X-ray, increase intervals after 24 months and after 5 years, annually as clinically indicated (indefinitely) (*NOTE: Consider PET/CT [head-to-toe] and/or bone scan.)
- 4. Giant cell tumor of the bone surveillance with **ALL** of the following:
 - a. Chest imaging every 6 to 12 months for 4 years, then annually thereafter as clinically indicated
 - b. Surgical site imaging as clinically indicated (eg, CT and/or MRI, both with contrast, X-ray)
- 5. Osteosarcoma surveillance with primary site and chest imaging (using same imaging that was done for initial work-up) for **ANY** of the following: (***NOTE**: Consider PET/CT [head-to-toe] and/or bone scan.)
 - a. Image every 3 months for years 1 and 2



VINO COMI ANT

- b. Image every 4 months for year 3
- c. Image every 6 months for years 4 and 5
- d. Image annually for year 6 and thereafter, as clinically indicated

Breast Cancer Surveillance

NCCN Breast Cancer Version 4.2024

Breast cancer surveillance includes **ANY** of the following²: (***NOTE**: The waiting period to begin annual surveillance after breast-conserving therapy (BCT) is 6 to 12 months after completing RT.)

- 1. Ductal carcinoma in situ includes a mammogram 6 to 12 months after breast conservation therapy (category 2B) and annually thereafter.
- 2. Invasive breast cancer surveillance includes a mammogram every 12 months, beginning 6 months or more after completion of BCT. (*NOTE: routine imaging of reconstructed breast is **NOT** indicated.)

Esophageal and Esophagogastric Junction Cancer Surveillance

NCCN Esophageal or Esophagogastric Junction Cancers Version 4.2024

Esophageal and esophagogastric junction cancer surveillance includes ANY of the following:3

- 1. Adenocarcinoma, squamous cell carcinoma; imaging studies as clinically indicated
- 2. Tumor classification is Tis (tumor in situ) or T1a (<u>+</u> Barret's esophagus [BE]), after endoscopic resection or ablation, imaging surveillance includes **ALL** of the following⁴:
 - a. Upper gastrointestinal endoscopy (EGD) every 3 months for the first year
 - b. EGD every 6 months for the second year
 - c. EGD annually thereafter (indefinitely)
- 3. Tumor classification is Tis, T1a, N0, after esophagectomy, imaging surveillance includes **ALL** of the following⁵:
 - a. Upper gastrointestinal endoscopy (EGD) every 3 months for the first year
 - b. EGD every 6 months for the second year
 - c. EGD annually thereafter (indefinitely)

²Routine imaging of reconstructed breast is not indicated.

³Routine esophageal/esophagogastic junction cancers are not recommended for cancer-specific surveillance, for more than 5 years after the end of treatment.

⁴Imaging studies for surveillance are **NOT** recommended.

⁵Imaging studies for surveillance are **NOT** recommended.



- 4. Tumor classification T1b^a (N0 on ultrasound) after endoscopic resection or ablation, imaging surveillance includes **ALL** of the following:
 - a. Computed tomography (CT) chest/abdomen (+ contrast, unless contraindicated)
 may be considered every 6 months for the first 2 years and annually for up to 5
 years
 - b. EGD every 3 months for the first year, every 4 to 6 months for the second year, then annually thereafter (indefinitely)
- 5. Tumor classification T1b or greater, any Na or T1a N+, imaging surveillance includes esophagectomy performed with or **WITHOUT** adjuvant therapy then surveillance includes **ALL** of the following:
 - a. Chest/abdomen CT (+ contrast, unless contraindicated) every 6 months for the first 2 years and annually for up to 5 years
 - EGD as clinically indicated **OR** if incompletely resected BE after ablation: EGD
 every 3 months for the first year, every 6 months for the second year, then
 annually indefinitely
- 6. Tumor classification any T and/or any N, with neoadjuvant chemotherapy **OR** chemoradiotherapy **AND** esophagectomy, with or **WITHOUT** adjuvant treatment, imaging surveillance includes chest/abdomen CT (+ contrast, unless contraindicated) every 6 months for up to 2 years, then annually for up to 5 years and EGD as clinically indicated.
- 7. Tumor classification (pretreatment) N0 to N+, T1b to T4, T4b, with definitive chemoradiation (without esophagectomy), surveillance imaging includes **ALL** of the following:
 - a. Chest/abdomen CT (+ contrast unless contraindicated) every 3 to 6 months for the first 2 years and annually for up to 5 years
 - b. EGD every 3 to 6 months for the first 2 years, then annually for 3 more years

Mesothelioma: Pleural Surveillance

NCCN Mesothelioma: Pleural Version 2.2024

Mesothelioma: Pleural: No imaging surveillance suggested.

