Subject: Breast Ultrasound

Medical Policy #: 24.1 **Original Effective Date:** 03/28/2005

Status: Reviewed **Last Review Date:** 12/13/2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Breast ultrasound is a noninvasive diagnostic imaging technique that produces images used to assess breast tissues.

Two types of ultrasound have been identified for supplemental screening: handheld ultrasound and automated breast ultrasound (ABUS). Automated breast ultrasound (ABUS) are not widely available. Most studies assessing the use of ultrasound for supplemental screening in women with abnormal and inconclusive findings such as dense breasts have been performed with handheld ultrasound.

Coverage Determination

Prior Authorization is not required.

For Medicare, Medicaid and Commercial.

Breast Ultrasound is covered when an abnormal and inconclusive finding are seen on diagnostic mammogram of the breast, this may include microcalcification; calcification; inconclusive mammography due to dense breasts; and other abnormal and inconclusive findings.

Covered Indication:

Breast Ultrasound is covered when **all** the following are met.

1. A treating provider's (physician or qualified non-physician practitioner) order is required for breast ultrasound. This requirement is not applicable to radiologists for inpatient or outpatient breast ultrasound.
2. Breast sonography should be performed under the general supervision of a physician qualified in breast ultrasonography.
3. Breast Ultrasound may be indicated for any of the following conditions:
    - Use in guidance for breast interventional procedures
    - Planning for Radiation treatment
    - Initial evaluation of palpable masses in women under age 30
    - In lactating and pregnant women
    - To assess:
        - breast implant related conditions,
        - palpable abnormalities on physical exam,
        - to distinguish simple mastitis from abscess formation,
        - any mass to determine whether it is suitable for percutaneous intervention (such as core biopsy),
        - stability of a sonographically visible mass that is mammographically invisible
    - Non-palpable masses, detected by mammography, to differentiate cysts from solid lesions
    - Palpable masses, if needle aspiration is not performed
    - Symptomatic, possible ruptured silicone breast prosthesis when an MRI is not planned
    - Calcifications to determine if an invasive component exists that would be amenable to core biopsy when supported by additional clinical indications.
    - Ultrasonography may be indicated in addition to diagnostic mammography for the evaluation of some ambiguous mammographic or palpable masses or focal asymmetric densities that may represent or mask a mass. **Breast ultrasonography should not be routinely used along with diagnostic mammography**.

Breast Ultrasound may be covered when no prior diagnostic mammography was performed:

- Breast ultrasonography may be performed, in some cases, without having a diagnostic mammography first. However, an order from the treating physician for the ultrasonography is required. For example: A 22-year-old female presents with a painful breast lump. An ultrasound is performed and documents a large simple cyst, which subsequently is aspirated and resolved without the need for a prior diagnostic mammography.

Non-Covered

For Medicare, Medicaid and Commercial.

Whole Breast Ultrasound (ABUS) is non-covered: The system device referred to as Automated Whole Breast Ultrasound System (ABUS) devices such as Invenia™ ABUS and Somo V® ABUS system (using CPT code 76641) are considered investigational. Automated, Whole-Breast Ultrasound (ABUS) should not be used as a replacement for diagnostic mammography or diagnostic handheld ultrasound. Clinical evidence is inconclusive to show whether automated breast ultrasound improves the detection rate of breast cancer in comparison to screening mammography and handheld ultrasound. Therefore, ABUS system is considered investigational and is not a covered benefit for Medicare, Commercial and Medicaid. See Investigative & New Technology Assessment List (Non-Covered Services), MPM 36.0.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Breast Ultrasound
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete. **Non-covered for ABUS system**
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited
ICD-10	For a listed of covered diagnoses see LCA (A56448)

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD
Medical Director: Ana Maria Rael MD
Date Approved: 12-13-2023

