RadSite
Accreditation Reinvented

Clinical Coverage Guideline

Breast Cone Beam Computed Tomography (Breast CBCT)

POWERED BY TRAJECTORY Health Solutions

RadSite
Accreditation Reinvented

This clinical coverage guideline establishes criteria for the appropriate clinical use of Breast Cone Beam Computed Tomography (Breast CBCT) in diagnostic breast imaging based on generally accepted standards of care. It is intended for ordering clinicians, imaging facilities, payer medical directors, and utilization management reviewers who evaluate whether Breast CBCT is appropriate for a specific diagnostic or treatment-planning indication.

Disclaimer

This RadSite clinical coverage guideline for Breast CBCT is for informational purposes only. It does not constitute medical advice, a substitute for professional clinical judgment, or a guarantee of reimbursement. Coverage determinations remain subject to payer policies, applicable clinical guidelines, and member benefits. Users must verify current evidence, coding requirements, and regulatory status before making clinical or coverage decisions.

Acknowledgements

- Authors: Mark D. Hiatt, MD, Adam C. Powell, PhD, and Ted Winstead, MA
- Technical Experts: David Bodne, MD, David Georges, Richard Reaven, MD, and Roger Zhang, PhD
- Editorial Support: Mark Casner, MBA, Garry Carneal, JD, and Eliot Siegel, MD
- Peer Review: RadSite's CBCT Standards Committee
- Financial Support: Schooner Strategies and Trajectory Healthcare Solutions
- Graphic Design: A. Jill Wagner, MA, IconoGraph Designs

Key Coverage Principles

Breast CBCT is intended for diagnostic evaluation of breast abnormalities requiring three-dimensional imaging.

Coverage is generally appropriate when:

- The clinical question requires volumetric evaluation of the breast;
- The results are expected to affect a specific clinical management decision; and
- Breast CBCT is the most appropriate imaging modality to answer the clinical question.

Standard breast imaging should generally be performed first when clinically feasible. Breast CBCT may be appropriate when standard imaging is inconclusive or technically limited, or when MRI cannot be performed.

Contents

PART I: INTRODUCTION 4
A. Covered Clinical Contexts 4
B. Summary of Clinical Evidence 5

PART II: COVERAGE GUIDELINES 7
A. Medical Necessity 7
B. Coverage Rationale 9
C. Required Prior Evaluation 9
D. Exclusions 10

PART III: DOCUMENTATION REQUIREMENTS 11

PART IV: EMERGING AND INVESTIGATIONAL USES 13
A. Supplemental Screening in Dense Breast or High-Risk Populations 13
B. Tumor Angiogenesis and Dynamic Contrast Enhancement Functional Imaging 13

PART V: REGULATORY STATUS AND CODING 14
A. FDA Status 14
B. CPT Coding 14

PART VI: SUMMARY 16

REFERENCES 17

APPENDIX: MODALITY DEFINITION AND TECHNICAL OVERVIEW 19

Part I: Introduction

Breast Cone Beam Computed Tomography (Breast CBCT) is a three-dimensional imaging technique used to evaluate breast tissue. Unlike conventional mammography, Breast CBCT scans do not require breast compression, which may make the examination more comfortable, particularly for patients with implants or conditions that make compression difficult.

Available evidence suggests that Breast CBCT, particularly when performed with contrast enhancement, may demonstrate higher sensitivity (the ability to detect cancer when present) than standard mammography in selected diagnostic settings.[1,2]

Coverage is limited to situations in which Breast CBCT is expected to inform a specific clinical decision and standard imaging is insufficient to answer the clinical question or MRI is not feasible.

A. Covered Clinical Contexts

Breast CBCT may be considered only when the medical-necessity criteria in Part II are met. Covered use requires:

- A specific clinical management decision; and
- Either documented insufficiency of standard imaging or documented infeasibility of MRI.

Potential covered contexts include:

- Evaluation of symptoms or abnormal imaging findings;
- Resolution of diagnostic questions following inconclusive or technically limited mammography, digital breast tomosynthesis, or ultrasound;
- Three-dimensional characterization of lesions to support biopsy planning or surgical decision-making;

- Assessment of implant-adjacent or otherwise technically challenging anatomy; and
- Preoperative assessment of disease extent when the result is reasonably expected to affect management.

