Medical Policy Manual Radiology, Policy No. 59

Cone Beam Computed Tomography of the Breast

Effective: March 1, 2024

Next Review: November 2024
Last Review: January, 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cone beam computed tomography (CT) provides three dimensional images for the diagnosis of breast cancer in patients with signs or symptoms of disease and individuals who have abnormal imaging findings.

MEDICAL POLICY CRITERIA

Cone beam computed tomography (CT) is considered **investigational** for imaging of the breast.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Computed Tomography to Detect Coronary Artery Calcifications, Radiology, Policy No. 6
2. Whole Body CT Screening, Radiology, Policy No. 40

BACKGROUND

Breast cancer diagnostic testing and imaging is performed in patients with signs or symptoms of breast disease and for individuals who have abnormal imaging findings. For these

individuals, follow-up includes imaging, such as diagnostic mammogram, ultrasound, or MRI, as well as clinical examination and potentially biopsy and laboratory testing. While MRI has the highest sensitivity of breast imaging methods, it has lower specificity, especially when used to assess dense breasts. Cone beam breast computed tomography (CT) is a new technology that has been approved by the FDA for diagnostic breast imaging.

Cone beam CT uses a cone-shaped x-ray beam and two-dimensional detectors, as opposed the fan-beam and one-dimensional detectors used by conventional CT. Cone beam CT of the breast is performed with a dedicated breast imaging system. The patient lies on the imaging table with a built-in breast opening and a tube/detector system rotates around the breast below the table. A three-dimensional volume of the breast is reconstructed from the acquired images.

Cone beam breast CT can be performed with or without contrast. When contrast is used, images are taken pre- and post-administration of intravenous iodine-based contrast agents. The contrast agent facilitates visualization of breast lesion vascularization. The cone-shaped beam used in cone beam breast CT may allow for better accuracy by reducing problems caused by overlapping tissue. Cone beam breast CT has also been proposed to improve comfort compared with mammography with breast compression.

REGULATORY STATUS

In 2015, the U.S. Food and Drug Administration (FDA) approved the Koning Breast CT (CBCT1000) under the PMA process for three-dimensional diagnostic imaging of the breast.

EVIDENCE SUMMARY

Validation of a new imaging technique involves the following steps:

1. Demonstration of its technical feasibility, including assessment of its reproducibility and precision. For comparison among studies, a common standardized protocol is necessary.

2. Establishment of normal and abnormal values as studied in different clinical situations. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to a gold standard must be known.

3. Assessment of the clinical utility of both positive and negative tests. The clinical utility of an imaging study is related to how the results of that study can be used to benefit patient management. Relevant outcomes of a negative test (i.e., suspected pathology is not present) may be avoidance of more invasive diagnostic tests or avoidance of ineffective therapy. Relevant outcomes of a positive test (i.e., suspected outcome is present) may also include avoidance of a more invasive test plus the institution of specific, effective therapy.

Studies evaluating sensitivity and specificity of cone beam breast CT and comparing this technology to existing standard imaging techniques are described below.

SYSTEMATIC REVIEW

Komolafe (2022) published a systematic review to evaluate and meta-analysis the comparison of diagnostic accuracy of Cone-beam breast computed tomography (CBBCT) and digital breast tomosynthesis (DBT) to characterize breast cancers.[1] Two independent reviewers

identified screening on diagnostic studies from 1 January 2015 to 30 December 2021, with at least reported sensitivity and specificity for both CBBCT and DBT. The pooled sensitivity specificity, positive likelihood ratio and negative likelihood ratio and AUC at 95% confidence interval are 86.7% (80.3-91.2), 87.0% (79.9-91.8), 6.28 (4.40-8.96), 0.17 (0.12-0.25) and 0.925 for the 17 included studies in DBT arm, respectively, while, 83.7% (54.6-95.7), 71.3% (47.5-87.2), 2.71 (1.39-5.29), 0.20 (0.04-1.05), and 0.831 are the pooled sensitivity specificity, LR+ and LR- and AUC for the five studies in the CBBCT arm, respectively. The authors concluded that DBT shows improved diagnostic performance over CBBCT regarding all estimated diagnostic parameters. They added that CBBCT might be a useful modality for breast cancer detection and that more prospective studies on CBBCT application should be conducted.