Non-Small Cell Lung Cancer Surveillance

NCCN Non-Small Cell Lung Cancer Version 11.2024

Non-small cell lung cancer imaging surveillance includes **ANY** of the following:

1. Stage I to stage II (primary treatment includes radiation therapy) **OR** stage III or stage IV (oligometastatic with all sites treated with definitive intent); follow-up with chest CT (+



- contrast) every 3 to 6 months for 3 years, followed by every 6 months for 2 years, then low-dose (- contrast) chest CT annually
- Stage I to stage II (primary treatment includes surgery <u>+</u> chemotherapy); follow-up with chest CT (<u>+</u> contrast) every 6 months for 2 to 3 years, then low-dose (- contrast) chest CT annually

Occult Primary Cancer Surveillance

NCCN Occult Primary Cancer Version 2.2025

Occult primary cancer surveillance imaging for long-term surveillance includes diagnostic tests based on symptomatology.

Small Cell Lung Cancer Surveillance

NCCN Small Cell Lung Cancer Version 2.2025

Small cell lung cancer surveillance includes **ANY** of the following:

- 1. Brain MRI (preferred) or CT (+ contrast) every 3 to 4 months for 1 year, then every 6 months thereafter, then as clinically indicated (regardless of PCI status).
- 2. Chest CT (<u>+</u> abdomen/pelvis CT) every 2 to 6 months (more frequently in years 1 and 2, less frequently thereafter)
- 3. FDG PET/CT is **NOT** recommended for routine follow-up unless **CT chest/abdomen/ pelvis or MRI is contraindicated or unavailable**.

Soft Tissue Sarcoma Surveillance

NCCN Soft Tissue Sarcoma Version 3.2024

Soft tissue sarcoma surveillance includes **ANY** of the following: ***NOTE**: Contrasted imaging is preferred; for long term surveillance to minimize radiation exposure, X-rays or MRI may be substituted.

- 1. Desmoid tumor (aggressive fibromatosis) imaging surveillance includes **ANY** of the following:
 - a. CT or MRI every 3 to 6 months for 2 to 3 years, then every 6 to 12 months thereafter
 - Ultrasound may be considered for select locations (eg, abdominal wall) for longterm follow-up
- 2. Retroperitoneal/intra-abdominal, after resection imaging surveillance includes CT or MRI (consider PET/CT) every 3 to 6 months for 2 to 3 years, then every 6 months for the next 2 years, then annually.



- 3. Stage IA/IB tumor surveillance includes **ALL** of the following:
 - a. Chest imaging with CT (+contrast) or MRI (± contrast) as clinically indicated
 - b. Magnetic resonance imaging (MRI) at baseline and periodically (frequency based on estimated recurrence)
- 4. Stage II/III resectable with acceptable functional outcomes surveillance includes **ANY** of the following:
 - a. Chest imaging with CT (+contrast) or MRI (± contrast) at end of treatment and periodic imaging of primary site (based on estimated risk of locoregional recurrence)
 - b. Chest imaging and imaging of primary site with CT (+contrast) or MRI (± contrast) as clinically indicated
- 5. Stage II, III or select stage IV (any T, N1, M0), resectable with adverse functional outcomes **OR** unresectable primary disease surveillance imaging includes **ANY** of the following:
 - a. Baseline and periodic imaging of primary site as clinically indicated
 - b. Chest imaging with CT (+contrast) or MRI (± contrast) as clinically indicated
- 6. Stage IV synchronous disease imaging surveillance includes **ANY** of the following:
 - a. Chest and other known metastatic sites imaging with CT (\pm contrast) or MRI (\pm contrast) as clinically indicated
 - b. MRI (± contrast) (preferred) and/or CT (+ contrast) at baseline and periodically (frequency based on estimated recurrence)

MRI Breast Procedure Codes

Table 1. MRI Breast Associated Procedure Codes

CODE	DESCRIPTION
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	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
77049	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
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); single organ
C8903	Magnetic resonance imaging with contrast, breast; unilateral



CODE	DESCRIPTION
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

MRI Breast Summary of Changes

MRI Breast guideline had the following version changes from 2023 to 2024:

