

Breast Imaging



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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Internet-Only Manuals (IOMs)	Pub. 100-04, Medicare Claims Processing Manual, Chapter 18	§20 Mammography Services (Screening and Diagnostic)		
LCA	Independent Diagnostic Testing Facilities- physician supervision and technician requirements	A54953	J05 - Wisconsin Physicians Service Insurance Corporation (Part B MAC) J08 - Wisconsin Physicians Service Insurance Corporation (Part B MAC)	IA, KS, MO, NE IN, MI
LCD	Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography	L33950	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCA	Billing and Coding: Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography	A56448		
LCD	Positron Emission Tomography (PET) Scan for Inflammation and Infection	L39521	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCA	Billing and Coding: Positron Emission Tomography (PET) Scan for Inflammation and Infection	A59318		
LCA	Billing and Coding: Positron Emission Tomography Scans Coverage	A54666	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands

LCA	Billing and Coding: Tomosynthesis-Guided Breast Biopsy	A57848	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Positron Emission Tomography Scans Coverage	A54668	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCA	Billing and Coding: Tomosynthesis-Guided Breast Biopsy	A57849	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD	Independent Diagnostic Testing Facility (IDTF)	L35448	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCA	Billing and Coding: Independent Diagnostic Testing Facility (IDTF)	A53252	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCA	Billing and Coding: Independent Diagnostic Testing Facilities (IDTF)	A58559	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD	Breast Imaging: Breast Echography (Sonography)/Breast MRI/Ductography	L33585	J06 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCA	Billing and Coding: Breast Imaging: Breast Echography (Sonography)/Breast MRI/Ductography	A52849	JK - National Government Services, Inc. (Part A/B MAC)	CT, NY, ME, MA, NH, RI, VT
LCD	Independent Diagnostic Testing Facility (IDTF)	L33910	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCA	Billing and Coding: Independent Diagnostic Testing Facility (IDTF)	A57807		

Description

Breast cancer screening is performed on a regular basis when there are no symptoms present and timing is often based on age, family history and/or other contributing factors. Diagnostic breast imaging occurs when there are signs or symptoms suggestive of breast cancer (eg, palpable lump, nipple discharge, skin changes) or a history of breast cancer. A variety of breast imaging techniques have been developed for these purposes.

Mammography (or mammogram) is the most widely used imaging modality for the detection of breast cancer. This specialized test uses a low dose X-ray which is transmitted through the breast tissue, as well as the surrounding tissue, and is performed by compressing the breast firmly between two plates. The two dimensional (2D) radiographic images are analyzed for abnormal findings. Conventional mammography was recorded onto screen-film cassettes. Today, images are more often recorded via digital detectors, known as full field digital mammography (FFDM). FFDM enables radiologists to manipulate the mammographic data (eg, brightness, contrast, magnification) to improve the ability of distinguishing between normal and malignant tissue.

Digital breast tomosynthesis (DBT) is a three-dimensional (3D) breast imaging technique based on 2D FFDM mammography. DBT is similar to a computed tomography (CT) scan that only images the breasts. An X-ray source repeatedly sweeps over the breast at regularly spaced intervals to obtain cross-sectional images of adjacent segments of tissue.

Magnetic resonance imaging (MRI) of the breast is another tool for the detection of breast cancer in select circumstances, as well as for the assessment of silicone implant integrity. MRI creates images of the breast by measuring changes in the movement of protons in fat and water with the application of changing magnetic fields. An image is acquired by processing signal changes that occur following application of pulses of energy.

Computer-aided detection (CAD) software systems (CADe [detection], CADx [diagnosis]) assess images for patterns that may represent microcalcifications or masses indicative of breast cancer. CAD is not intended to be used in place of a radiologist, but rather as a second examination of the images. CAD has been incorporated into many mammography systems over the past several years, including their billing and coding. However, its use in DBT, MRI or ultrasound has not become as routine.

Positron emission tomography (PET) generates 3D images of tissue metabolism by using a radioactive tracer. The tracer is thought to accumulate in rapidly dividing and metabolizing tissue, such as tumors. PET scanning is not indicated for surveillance or monitoring. **(Refer to Coverage Limitations section)** However, it may be performed to obtain additional information on suspicious or equivocal findings and for locally advanced disease.