References

1. Hayes, Computer-Aided Diagnosis (CADx) Systems for Breast Ultrasonography: Cancer Detection and Diagnosis,Annual review: Jul 09, 2015. [Cited 10/03/2023]
2. MCG, Ambulatory Care 27th Edition, Breast Ultrasound, ACG: A-0101 (AC), last update: 9/21/2023. [Cited 10-03-2023]
3. UpToDate, Breast imaging for cancer screening: Mammography and ultrasonography, Literature review current through Oct 2023 last updated Sep 15, 2023 [Cited 10/03/2023]
4. UpToDate, Breast density and screening for breast cancer, Literature review current through Oct 2023, last updated Aug 04, 2023. [Cited 10/03/2023]
5. U.S. Preventive Services Task Force, Breast Cancer: Screening, January 11, 2016[Cited 10/03/2023]
6. CMS, Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography, LCD (L33950), Revision date: 12/01/2022, R20; related LCA (A56448), revision date: 12/01/2022, R10. [Cited 10-03/2023]
7. CMS, Novitas, Independent Diagnostic Testing Facility (IDTF), LCD (L35448), Revision History Date, 05/13/2021, R17. Related LCA (A53252), Revision History Date: 10/01/2023, R41. [Cited 10-03-2023]
8. NCD Ultrasound Diagnostic Procedures (220.5), V3, Effective date: 05/22/2007 [Cited 10-03/2023]

Publication History

03-28-05	Original effective date of Benefit Alert
01-27-10	Transition to Medical Policy, Review and Revision
06-27-12	Biennial Review
03-28-05	Original effective date of Benefit Alert
01-27-10	Transition to Medical Policy, Review and Revision
06-27-12	Biennial Review
01-29-14	Presbyterian Policy Retired
01-29-14	Presbyterian now uses Hayes
05-25-16	Annual Review. Accessed Hayes Computer Guided System for Breast Ultrasound. Last reviewed 7/9/15. No change.
09-27-17	Annual Review. Accessed Hayes. Computer Guided System for Breast Ultrasound archived Sep 30th, 2016. Currently not covered.
05-22-19	Annual Review. Went to CQUMC 09-27-17 but policy on webpage was unchanged from (01-29-14). No change. Remains as insufficient evidence to use ultrasound as an adjunct imaging test with mammography in screening for breast cancer. Updated references, Hayes and MCG.
11-18-20	Annual Review. Reviewed 10-30-20 and PHP Medical Policy Committee reviewed on 11-18-20. Coverage status changed. Removed Hayes. Will now follow USPSTF guideline that the use ABUS as an adjunct imaging test with mammography ***screening*** for breast cancer in women identified to have dense breasts on an otherwise negative

	screening mammogram is insufficient. Add to policy to use MCG A-0101 criteria for ***diagnostic*** purposes. Will set to deny CPT codes: 76641 and 76642 using ICD-10 R92.0, R92.1, R92.2 and R92.8 for all LOB.
05-26-21	Policy retired: No change to criteria. continue to follow USPSTF for ABUS to be non-covered and follow MCG for the limited US.
11-17-21	Reviewed by PHP Medical Policy Committee on 11/17/2021. This policy was formerly titled as Whole Breast Ultrasound, Semi-Automatic (ABUS). On last review (05-26-2021) the policy was specific to ABUS and codes (76641 and 76642) were configured as experimental and the policy was retired. These codes (76641 and 76642) upon further review were also used for the hand-held ultrasound. On this review the policy title changed to Breast Ultrasound and all previous configuration and coverage determination for 76641 and 76642 has been recalled. Coverage for breast ultrasound, complete or limited (using codes 76641 and 76642) will be covered, but only those diagnoses listed in the out-of-our region CMS LCA: (A56448) - Breast Imaging Mammography/Breast Echography (Sonography)/Breast MRI/Ductography, (the related LCD L33950), will be considered medically necessary for both 76641 and 76642 for Medicare, Commercial and Medicaid. Continue no Prior Authorization requirement for 76641 and 76642. Continue Non-Covered: The system device referred to as Automated (Whole) Breast Ultrasound System (ABUS) devices such as Invenia™ ABUS and Somo V® ABUS system (using CPT code 76641) are considered investigational. Automated Whole-Breast Ultrasound (ABUS) should not be used as a replacement for diagnostic mammography or diagnostic handheld ultrasound. ABUS system is considered investigational and is not a covered benefit for Medicare, Commercial and Medicaid. The ABUS system is listed in the Investigative & New Technology Assessment List (Non-Covered Services), MPM 36.0.
11-16-22	Annual Review. Reviewed by PHP Medical Policy Committee on 10/28/2022. Removed language that says PHP follows LCD (L33950). Criteria was added which essentially remain unchanged. Continue configuration of ICD-10 listed in LCA (A56448), which is on same revision. Language added in the Description section to define the two types of ultrasound (handheld vs ABUS). Continue no PA requirement for 76641 and 76642.
12-13-23	Annual Review. Reviewed by PHP Medical Policy Committee on 10/04/202. No change to criteria. Continue configuration of ICD-10 listed in LCA (A56448). Continue no PA requirement for 76641 and 76642.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.