Limitations and exclusions:

- Use of contrast-enhanced Breast CBCT for functional assessment of tumor vascularity or angiogenesis is investigational and is addressed in Part IV;
- Supplemental screening in asymptomatic patients is not a covered use and is discussed in Part IV; and
- Use of contrast-enhanced Breast CBCT for diagnostic indications is addressed in Part II.

B. Summary of Clinical Evidence

The following summarizes current clinical evidence regarding Breast CBCT and its role in diagnostic breast imaging.

Diagnostic Accuracy Compared with Mammography

- In diagnostic settings, contrast-enhanced Breast CBCT has shown higher sensitivity than standard mammography in several studies, with similar specificity (the ability to correctly rule out disease);
- Recent meta-analyses indicate that Breast CBCT has higher pooled sensitivity than mammography, although study heterogeneity and limited prospective data remain important limitations;
- A 2024 meta-analysis reported pooled sensitivity of 0.92 for Breast CBCT versus 0.77 for mammography, with comparable specificity (0.79 vs. 0.75)[1];
- Other studies have shown smaller differences in sensitivity between Breast CBCT and mammography.[2,4]

Comparison with MRI

- Small comparative studies suggest that contrast-enhanced Breast CBCT may show diagnostic performance approaching that of MRI in selected settings;
- MRI remains the more established modality, and evidence for Breast CBCT remains limited.[3]

Microcalcifications and DCIS

- As Breast CBCT provides true three-dimensional imaging without tissue overlap, it may improve visualization of microcalcifications, a key feature of ductal carcinoma in situ (DCIS), although supporting clinical evidence remains limited;[5,6]
- Early studies suggest that contrast-enhanced imaging may help distinguish benign from malignant patterns, although clinical experience remains limited.

Biopsy Guidance

- Breast CBCT-guided biopsy allows visualization of lesions in three planes and may support biopsy guidance when the target cannot be adequately visualized or accessed using standard stereotactic, ultrasound-guided, or MRI-guided approaches, including selected lesions in technically challenging locations;[7]
- Breast CBCT additionally provides an option for patients who cannot undergo MRI-guided biopsy.

Radiation Dose

- Radiation exposure from diagnostic Breast CBCT falls within the range of diagnostic mammography;
- Doses vary by system, but are generally comparable to multi-view mammographic evaluations;[8,9]
- As with any imaging that uses ionizing radiation, appropriate patient selection and dose management remain important.

Unlike conventional mammography, Breast CBCT scans do not require breast compression, which may make the examination more comfortable, particularly for patients with implants or conditions that make compression difficult.

Part II: Coverage Guidelines

A. Medical Necessity

Breast CBCT is considered medically necessary for diagnostic or treatment-planning purposes only when all of the following criteria are met:

1. ***Defined Clinical Question.*** There must be a well-defined clinical question requiring three-dimensional evaluation of the breast, arising from:
   - Signs or symptoms of disease; or
   - Abnormal findings on prior imaging.
2. ***Expected Effect on Management.*** The results must be expected to inform a specific clinical decision, such as:
   - Whether to perform a biopsy;
   - How to plan surgery; or
   - Which treatment to select.

Imaging ordered primarily for reassurance or documentation, without a management decision that depends on the result, does not meet this criterion.

3. ***Prior Imaging Insufficient or Not Feasible.*** Standard imaging — mammography, digital breast tomosynthesis, or ultrasound — must have been:

- Performed and found to be inconclusive, technically limited, or insufficient; or
- Infeasible or contraindicated.

Where prior mammography has been performed, the findings should support the need for additional diagnostic evaluation.

4. ***Advanced Imaging Requirement.*** One of the following pathways must apply.

Pathway A — MRI Substitution

Volumetric three-dimensional imaging is required, and Breast CBCT is being used in place of breast MRI because MRI cannot be performed.