Uhlig (2019) published a systematic review of the diagnostic accuracy of cone beam breast CT.[2] A total of six studies met inclusion criteria, of which some evaluated both contrast-enhanced cone beam breast CT (CE-CBBCT) and non-contrast CBBCT (NC-CBBCT) and some evaluated only one or the other. Five studies included NC-CBBCT and three included CE-CBBCT. Overall, the study quality was high, except for one study of NC-CBBCT which was presented as a conferenced abstract and was given a lower rating due to lack of complete study design and conduct details. There was high between-study heterogeneity among the NC-CBBCT studies (I^2=98.4%, 95% CI 80.6 to 94.2%, p<0.001). Using NC-CBBCT, pooled sensitivity was 0.789 (95% CI 0.66 to 0.89) and pooled specificity was 0.697 (95% CI 0.471 to 0.851). The NC-CBBCT partial area under the curve (AUC), calculated from only regions with reported study specificities and standardized to the whole space, was 0.817. There was no statistically significant heterogeneity among the three studies that evaluated CE-CBBCT (I^2=57.3, 95% CI 0 to 84.1%, p=0.0527). Protocols for administration of iodinated intravenous contrast media were different in each study. The pooled sensitivity was 0.899 (95% CI 0.785 to 0.956) and the pooled specificity was 0.788 (95% CI 0.709 to 0.85). The CE-CBBCT partial AUC for was 0.869. Only one study compared cone beam breast CT with MRI, the gold standard (discussed below).

NONRANDOMIZED STUDIES

Wienbeck (2018) was the only comparative study in the Uhlig systematic review.[3] This prospective study evaluated the diagnostic accuracy of CE-CBBCT in dense breast tissue (type C and D) and compared CE-CBBCT to mammogram, NC-CBBCT, and MRI. Two readers analyzed all images for a total of 41 patients and 100 lesions. Data from each reader were analyzed separately. For NC-CBBCT, for reader 1 and 2, respectively, sensitivity was 0.57 and 0.47, specificity was 0.84 and 0.71, and AUC was 0.73 and 0.66. For CE-CBBCT, for reader 1 and 2, respectively, sensitivity was 0.88 and 0.78, specificity was 0.71 and 0.71, and the AUC was 0.83 and 0.77. Compared to mammogram and NC-CBBCT, CE-CBBCT improved sensitivity and AUC (sensitivity p<0.001; AUC vs. mammogram p=0.0081, 0.207 for reader 1 and 2; AUC vs. NC-CBBCT p=0.0380, 0.0186 for reader 1 and 2). Compared to MRI, CE-CBBCT had lower sensitivity but and equivalent specificity and AUC (sensitivity p=0.0253, 0.0027 for reader 1 and 2).

Weinbeck performed a separate analysis for each density classification of breasts. For type C breasts, specificity and AUC were not significantly different between any of the imaging modalities. For type D breasts, AUC was not significantly different between CE-CBBCT and MRI or mammogram, and was significantly lower for NC-CBBCT. Sensitivity was not significantly different between CE-CBBCT and MRI, but was significantly lower for the other

two modalities. Specificity was not significantly different except for one reader for NC-CBBCT (whose score was higher than CE-CBBCT, p=0.0339).

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of cone beam CT imaging of the breast.

SUMMARY

There is not enough research to show that cone beam CT of the breast improves health outcomes. No clinical guidelines based on research recommend the use of cone beam CT of the breast. Therefore, cone beam CT of the breast is considered investigational for all indications.

REFERENCES

1. Komolafe TE, Zhang C, Olagbaju OA, et al. Comparison of Diagnostic Test Accuracy of Cone-Beam Breast Computed Tomography and Digital Breast Tomosynthesis for Breast Cancer: A Systematic Review and Meta-Analysis Approach. *Sensors (Basel).* 2022;22(9). PMID: 35591290
2. Uhlig J, Uhlig A, Biggemann L, et al. Diagnostic accuracy of cone-beam breast computed tomography: a systematic review and diagnostic meta-analysis. *European radiology.* 2019;29(3):1194-202. PMID: 30255249
3. Wienbeck S, Fischer U, Luftner-Nagel S, et al. Contrast-enhanced cone-beam breast-CT (CBBCT): clinical performance compared to mammography and MRI. *European radiology.* 2018;28(9):3731-41. PMID: 29594402

CODES

Codes	Number	Description
CPT	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)
HCPCS	None	

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