- Added the following to keep in line with current research:
 - "ADH, ALH, LCIS are known" indication under "Breast cancer detection screening"
 - "Diagnostic mammogram" indication under "Mass, lesion or abnormality in breast"
 - "Lobular carcinoma" indication under "Cancer is known"
 - Pediatric preamble
 - "Phyllodes tumor" indication under "Mass, lesion or abnormality in breast..."
- Changed age and time span in "Bannayan-Riley-Ruvalcaba syndrome" and "Cowden syndrome" indications to keep in line with current research.
- Removed the following as the indication is not supported by current research:
 - "Anatomic guidance" indication under "Peri-procedural"
 - "Invasive breast cancer" indication under "Cancer is known"
 - "Lesion, palpable" indication under "Mass, lesion or abnormality"
 - "Mammogram results are equivocal" indication under "Mass, lesion or abnormality"
 - "Metastasis, axillary node" indication under "Cancer is suspected"
 - "Post breast-area procedure" indication under "Peri-procedural"
 - "Screening mammogram" indication under "Breast cancer detection"
 - "Screening mammogram" indication under "Mass, lesion, or abnormality"
 - "Symptom evaluation" indication
 - The words "for high-risk individuals is indicated" from "Breast cancer detection screening..."
 - The words "prior imaging is non-diagnostic or indeterminate" from "Surveillance annually"
 - "Transmasculine" indication under "Breast cancer detection"



Mid-cycle update: added Pediatric Preamble and pediatric indications

MRI Breast Definitions

Adenocarcinoma is a malignant tumor originating in glandular epithelium.

Ataxia Telangiectasia Mutated (ATM) gene refer to changes in a gene that causes a rare neurodegenerative, autosomal recessive disorder characterized by chromosome instability, radiosensitivity, immunodeficiency and a predisposition for cancer.

Atypical ductal hyperplasia is the accumulation of abnormal epithelial proliferative breast lesions that are not qualitatively or quantitatively abnormal enough to be classified as carcinoma in situ. Atypical hyperplasia is a premalignant condition and may occur in either ductal or lobular epithelium.

Atypical lobular hyperplasia is the accumulation of abnormal cells in a breast lobule (the milk-making parts of the breast).

Bannayan-Riley-Ruvalcaba syndrome (BRRS) is a rare genetic disorder that is present at birth and is characterized by a large head size (macrocephaly), pigmented spots (maculae) on the penis and benign tumors and tumor-like growths in the intestine called hamartomas.

Breast Imaging-Reporting and Data System (BI-RADS™) Classifications

Table 1. BI-RADS™ Categories

able 11 bi NADS categories	
BI-RADS™ CATEGORY	DESCRIPTION
Category 0: Incomplete	Additional imaging evaluation needed or prior mammography unavailable
Category 1: Negative	Symmetrical and no masses, architectural distortions or suspicious calcifications
Category 2: Benign Finding	No probability of malignancy
Category 3: Probably Benign Finding - Short Interval Follow-up Suggested	Less than 2% probability of malignancy and short follow-up interval recommended
Category 4: Suspicious Abnormality - Biopsy Should Be Considered	2% to 94% probability of malignancy, consider biopsy
Category 5: Highly Suggestive of Malignancy - Appropriate Action Should Be Taken	More than 95% probability of malignancy and appropriate action recommended
Category 6: Known Biopsy-Proven Malignancy - Appropriate Action Should Be Taken	Malignancy known from biospy and appropriate action recommended

Table 2. BI-RADS™ Breast Density Categories

RT-RA	CTM	DDEA	CT DE	NCTTV	CATE	CODV
BI-KA		BKFA	SI 1) F			TURY

Category A: Almost entirely fatty

Category B: Scattered Fibroglandular Densities

Category C: Heterogeneously Dense



BI-RADS™ BREAST DENSITY CATEGORY

Category D: Extremely Dense

BReast CAncer gene (BRCA 1 or 2) are sometimes called tumor suppressor genes that change into harmful mutations resulting in cancer, notably breast and ovarian cancers.

Cadherin1 (CDH1) is a gene that provides instructions for making a protein called epithelial cadherin, which is found within the membrane that surrounds the epithelial cells.

Capsular is relating to a membrane or sac enclosing a body part.

Checkpoint Kinase 2 (CHEK2) is a tumor suppressor gene that produces the CHK2 protein. CHK2 is a serine-threonine kinase that is involved in DNA repair, cell cycle arrest and apoptosis.

Cowden syndrome is a genetic disorder characterized by multiple noncancerous, tumor-like growths called hamartomas and an increased risk of developing certain cancers.

