

Clinical Policy: Diagnostic Digital Breast Tomosynthesis

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Effective Date: 11/11

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[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Digital breast tomosynthesis (DBT) (three-dimensional [3-D] mammography) is a non-invasive imaging technique used for the screening and diagnosis of breast cancer. Tomosynthesis combines the use of tomography and 3-D reconstruction with breast imaging to improve the visibility of breast lesions.

Policy/Criteria

It is the policy of California Health & Wellness (CH&W) that digital tomosynthesis **for diagnostic breast imaging is not medically necessary** because it is considered experimental, investigational or unproven. This policy does not apply to the use of screening digital breast Tomosynthesis (CPT-4 Code 77603) as an imaging option for breast cancer screening. The California Department of Health Care Services issued a Medi-Cal Update on February of 2016 listing screening digital breast Tomosynthesis (CPT-4 Code 77603) as an imaging option for breast cancer screening effective for dates of service on or after March 1, 2016. Medi-Cal's policy on reimbursement for screening digital breast Tomosynthesis (CPT-4 Code 77603) is consistent with the U.S. Preventive Services Task Force's 2002 recommendation of breast cancer screening mammography every year for women 40 years of age and older. CH&W follows Medi-Cal's policy on reimbursement for screening digital breast Tomosynthesis.

Background

There currently are no large prospective studies to justify routine use of DBT, but the technique shows promise in preliminary studies in screening women with dense breast tissue and with high risk for breast cancer.

DBT is a modification of DM. Tomosynthesis is a 3-D imaging technique that involves acquiring images of a stationary compressed breast at multiple angles during a short scan. The individual images are projections through the breast at different angles and are reconstructed into a series of thin, high-resolution slices that can be displayed in a variety of formats. While the breast is positioned and compressed similarly to a standard mammogram, images are captured through a number of different x-ray source angles. Objects at different heights in the breast project differently for each angle. The data are then reconstructed to generate images that enhance objects from a given height by appropriate shifting of the projections relative to one another.

The California Department of Health Care Services issued a Medi-Cal Update on February of 2016 listing screening digital breast Tomosynthesis (CPT-4 Code 77603) as an imaging option for breast cancer screening effective for dates of service on or after March 1, 2016. The U.S. Preventative Services Task Force (2016) concluded that the evidence on DBT as a primary screening method for breast cancer is insufficient, and the balance of benefits and harms cannot be determined. The American Congress of Obstetricians and Gynecologists (ACOG, 2015) states

CLINICAL POLICY

Diagnostic Digital Breast Tomosynthesis

that there is not sufficient evidence that DBT leads to meaningful outcome benefits (e.g., reduction in breast cancer mortality) in women with dense breasts and no other risk factors. ACOG’s 2013 practice bulletin says that while results are promising, further study is needed to determine whether DBT is a cost-effective approach capable of replacing digital mammography alone as the first-line screening modality of choice for breast cancer screening. The National Comprehensive Cancer Network states that “multiple studies show a combined use of digital mammography and tomosynthesis appears to improve cancer detection and decreased call back rates. Of note, most studies used double the dose of radiation. The radiation dose can be minimized by synthetic 2-D reconstruction.” However, it is thought that few centers currently have the capability for synthetic 2-D reconstruction.

It should be noted that for any new mammography technology, such as DBT, the Mammography Quality Standards Act (MQSA) requires that all health care professionals obtain eight hours of training prior to using new mammography technology on patients.

Coding Implications

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CPT®*	Description
77061	Digital breast tomosynthesis; unilateral
77062	Digital breast tomosynthesis; bilateral

HCPCS	Description
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated; added supporting background information.	09/16	10/16
CA State Specific Version - removed 77063	10/16	10/16
Updated to clarify that CH&W version applies only to diagnostic digital breast tomosynthesis. Added language and references from applicable Medi-Cal Updates. Updated logo and references to CH&W.	06/17	06/17
References reviewed and updated.	12/17	12/17

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CLINICAL POLICY

Diagnostic Digital Breast Tomosynthesis

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means CH&W, a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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CLINICAL POLICY

Diagnostic Digital Breast Tomosynthesis

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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