Breast Imaging for Screening and Diagnosing Cancer (for Ohio Only)

Policy Number: CS010OH.A – P
Effective Date: February 1, 2023

Instructions for Use

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Related Policy

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Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

For medical necessity clinical coverage criteria for breast cancer screening, refer to Ohio Revised Code Annotated, Section 5164.08.

Note: For breast computed tomography (CT) and 3D rendering of the breast, or additional indications for breast MRI, refer to the Community Plan Radiology & Cardiology Clinical Guidelines - Breast Imaging Guidelines.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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)

CPT Code	Description
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)
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with; image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
76391	Magnetic resonance (e.g., vibration) elastography
76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
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
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
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

HCPCS Code	Description
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

Description of Services

Regular screening is the most reliable method for detecting breast cancer early when treatment is the most effective. Screening recommendations vary according to breast cancer risk, and several tools are available to approximate breast cancer risk based on various combinations of risk factors. Current methods of breast screening and diagnosis include breast self-examination, clinical breast exam, ultrasonography, mammography, and magnetic resonance imaging.

Mammography remains the generally accepted standard for breast cancer screening and diagnosis. However, efforts to provide new insights regarding the origins of breast disease and to find different approaches for addressing several key

challenges in breast cancer, including detecting disease in mammographically dense tissue, distinguishing between malignant and benign lesions, and understanding the impact of neoadjuvant chemotherapies, has led to the investigation of several novel methods of breast imaging for breast cancer management.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Mammographic x-ray systems are classified as Class II devices. The FDA regulates the marketing of mammography devices and regulates the use of such devices via the Mammography Quality Standards Act (MQSA). The FDA has granted pre-market approval to several digital mammography systems (product code MUE) for breast cancer screening and diagnosis.

Magnetic Resonance Elastography of the Breast

Refer to the following website for more information on devices used for elastography of the breast (search by product name LNH in device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 1, 2022)

Breast Specific Gamma Imaging (BSGI)

BSGI for diagnosing breast cancer is a procedure and, therefore, is not subject to FDA regulation. However, the equipment used to conduct BSGI is subject to FDA regulation. The cameras used during BSGI are considered Class I radiologic devices. A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 1, 2022)

Automated Breast Ultrasound System (ABUS)

Automated breast (or whole breast) ultrasound devices are regulated by the FDA as Class III devices. Refer to the following website for more information on devices used for Automated Breast Ultrasound Systems (search by product name in device name section or Product Code ITX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed June 1, 2022)

Electrical Impedance Scanning

These devices are approved as an adjunct to mammography in patients whose lesions are American College of Radiology (ACR) Breast Imaging-Reporting and Data System (BI-RADS) category III (probably benign) or IV (suspicious abnormality), based on mammography. Refer to the following website for more information on devices used for Electrical Impedance Scanning (search by product name in device name section):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 1, 2022)

Computer-Aided Detection for MRI of the Breast

Refer to the following website for more information on devices used for Computer-Aided Detection for MRI of the Breast (search by product name in device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed June 1, 2022)

Computer-Aided Detection for Ultrasound

Refer to the following website for more information on devices used for Computer-Aided Detection for Ultrasound (search by product names MYN and LLZ in device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed June 1, 2022)

Computed Tomography of the Breast

Refer to the following website for more information on devices used for computed tomography of the breast (search by product name JAK in device name section): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed June 1, 2022)

References

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed December 2, 2022.

Ohio Revised Code Annotated, Section 5164.08 Breast cancer and cervical cancer screenings. Available at https://codes.ohio.gov/ohio-revised-code/section-5164.08. Accessed December 2, 2022.

Policy History/Revision Information

Date	Summary of Changes
02/01/2023	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.