Gail Model incorporates six breast cancer risk factors, namely: age, age at menarche, age at first live birth, number of breast biopsies, history of atypical hyperplasia, and number of first-degree relatives with breast cancers. It is for use in women with no history of breast cancer, ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS). Other tools may be more appropriate for women with known mutations in BRCA1, BRCA2, or other hereditary syndromes associated with breast cancer. The calculator can be found at https://www.mdcalc.com/calc/3647/gail-model-breast-cancer-risk

Germline mutation is a genetic change in a body's reproductive cell (egg or sperm) that becomes incorporated into the DNA of every cell in the body of the offspring.

Indeterminate findings are inconclusive or insufficient for treatment planning.

Li-Fraumeni syndrome (TP53 mutation) is a rare familial syndrome that is characterized especially by a high risk of developing early breast cancer and sarcomas of soft tissue.

Lobular carcinoma in situ (LCIS) is a rare condition that causes abnormal cells to form in the breast's milk glands. LCIS is not cancer, but it does increase the risk of developing breast cancer.

Lobular neoplasia is a benign condition that describes a group of atypical epithelial lesions in the breast. These lesions originate in the terminal duct lobular unit (TDLU) of the breast. They are characterized by the proliferation of small, uniform cells that do not infiltrate the mammary gland basement membrane.

Lymphoma is a type of blood cancer that affects the immune system. Lymphoma occurs when abnormal white blood cells, called lymphocytes, grow in the lymphatic system.

Magnetic resonance imaging (MRI) is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.

Mammogram is an X-ray of the breasts that can be used to screen for breast cancer or for diagnostic purposes. During a mammogram, the breasts are compressed between two firm surfaces to spread them out.



Mammoplasty is cosmetic surgery performed on the breasts and fall into three categories: breast augementation, breast reduction and breast reconstruction.

Neoadjuvant treatment is treatment (such as chemotherapy or hormone therapy) administered before primary cancer treatment (such as surgery) to enhance the outcome of primary treatment. **Neurofibromatosis** is a rare genetic disorder that causes benign tumors to grow on nerves and other parts of the body. There are three types of neurofibromatosis: neurofibromatosis 1 (NF1), neurofibromatosis 2 (NF2) and schwannomatosis.

Non-diagnostic is a result that does not lead to a confirmed diagnosis.

Partner and Localizer of BRCA2 (PALB2) is a partner gene and localizer of the BRCA2 gene that provides instructions to make a protein that works with the BRCA2 protein to repair damaged DNA and stop tumor growth.

Paget's disease of the breast is a rare condition associated with breast cancer. It causes eczema-like changes to the skin of the nipple and the area of darker skin surrounding the nipple (areola). It's usually a sign of breast cancer in the tissue behind the nipple.

Pediatric approximate ages are defined by the US Department of Health (USDH), the Food and Drug Administration (FDA), and the American Academy of Pediatrics (AAP) as the following:

- Infancy, between birth and 2 years of age
- Childhood, from 2 to 12 years of age
- Adolescence, from 12 to 21 years of age, further defined by the AAP into:
 - 1. Early (ages 11–14 years)
 - 2. Middle (ages 15-17 years),
 - 3. Late (ages 18–21 years)
 - 4. Older ages may be appropriate for children with special healthcare needs.

Peutz-Jeghers syndrome (PJS) is a familial polyposis inherited as an autosomal dominant trait that is characterized by numerous polyps in the stomach, small intestine and colon along with melanin-containing spots on the skin and mucous membranes especially the lips and gums.

Phyllodes tumor is a rare breast tumor that starts in the connective (stromal) tissue of the breast.

Screening does not diagnose the illness. The goal is early detection and lifestyle changes or surveillance, to reduce the risk of disease, or to detect it early enough to treat it most effectively. **Surveillance** in cancer is the ongoing, timely and systematic collection and analysis of information on new cancer cases, extent of disease, screening tests, treatment, survival and cancer deaths.

Transmasculine people were assigned female gender at birth and identify as male.

Tyrer-Cuzick model is a risk assessment tool that estimates a woman's likelihood of developing breast cancer in 10 years or over her lifetime. The model also estimates the likelihood of



being a BRCA1 or BRCA2 mutation carrier. The calculator can be found at https://ibis-risk-calculator.magview.com/

Ultrasound is the diagnostic or therapeutic use of ultrasound and especially a noninvasive technique involving the formation of a two-dimensional image used for the examination and measurement of internal body structures and the detection of bodily abnormalities.