Acceptable reasons include:

- An MRI-incompatible implanted device;
- Severe claustrophobia refractory to standard management;
- Contraindication to gadolinium contrast, such as severe allergy or advanced renal dysfunction; or
- Unavailability of MRI within a clinically appropriate timeframe, as documented by the ordering clinician.

Because contrast-enhanced Breast CBCT uses iodinated contrast rather than gadolinium, renal safety thresholds for iodinated contrast must be assessed independently using standard iodinated contrast safety considerations.

Pathway B — Three-Dimensional Characterization

Breast CBCT may be medically necessary when all general criteria are met and one of the following applies:

- Prior mammography, digital breast tomosynthesis, or ultrasound shows an abnormality that remains equivocal and requires true volumetric characterization;
- Calcification distribution requires characterization to assess possible DCIS when standard imaging is insufficient to provide adequate characterization;
- Preoperative mapping of known or suspected multifocal or multicentric disease is necessary and MRI is not feasible or is not expected to resolve the specific clinical question;
- Further characterization of a specific, targeted equivocal finding previously identified on 2D imaging, where tissue overlap in heterogeneously or extremely dense breasts prevents definitive diagnostic evaluation;
- Biopsy guidance is required and stereotactic, ultrasound-guided, or MRI-guided approaches are not feasible or adequate; or
- Architectural distortion, implant-adjacent anatomy, or another technically challenging anatomic relationship cannot be adequately characterized using standard imaging.

Patient preference for compression-free imaging does not satisfy this criterion.

Dense breast tissue, elevated breast cancer risk, compression-related discomfort, or preference for compression-free imaging do not establish medical necessity, either individually or in combination, for Breast CBCT in an asymptomatic patient.

B. Coverage Rationale

Coverage depends on whether Breast CBCT is expected to inform a defined diagnostic or treatment-planning decision.

Patient comfort alone does not establish medical necessity for Breast CBCT, and the potential for additional imaging detail beyond standard imaging does not independently establish coverage.

The compression-free design of Breast CBCT may improve patient comfort, including for patients with breast implants. Breast CBCT may be appropriate when implants or implant-related anatomy limit the diagnostic performance of standard imaging and the examination is expected to inform a specific clinical management decision.

The study must address:

- A documented limitation of standard imaging; or
- A documented inability to perform MRI.

The ordering record must identify the management decision the study is intended to inform.

C. Required Prior Evaluation

Before Breast CBCT is performed, the record must document a clinical evaluation establishing the need for advanced imaging. Prior standard breast imaging should be obtained when clinically feasible.

Documentation requirements include:

- Recent mammography, digital breast tomosynthesis, or ultrasound relevant to the current episode of care, generally within the past 90 days or otherwise sufficiently recent to address the current diagnostic episode;
- Evidence that prior imaging is nondiagnostic, equivocal, or technically limited; or
- An explanation of why prior imaging was not obtained.

Exceptions to prior imaging:

Prior imaging may not be obtained when it is:

- Contraindicated;
- Technically limited;
- Not tolerated;
- Refused after documented counseling; or
- Not expected to answer the clinical question.

Patient refusal alone does not establish medical necessity unless Breast CBCT is expected to affect a specific management decision.

D. Exclusions

Breast CBCT is not covered for:

- Imaging ordered without a specific management decision;
- First-line evaluation when standard imaging (mammography, digital breast tomosynthesis, or ultrasound) is feasible and has not yet been performed and interpreted;
- Use as a redundant study when breast MRI or another cross-sectional imaging study has already addressed the same clinical question;
- Research or other non-established uses, unless separately authorized; or
- Screening in asymptomatic patients, as the FDA PMA-approved Koning Breast CT system expressly states it is not intended for this use.

Part III: Documentation Requirements

The record must:

- Identify the clinical indication, including the patient's relevant symptoms or abnormal imaging findings;
- State the decision the study is expected to inform, such as:
  - The need for biopsy;
  - The extent of disease for surgical planning; or
  - The significance of a finding that prior imaging could not resolve.
- Explain why advanced imaging is necessary, either because:
  - Prior imaging was inconclusive or technically limited; or
  - Standard imaging could not adequately address the clinical question.
- Establish why Breast CBCT is the appropriate modality, either because:
  - MRI cannot be performed; or
  - The clinical question requires three-dimensional characterization that two-dimensional imaging cannot provide.

