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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Digital Breast Tomosynthesis

Criteria

For Medicare Members and Non-Medicare Members

Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Mammography is the gold-standard for population-based breast cancer screening. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore 2005). However, mammography is less sensitive in women with dense breasts (Brem 2008; Killela 2009). Because of these new technologies are being developed to improve detection and characterization of breast lesions. One of these technologies is digital breast tomosynthesis (Helvie 2010).

Digital breast tomosynthesis is a modified form of digital mammography. With digital breast tomosynthesis, multiple views of a stationary compressed breast are taken at different angles. These images are then reconstructed using an algorithm to create 3D radiographic images of the breast. It has been hypothesized that this technology may be able to decrease the number of false positive and false negative results and decrease recall rates. One limitation of digital breast tomosynthesis is that the specifications of many parameters including the number of projections, dose, angle, and post-processing algorithm differ across manufactures making clinical comparisons between manufactures difficult (Helvie 2010, Holloway 2010).

The Selenia Dimensions 3D System (Holistics, Inc.) has received approval from the FDA.

Medical Technology Assessment Committee (MTAC)

Digital Breast Tomosynthesis

12/19/2011: MTAC REVIEW

Evidence Conclusion: Based on evidence from observational studies, the Kaiser MTAT concluded that the evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer in average-risk or high risk women, in evaluating those with equivocal/indeterminate mammography and/or ultrasound, or evaluating women considering breast conserving therapy. The current evidence base consists primarily of studies reporting diagnostic results of women with abnormal screening mammograms and is not representative of key populations under consideration. In addition, the sample sizes were too small and not powered to compare accuracy measures (Kaiser 2011). Conclusion: The evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer.

Articles: The Kaiser Permanente Medical Technology Assessment Team (MTAT) reviewed digital breast tomosynthesis in 2009, 2010, and 2011. No additional studies were identified since the 2011 review. The

Back to Top

following technology assessments were selected for review: Kaiser Permanente Interregional New Technologies Committee. Tomosynthesis. 2011; http://pkc.kp.org/national/cpg/intc/topics/04_04_116.html Kaiser Permanente Medical Technology Assessment Team. Breast Imaging: Digital Breast Tomosynthesis. 2010; See Evidence Table.

The use of digital breast tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/20/2015: MTAC REVIEW
Digital Breast Tomosynthesis
Evidence Conclusion: The external technology assessments by HTA, INTC, and TEC all concluded that there is insufficient evidence to determine that benefits of using breast tomosynthesis for screening asymptomatic women for breast cancer.
Health Technology Assessment (HTA), January 2015

Studies comparing DBT to DM for screening asymptomatic women
(Table reproduced from HTA Executive Summary)

Study	Sensitivity		Specificity	
	M %	DBT %	M %	DBT %
Ciatto, 2013 * (Italian STORM)	66.1	100	95.5	96.6
Skaane, 2013* (Oslo trial)	62.6	82.1	93.8	94.6
Haas2013 **‡	100	100	NR	NR
Friedwald, 2014 ‡	NR	NR	NR	NR
Rose, 2013 ‡	100	100	91.7	95.1
Destounis, 2014 ‡‡**	100	75	97.9	99.4
Lorenco, 2014 ‡‡	NR	NR	91.1	94.0
Greenberg, 2014‡	NR	NR	84.3	87.0
McCarthy,2014‡‡	NR	NR	NR	NR

M=mammography, DBT=digital breast tomosynthesis.
* Prospective studies
‡ Retrospective multicenter study
‡‡ Retrospective single center study
** US study
The majority of the studies compared DBT+DM vs DM alone.
There was population overlap between Greenberg, McCarthy, and Friedwald studies
All the trials had their limitations

Estimated yield of DBT in combination with digital mammography
Vs. digital mammography alone in women presenting for population screening
(Table reproduced from HTA review Executive Summary)

	DM	DBT+DM	Uncertainty
Recall rate /1,000	100-160	80-140	Moderate-high
Biopsy rate /1,000	14-22	12-27	Moderate
Cancer detection rate/1,000	3-5	4-6	Moderate-high
Positive biopsy among total biopsied	20-25%	25-30%	Low-moderate

The HTA review summary indicates that the 9 studies reviewed showed a substantial decrease in the recall rate with DBT vs. mammography and most found an increase in cancer detection. The evidence on biopsy rate was mixed, with the more recent studies showing an increase in the biopsy rate with DBT. Studies reporting on subgroups of women with dense and non-dense breasts found consistent findings.
There were limitations in the studies, including heterogeneity and differences among the screened populations, short follow-up duration, and lack of large prospective studies with patient outcomes. In addition, the only 2 prospective studies were conducted overseas, where the patterns of recall differ from that in the US. *Kaiser Interregional New Technologies Committee (INTC), November 2014* the evidence reviewed by the committee included 8 published comparative studies of DBT + mammography vs. mammography alone for routine screening (from a previous review) plus four more recent comparative studies. There were no published studies that investigated the impact of DBT screening on mortality or other health outcomes among women at low, average or high risk of breast cancer. The review concluded that there is insufficient evidence to determine that breast