MRI Breast References

- [1] Alaref, A., Hassan, A., . . . Jahan, N. (2021). Magnetic Resonance Imaging Features in Different Types of Invasive Breast Cancer: A Systematic Review of the Literature. *Cureus*, 13(3), e13854.
- [2] The American Society of Breast Surgeons. (2017). Consensus
 Guideline on Diagnostic and Screening Magnetic Resonance Imaging of
 the Breast. *The American Society of Breast Surgeions*. Retrieved:
 September 2023. https://www.breastsurgeons.org/docs/statements/Consensus-Guidelineon-Diagnostic-and-Screening-Magnetic-Resonance-Imaging-of-the-Breast.pdf
- [3] Berg, W.A., Rafferty, E.A., . . . Rahbar, H. (2021). Screening Algorithms in Dense Breasts: AJR Expert Panel Narrative Review. *American Journal of Roentgenology*, 216(2), 275-294.
- [4] Bevers, T.B., Helvie, M., . . . Wolverton, D.E. (2023). Breast Cancer Screening and Diagnosis Version 1.2023. *National Comprehensive Cancer Network*. Retrieved: September 2023. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf
- [5] Blaes, A., Vogel, R.I., . . . Wyman, J.F. (2020). Breast Cancer Screening Practices for High-Risk Women: A Cross-Sectional Survey of Primary Care Providers. *Journal of Women's Health*, 29(5), 686-692.
- [6] Brown, A., Lourenco, A.P., . . . Moy, L. (2021). ACR Appropriateness Criteria Transgender Breast Cancer Screening. *Journal of the American College of Radiology, 18*(11S), S502-S515.
- [7] Carpenter, J.P., Litt, H. & Gowda, M. (2023). Magnetic Resonance Imaging and Arteriography. A.N. Sidawy (Eds.). *Rutherford's Vascular Surgery and Endovascular Therapy* (30). (pp. 336-394.e4). Philadelphia, PA: Elsevier, Inc.
- [8] Filipe, M., Patuleia, S., . . . Witkamp, A.J. (2020). Network Meta-analysis for the Diagnostic Approach to Pathologic Nipple Discharge. *Clinical Breast Cancer*, *20*(6), e723-e748.
- [9] Gradishar, W.J., Moran, M.S., . . . Yeung, K. (2023). Breast Cancer Version 4.2023. *National Comprehensive Cancer Network*. Retrieved: September 2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf



- [10] Gupta, S.K., Ya'qoub, L., . . . Saeed, I.M. (2020). Safety and Clinical Impact of MRI in Patients with Non–MRI-conditional Cardiac Devices. *Radiology: Cardiothoracic Imaging*, 2(5), e200086.
- [11] Haas, C.B., Nekhlyudov, L., . . . Wernli, K.J. (2020). Surveillance for second breast cancer events in women with a personal history of breast cancer using breast MRI: a systematic review and meta-analysis. *Breast Cancer Research and Treatment, 181*(2), 255-268.
- [12] Hayward, J.H., Linden, O.E., . . . Slanetz, P.J. (2022). ACR Appropriateness Criteria Monitoring Response to Neoadjuvant Systemic Therapy for Breast Cancer. *The Journal of the American College of Radiology*. Retrieved: September 2023. https://acsearch.acr.org/docs/3099208/Narrative
- [13] Jiang, N., Zhong, L., . . . Li, X. (2017). Value of Conventional MRI Texture Analysis in the Differential Diagnosis of Phyllodes Tumors and Fibroadenomas of the Breast. *Breast Care*, 16(3), 283-290.
- [14] Klein, K.A., Kocherr, M., . . . Moy, L. (2023). ACR Appropriateness Criteria Palpable Breast Masses: 2022 Update. *Journal of the American College of Radiology, 20*(5), S146-S163.
- [15] Le-Petross, H.T., Slanetz, P.J., . . . Moy, L. (2022). ACR Appropriateness Criteria Imaging of the Axilla. *Journal of the American College of Radiology*, 19(5S), S87-S113.
- [16] Liu, X., Xu, Y., . . . Lu, H. (2022). Pathological and imaging features of Paget's disease and nipple adenoma: a comparative study. *Gland Surgery*, 11(1), 207-215.
- [17] Lourenco, A.P., Moy, L., . . . Newell, M.S. (2018). ACR Appropriateness Criteria Breast Implant Evaluation. *Journal of the American College of Radiology*, 15(5S), S13-S25.
- [18] Maniero, M.B., Moy, L., . . . Newell, M.S. (2017). ACR Appropriateness Criteria Breast Cancer Screening. *Journal of the American College of Radiology*, *14*(11), S383-S390.
- [19] Mann, R.M., Athanasiou, A., . . . Kuhl, C.K. (2022). Breast cancer screening in women with extremely dense breasts recommendations of the European Society of Breast Imaging (EUSOBI). *European Radiology*, 32(6), 4036-4045.
- [20] Markarian, S. & Holmes, D.R. (2022). Mammary Paget's Disease: An Update. *Cancers*, 14(10), Article 2422.
- [21] Maralani, P.J., Schieda, N., . . . Weinreb, J. (2020). MRI safety and devices: An update and expert consensus. *Journal of Magnetic Resonance Imaging*, *51*(3), 657-674.
- [22] Mehta, T.S., Lourenco, A.P., . . . Moy, L. (2022). ACR Appropriateness Criteria Imaging After Breast Surgery. *Journal of the American College of Radiology*, 19(11S), S341-S356.
- [23] Mulder, R.L., Hudson, M.M., . . . Oeffinger, K.C. (2020). Updated Breast Cancer Surveillance Recommendations for Female Survivors of Childhood, Adolescent, and Young Adult Cancer From the International Guideline Harmonization Group. *Journal of Clinical Oncology, 38*(35), 4194-4207.
- [24] Newell, M.S., Giess, C.S., . . . Zheng, K.S. (2018). ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF CONTRAST-ENHANCED MAGNETIC RESONANCE IMAGING (MRI) OF THE