When Breast CBCT is used in place of MRI, the specific reason must be documented. General statements such as "the patient cannot undergo MRI" are not sufficient. Appropriate documentation includes:

- Identification of the implanted device and confirmation that it is MRI-incompatible;
- Documentation of severe gadolinium allergy or a recent GFR result for renal dysfunction;
- A note on severe claustrophobia or inability to tolerate positioning; and
- A clinical explanation of why MRI is unavailable within an appropriate timeframe.

When contrast-enhanced Breast CBCT is used under Pathway A (MRI Substitution) due to a gadolinium allergy or MRI-related renal contraindication, the clinical record must explicitly confirm the patient has been screened for contraindications to iodinated contrast media and that none are present.

Incomplete documentation or an unclear management rationale may support denial of coverage.

Part IV: Emerging and Investigational Uses

While routine use of contrast-enhanced Breast CBCT for neoadjuvant treatment monitoring remains investigational, it may be considered medically necessary on a case-by-case basis when functional three-dimensional monitoring is required to inform treatment and MRI is explicitly contraindicated (e.g., MRI-incompatible implanted devices, severe claustrophobia).

The following applications have been described in the literature but are not supported by sufficient evidence for routine clinical use or coverage. They are included to clarify the boundaries of this policy and to distinguish established uses from areas of ongoing study.

A. Supplemental Screening in Dense Breast or High-Risk Populations

Contrast-enhanced Breast CBCT has been explored as a supplemental screening tool, particularly for women with dense breasts or elevated risk. Evidence is still too limited to support routine screening use, and current ACR guidance does not establish Breast CBCT as a recommended modality for routine breast cancer screening.[10] The FDA PMA-approved Koning Breast CT system is not approved for screening in asymptomatic patients, and any future consideration of a screening indication would require stronger prospective evidence.[11]

Prospective clinical trials evaluating Breast CBCT for primary screening are ongoing (e.g., ClinicalTrials.gov Identifier NCT05036096). As additional evidence becomes available, this clinical coverage guideline will be reviewed and updated as appropriate.

B. Tumor Angiogenesis and Dynamic Contrast Enhancement Functional Imaging

Dynamic contrast-enhanced Breast CBCT can demonstrate patterns of tumor enhancement over time and has been investigated as a functional imaging technique, including for assessment of treatment response during neoadjuvant therapy. Quantitative measures of dynamic enhancement may have diagnostic potential, but the evidence remains early.[12] Use of contrast-enhanced Breast CBCT for functional imaging, including serial monitoring of treatment response during neoadjuvant therapy, is investigational and is not a covered use except as provided in the case-by-case exception described at the beginning of this section.

Part V: Regulatory Status and Coding

A. FDA Status

The Koning Breast CT system is an FDA PMA-approved device under Premarket Approval (PMA P130025), granted on January 14, 2015.[11] According to the Summary of Safety and Effectiveness Data, the system is intended to provide three-dimensional images for diagnostic breast imaging. The labeling indicates that it should be interpreted in conjunction with standard two-view mammography.

The device is intended for use in patients with signs, symptoms, or abnormal imaging findings and is not indicated for screening in asymptomatic individuals.

Additional screening-related regulatory pathways may be explored in the future.

B. CPT Coding

Breast CBCT is represented by Category III CPT codes, introduced by the American Medical Association in 2021,[13] covering breast CT examinations performed with or without contrast, including both unilateral and bilateral studies. The code range includes 0633T through 0638T.

Because Category III CPT codes designate emerging technologies, they are temporary tracking codes that are subject to sunset or conversion to Category I status. Facilities and billing departments are strongly advised to monitor the American Medical Association's annual CPT updates. A future transition to Category I codes could establish more standardized billing pathways and may affect payer processing, pre-authorization requirements, and national coverage policies for Breast CBCT.