 Back to Top

tomosynthesis is appropriate for screening asymptomatic women for breast cancer. The estimated absolute benefits in cancer detection and reduction in recall are small and the overall evidence is of low-to moderate quality. The review also concluded that the positive results observed may not translate to outcomes and there is insufficient evidence to determine that DBT prevents mortality or advanced disease from breast cancer, *Blue Cross Blue Shield/ Kaiser Permanente Technology Evaluation Center (TEC), January 2014* The addition of DBT to screening or diagnostic mammography did not meet the TEC criteria. The review included six studies that compared the use of mammography versus DBT with or without mammography for screening asymptomatic women. Four of the studies (Rose 2013, HAAS 2013, Skaane 2013, and Ciatto 2013) were also included in the HTA review. The two other studies included in the review were Rafferty et all's study (2013) and Good et all's study 2008 (Gur 2009). The TEC review did not include studies published in 2014 as the literature search was conducted in June 2013. TEC also evaluated the use of DBT for breast cancer diagnosis. The review concluded that the available evidence (at the time) on adding DBT to mammography for screening for breast cancer or to diagnostic mammography is insufficient to permit conclusions regarding the effect on health outcomes, or to determine the comparative benefit of adding DBT to mammography vs. mammography alone. *More recent published evidence after the HTA 2015 review* The literature search for more recently published studies identified a large (N=7,060) retrospective reading study embedded in a prospective study (TOMMY trial, Gilbert et al, 2015) that compared DBT plus 2D mammography vs. mammography alone, and a small (n=150) retrospective study (Thomassin-Naggara 2015) that evaluated the value of adding one view DBT to mammography to characterize breast lesions. TOMMY trial (Gilbert et al 2015 [Health Technology Assessment, NHS] Evidence table 1). This was a large retrospective reading study conducted by the UK National Institute for Health Research in six UK centers to compare the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography among 6,021 women 47-73 years of age, for further assessment after routine breast screening, and 1,040 women 40-49 years with moderate/high risk of developing breast cancer attending annual mammography screening. All participants underwent a two-view 2D mammography of both breasts and two-view DBT imaging. Image-processing software generated a synthetic 2D mammogram from the DBT data set. Blinded readers reviewed 2D or 2D+DBT, or synthetic 2D+ DBT images for each case without access to the original screening mammograms or prior examinations. Sensitivities and specificities were calculated for each reading arm and by subgroup analyses. Overall, the results indicate that the specificity of DBT plus 2D mammography was statistically significantly higher than that of 2D mammography alone. The improvement in sensitivity by adding DBT to 2D mammography was minimal and statistically insignificant among all participants combined. Subgroup analyses however, showed significantly higher sensitivity with DBT+2D mammography vs. 2D mammography for women in the age range of 50-59 years, women with invasive tumors 11-20mm in diameter, those with breast density >50%, and in women with grade 2 invasive tumors. The analysis suggests that there was no significant difference in specificity of synthetic 2D +DBT versus 2D +DBT. As regards the sensitivity of synthetic 2D+DBT, subgroup analysis suggested that it had higher sensitivity than 2D alone in the detection of 11-20 mm invasive cancers, but lower sensitivity than 2D or 2D+DBT in the detection of microcalcifications and DCIS (ductal carcinoma in situ) 11-20mm in size. The study included women recalled for suspicious lesions on 2D mammography (only 5% of the screened women were recalled) as well as younger women at high risk. DBT was not used for 95% of the women screened by 2D mammography who were not recalled. This inherent selection bias of the study could overestimate the true effect of adding DBT to 2D mammography on the specificity and underestimate its impact on the sensitivity. The study was not a screening trial and its results cannot be generalized to screening populations. Thomassin-Naggara and colleagues' study (2015) found that adding DBT to mammography improved reproducibility and diagnostic performance especially for radiologists with lower experience in reading mammography. Conclusion: There is insufficient evidence to determine the comparative benefit of screening with DBT versus conventional mammography. The published studies suggest that the addition of DBT to DM has no or minimal effect on improving sensitivity especially with experienced film readers. The studies, however, suggest that the addition of DBT to DM may reduce the recall rates, but that would depend on the reading protocol, recall policy and experience of radiologists reading the images. There is no published evidence, to date, to determine the benefit of using DBT alone or in addition to digital mammography on long-term health outcomes.

Articles: The literature search revealed over 130 articles on digital breast tomosynthesis published after the last MTAC review. DBT technology was recently assessed by TEC for breast cancer screening or diagnosis in January 2014, by INTC in November 2014, and more recently by HTA in January 2015, for breast cancer screening in patients with dense breasts. The search for additional large screening studies published after the literature search dates of these reviews identified one large retrospective reading study (TOMMY trial) that compared the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography, a small retrospective study (N=150) on the added value on DBT combined with DM according to reader experience, a post hoc analysis of the STORM study by Ciatto and colleagues' 2013 study (included in the HTA review), and a recent meta-analysis on the use of DBT as a diagnostic not a

 Back to Top

screening test. The TOMMY trial was selected for critical appraisal. Gilbert FJ, Tucker L, Gillan MG, et al. The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK National Institute for Health Research (NHS) Breast Screening Programme - a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. Health Technol Assess. 2015 Jan;19(4):1-136. See Evidence Table.

The use of Digital Breast Tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medical necessity review no longer required

CPT or HCPC code	Description
77061	Diagnostic digital breast tomosynthesis; unilateral
77062	Diagnostic digital breast tomosynthesis; bilateral
77063	Screening digital breast tomosynthesis; bilateral
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral *(List separately in addition to 77065 or 77066)*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/03/2012	01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 04/20/2015[MPC], 06/02/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC], 10/03/2023[MPC]	02/28/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/23/2015	Added CPT and HCPC codes
04/27/2015	Added April 2015 MTAC review
06/02/2015	MPC approved policy of insufficient evidence
08/25/2015	Added Medicare MLN MM8774 clarifying language
6/27/2017	Added WESCU rider language
02/28/2017	Medical necessity review no longer required.

Back to Top