Other techniques to evaluate breasts include, but may not be limited to, the following:

- **3D computed tomography (CT)** – Breast imaging system intended to provide 3D images to possibly aid in diagnosis of individuals with signs/symptoms of breast cancer or who may have had abnormal findings

on other imaging. CT breast imaging is not intended to screen an asymptomatic individual for breast cancer. An example of this technology is the Koning Vera Breast CT.

- **Artificial intelligence (AI) software** – Software purported to automatically detect and characterize suspicious soft tissue lesions and calcifications in mammography and DBT images to assess the likelihood of malignance. Genius AI Detection, MammoScreen, ProFound AI, QmTRIAGE and Saige-Density are examples of this type of technology.
- **Automated breast ultrasound (ABUS) or automated whole breast ultrasound (AWBU)** – A noninvasive imaging technology which utilizes high frequency sound waves to create detailed images of the breast tissue. It scans the entire breast, providing a 3D volumetric image that can potentially detect small or earlier stage tumors. It is not intended to be used as a replacement for mammography. Examples of systems which perform this type of ultrasound include, but may not be limited to, the Invenia ABUS 2.0, SoftVue Automated Whole Breast Ultrasound System and SonoCine. There are also automated 3D whole breast ultrasound systems such as the ATUSA Automated 3D Breast Ultrasound System, which is AI driven.
- **Contrast enhanced mammography (CEM) or contrast enhanced spectral mammography (CESM)** – Specialized vascular-based breast imaging technique that uses iodinated contrast to reveal areas of increased blood supply within the breast which purportedly depicts tumor vascularity. CEM is suggested for use when additional information is needed, such as during clinical studies.
- **Electrical impedance scanning (EIS)** – Involves the transmission of continuous electricity into the body via an electrical patch on the arm or a handheld device. As the current travels through the breast, it is measured by a probe on the surface of the skin. Cancerous and normal tissue theoretically conduct electricity differently, therefore cancerous images may appear as bright white areas.
- **Handheld ultrasound** – Using high frequency sound waves to create an image, this test is often completed to assist with biopsy. Investigators are studying the use of this technology as an adjunct to screening mammography in an individual with dense breasts and of average risk for developing breast cancer.
- **Optical imaging (diaphanography, light scanning, transillumination)** – Noninvasive test which is conducted by shining high intensity infrared light through the breast or reflecting such light off of the breast. The amount of light that returns is measured and is purportedly useful in visualizing lesions or the blood vessels that supply them. An example of optical imaging is Computed Tomography Laser Mammography (CTLM).
- **Opto-acoustic ultrasound** – Noninvasive scan that combines the use of light (laser optics) and sound (conventional ultrasound), in real time, to produce high-resolution images. This supposedly identifies tumors as small as 3mm and the ability to see submillimeter vascular structures. The Imagio Breast Imaging System is an example of this technology, and it includes an AI based software to assist in assessing the BI-RADS classification.

- **Positron emission mammography (PEM)** – High resolution nuclear medicine imaging modality that is suggested to detect or characterizes breast cancer. It is not recommended for routine use due to a higher radiation dose compared to other imaging.
- **Quantitative transmission ultrasound** – Without compression, radiation or injections this ultrasound calculates fibroglandular volume (FGV) of the breast and the ratio of FGV to total breast volume. This calculation purportedly helps assess the risk for breast cancer and changes to the ratio could potentially be used to measure the efficacy of the prevention or treatment of breast cancer. This device is known as the QTscan and is not intended to be used as a replacement for mammography screenings.
- **Scintimammography (or molecular breast imaging [MBI])** – Noninvasive imaging test that uses radiopharmaceuticals to detect abnormalities of breast tissue. The system visually illuminates enhanced metabolic activity in the breast allegedly associated with the occurrence of a tumor. One example of this technology is the LumaGem Molecular Breast Imaging System.
- **Tactile breast imaging with computer-aided sensors** – A hand-held medical device (eg, Bexa) which employs shear-wave elastography to produce a map of abnormal breast tissues and masses. Its sensor array samples breast tissue elasticity measurements thousands of times a second to define tissue detail. The proprietary algorithms then analyze these signals to create the map which purportedly records the presence (or absence), size, shape, hardness and location of breast lesions.
- **Thermography (digital infrared thermal imaging)** – Noninvasive imaging technique in which an infrared camera is used to measure temperature variations on the surface of the body, producing images that may reveal sites of abnormal tissue growth. The theory behind this technology is that tumors may exhibit higher metabolic activity and will demonstrate an increase in body temperature while new blood vessels formed in cancerous tissue should fail to constrict in response to cold because they lack a layer of muscle. A newer thermography device, the SMILE-100 Breast Thermography System, has also been developed which includes a computer aided diagnostic engine that is powered by AI (Thermalix).