- BREAST. *American College of Radiology*. Retrieved: September 2023. https://www.acr.org/-/media/acr/files/practice-parameters/mr-contrast-breast.pdfI
- [25] Ofri, A., Stuart, K.E., . . . O'Toole, S. (2022). Diagnosis and management of phyllodes tumours for the surgeon: An algorithm. *The Surgeon*, *20*(6), e355-e365.
- [26] Samreen, N., Madsen, L.B., . . . Heller, S.L. (2021). Magnetic resonance imaging in the evaluation of pathologic nipple discharge: indications and imaging findings. *The British Journal of Radiology*, 94(1120), Article 20201013.
- [27] Schunemann, H.J., Lerda, D., . . . Saz-Parkinson, Z. (2020). Breast Cancer Screening and Diagnosis: A Synopsis of the European Breast Guidelines. *Annals of Internal Medicine*, 172(1), 46-56.
- [28] Sterling, J. & Garcia, M.M. (2020). Cancer screening in the transgender population: a review of current guidelines, best practices, and a proposed care model. *Translational Andrology and Urology*, 9(6), 2771-2785.
- [29] Weinstein, S.P., Slanetz, P.J., . . . Moy, L. (2021). ACR Appropriateness Criteria Supplemental Breast Cancer Screening Based on Breast Density. *Journal of the American College of Radiology*, 18(11S), S456-S473.
- [30] Witte, D.H. (2021). Advanced Imaging in Orthopaedics. F.M. Azar & J.H. Beaty (Eds.). *Campbell's Operative Orthopaedics* (14), (pp. 141-176). Philadelphia, PA: Elsevier.
- [31] Yeh, J.M., Lowry, K.P., . . . Stout, N.K. (2020). Clinical benefits, harms and cost-effectiveness of breast cancer screening for survivors of childhood cancer treated with chest radiation: A comparative modeling study. *Annals of Internal Medicine*, 173(5), 331-341.

Disclaimer section

Purpose

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

Clinician Review

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines



are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

Payment

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

Registered Trademarks (®/™) and Copyright (©)

All trademarks, product names, logos, and brand names are the property of their respective owners and are used for purposes of information and/or illustration only. Current Procedural Terminology (CPT) \mathbb{R}^{TM} is a registered trademark of the American Medical Association (AMA). No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from HealthHelp.

National and Local Coverage Determination (NCD and LCD)



NOTICE

To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to https://www.cms.gov/medicare-coverage-database/search.aspx.

Background

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.

CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this



variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.

In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.

Medical Necessity Codes

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

For Internal Use Only:

11248 11249 11253 11282 11325 11328 11333 11349 11350 11351 11352 11354 11355 11356 11358 11359 11360 11361 11362 11365 11366 11367 11368 11369 11370 11374 11375 11394 11395 11396 11565