There is no Breast CBCT-specific national Medicare coverage determination (NCD); Breast CBCT falls under the general CT NCD (220.1).[14]

In the absence of Breast CBCT-specific biopsy codes, practices should verify payer-specific guidance. The use of existing image-guided breast biopsy codes, when applicable, is determined by payer policy.

Code	Description
Breast CBCT Category III Codes	
0633T	CT, breast, including 3D rendering, unilateral; without contrast material
0634T	CT, breast, including 3D rendering, unilateral; with contrast material(s)
0635T	CT, breast, including 3D rendering, unilateral; without contrast, followed by contrast
0636T	CT, breast, including 3D rendering, bilateral; without contrast material
0637T	CT, breast, including 3D rendering, bilateral; with contrast material(s)
0638T	CT, breast, including 3D rendering, bilateral; without contrast, followed by contrast
Related Biopsy Codes (Reference Only)	
19081	Percutaneous breast biopsy with stereotactic guidance, first lesion
19082	Each additional lesion, percutaneous breast biopsy with stereotactic guidance (add-on code)

These codes are provided for contextual reference only. Coverage, coding, and reimbursement for Breast CBCT-guided biopsy procedures remain subject to individual payer policy.

Part VI: Summary

This clinical coverage guideline establishes generally accepted standards of care for Breast CBCT, an advanced three-dimensional imaging modality that provides volumetric imaging without the need for breast compression. Under these standards, Breast CBCT is considered medically necessary primarily for diagnostic or treatment-planning purposes when standard imaging (such as mammography or ultrasound) is inconclusive or technically limited. It may provide an alternative imaging option for patients who require volumetric assessment but cannot undergo MRI because of contraindications such as MRI-incompatible implanted devices, severe claustrophobia, or gadolinium allergy. However, these standards do not support the use of Breast CBCT for routine screening in asymptomatic patients or as a first-line imaging tool, aligning with current FDA labeling and ACR guidance.

To ensure that these clinical standards are consistently met, facilities are encouraged to apply for RadSite accreditation. The accreditation process provides a framework for verifying essential documentation, such as the specific clinical management decisions informed by the scan. By achieving accreditation, facilities demonstrate their commitment to proper dose management and the technical proficiency required to interpret true volumetric datasets. This process not only supports patient safety but also helps providers align with complex coding and regulatory requirements.

References

[1] Yang L, Zhou Z, Wang J, et al. Head-to-head comparison of cone-beam breast computed tomography and mammography in the diagnosis of primary breast cancer: a systematic review and meta-analysis. Eur J Radiol. 2024;171:111292. *https://pubmed.ncbi.nlm.nih.gov/38211395/*

[2] Uhlig J, Uhlig A, Biggemann L, Fischer U, Lotz J, Wienbeck S. Diagnostic accuracy of cone-beam breast computed tomography: a systematic review and diagnostic meta-analysis. Eur Radiol. 2019;29(3):1194–1202. *https://pubmed.ncbi.nlm.nih.gov/30255249/*

[3] Wienbeck S, Fischer U, Luftner-Nagel S, Lotz J, Uhlig J. Contrast-enhanced cone-beam breast-CT (Breast CBCT): clinical performance compared to mammography and MRI. Eur Radiol. 2018;28(9):3731–3741. *https://pubmed.ncbi.nlm.nih.gov/29594402/*

[4] He N, Wu YP, Kong Y, et al. The utility of breast cone-beam computed tomography, ultrasound, and digital mammography for detecting malignant breast tumors: a prospective study with 212 patients. Eur J Radiol. 2016;85(2):392–403. *https://pubmed.ncbi.nlm.nih.gov/26781145/*

[5] Zhu Y, O'Connell AM, Ma Y, et al. Dedicated breast CT: state of the art — Part II. Clinical application and future outlook. Eur Radiol. 2022;32(4):2286–2300. *https://pubmed.ncbi.nlm.nih.gov/34476564/*

[6] Wienbeck S, Lotz J, Fischer U. Review of clinical studies and first clinical experiences with a commercially available cone-beam breast CT in Europe. Clin Imaging. 2017;42:50–59. *https://pubmed.ncbi.nlm.nih.gov/27875762/*