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance related to **breast imaging**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria.

Breast Imaging

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically

necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
76499	Unlisted diagnostic radiographic procedure	
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete	
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited	
77021	Magnetic resonance imaging guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation	
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	
77061	Diagnostic digital breast tomosynthesis; unilateral	
77062	Diagnostic digital breast tomosynthesis; bilateral	

77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral	
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	
78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)	
CPT® Category III Code(s)	Description	Comments
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral	
0633T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material	
0634T	Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)	
0635T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)	
0636T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)	
0637T	Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)	
0638T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)	
0857T	Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)	
HCPCS Code(s)	Description	Comments
C8903	Magnetic resonance imaging with contrast, breast; unilateral	

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	
C8937	Computer-aided detection, including computer algorithm analysis of breast MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	
C9788	Opto-acoustic imaging, breast (including axilla when performed), unilateral, with image documentation, analysis and report, obtained with ultrasound examination	
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)	
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)	

References

- Centers for Medicare & Medicaid Services (CMS). Internet-Only Manuals (IOMs). Pub. 100-04, Medicare Benefit Policy Manual Chapter 18 – Preventive and Screening Services. <https://www.cms.gov>. Published April 1, 2008. Updated July 10, 2023. Accessed November 2, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Independent Diagnostic Testing Facilities (IDTF) (A58559). <https://www.cms.gov/>. Published April 1, 2021. Updated October 1, 2023. Accessed November 2, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Positron Emission Tomography Scans Coverage (A54666). <https://www.cms.gov/>. Published October 1, 2015. Updated October 1, 2022. Accessed November 2, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Positron Emission Tomography Scans Coverage (A54668). <https://www.cms.gov/>. Published October 1, 2015. Updated October 1, 2022. Accessed November 2, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Tomosynthesis-Guided Breast Biopsy (A57848). <https://www.cms.gov/>. Published January 1, 2020. Updated January 1, 2023. Accessed November 2, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Tomosynthesis-Guided Breast Biopsy (A57849). <https://www.cms.gov/>. Published January 1, 2020. Updated January 1, 2023. Accessed November 2, 2023.

7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Independent Diagnostic Testing Facilities- physician supervision and technician requirements (A54953). <https://www.cms.gov/>. Published April 1, 2016. Updated October 26, 2023. Accessed November 2, 2023
8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Breast Imaging: Breast Echography (Sonography)/Breast MRI/Ductography (L33585). <https://www.cms.gov/>. Published October 1, 2015. Updated October 24, 2019. Accessed November 2, 2023.
9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography (L33950). <https://www.cms.gov/>. Published October 1, 2015. Updated December 1, 2022. Accessed October 31, 2023.
10. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Independent Diagnostic Testing Facility (IDTF) (L33910). <https://www.cms.gov/>. Published October 1, 2015. Updated May 13, 2021. Accessed November 2, 2023.
11. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Independent Diagnostic Testing Facility (IDTF) (L39521). <https://www.cms.gov/>. Published August 13, 2023. Accessed November 2, 2023.
12. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Positron Emission Tomography (PET) Scan for Inflammation and Infection (L35448). <https://www.cms.gov/>. Published October 1, 2015. Updated May 13, 2021. Accessed November 2, 2023.

Change Summary

- 01/01/2024 New Policy.

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