[7] Seifert PJ, Morgan RC, Conover DL, Arieno AL. Initial experience with a cone-beam breast computed tomography-guided biopsy system. J Clin Imaging Sci. 2017;7:1. *https://pubmed.ncbi.nlm.nih.gov/28217404/*

[8] O'Connell A, Conover DL, Zhang Y, et al. Cone-beam CT for breast imaging: radiation dose, breast coverage, and image quality. AJR Am J Roentgenol. 2010;195(2):496–509. *https://pubmed.ncbi.nlm.nih.gov/20651210/*

[9] Vedantham S, et al. Newer technologies in breast cancer imaging: dedicated cone-beam breast CT. Semin Oncol. 2018;45(3):174–186. *https://pubmed.ncbi.nlm.nih.gov/29317032/*

[10] Expert Panel on Breast Imaging. ACR Appropriateness Criteria: supplemental breast cancer screening based on breast density: 2024 update. J Am Coll Radiol. 2025;22(5S):S405–S423. PMID: 40409891. *https://pubmed.ncbi.nlm.nih.gov/40409891/*

[11] U.S. Food and Drug Administration. Koning Breast CT (KBCT): Summary of Safety and Effectiveness Data (SSED). PMA P130025. FDA; 2015. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130025*

[12] Wang Y, Ma Y, Liu A, et al. Longitudinal contrast-enhanced cone beam breast computed tomography for monitoring treatment response in breast cancer neoadjuvant therapy: a comprehensive assessment. Breast Cancer Res. 2025;27(1):199. PMID: 41194290. *https://pubmed.ncbi.nlm.nih.gov/41194290/*

[13] American College of Radiology. ***Anticipated 2022 CPT Changes.*** ACR Radiology Coding Source. March–April 2021.

[14] Centers for Medicare & Medicaid Services. National Coverage Determination: Computed Tomography. 220.1. CMS; 2008. *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=176*

[15] Aminololama-Shakeri S., Boone J. M. Dedicated breast CT: Getting ready for prime time. J Breast Imaging. 2024; 6:465–475. *https://pubmed.ncbi.nlm.nih.gov/39216084/*

Appendix: Modality Definition and Technical Overview

Technique

Breast CBCT is performed with the patient in the prone position, with the breast suspended through an opening in the imaging table. The x-ray tube and detector rotate around the breast, acquiring projection images during a single scan, which are then reconstructed into a three-dimensional dataset without breast compression.

Image Output

Breast CBCT produces volumetric images with isotropic spatial resolution, allowing the dataset to be reviewed in any plane without additional image acquisition. This differs from digital breast tomosynthesis, which uses a limited-angle approach and does not generate a fully volumetric dataset.[15]

Contrast Enhancement

Breast CBCT may be performed with or without intravenous iodinated contrast. When contrast is used, studies suggest improved lesion detection and characterization compared with non-contrast imaging, although the strength of evidence varies by indication. Use of iodinated contrast involves standard clinical considerations, including screening for contraindications and obtaining informed consent when appropriate.

RadSite

Accreditation Reinvented

About RadSite™

www.RadSiteQuality.com

Founded in 2005, RadSite promotes quality-based practices for imaging systems across the United States and its territories. Today, RadSite offers six accreditation programs, including CT accreditation, MRI accreditation, Nuclear Medicine and PET accreditation, Dental CBCT accreditation, Medical CBCT accreditation, and Remote Scanning accreditation. RadSite is recognized by the Centers for Medicare & Medicaid Services as an official accreditation organization under the Medicare Improvements for Patients and Providers Act of 2008. It is also recognized by more than 350 payers and has accredited more than 2,000 imaging systems. RadSite's programs help assess, track, and report imaging trends to enhance imaging procedures and outcomes. The organization also offers educational programs, publishes issue briefs, and underwrites research on a complimentary basis to raise awareness of safety issues and promote best practices. RadSite is governed by an independent advisory board and committee system that is open to a broad range of volunteers to ensure transparency and accountability.

To learn more, contact us at **443-440-6007** or *Info@RadSiteQuality.com*.