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Submitted By:

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NCCN Guidelines Panel: Breast Cancer Screening and Diagnostics

On behalf of Hologic, Inc., I respectfully request the NCCN Breast Cancer Screening and Diagnostics panel to review the enclosed data to support the use of digital breast tomosynthesis for breast cancer mammography screening.

Specific Changes: We request that the bullet point describing breast tomosynthesis (BSCR-A 1 of 2, 8th bullet point) be revised to state "Digital breast tomosynthesis is a standard mammography platform that is an established alternative to conventional digital screening and diagnostic mammography. Studies show that breast tomosynthesis significantly decreases call back rates, improves cancer detection, and represents an improvement in breast cancer screening as compared to conventional digital mammography. Most early studies used double the dose of radiation. New developments, including synthesized 2-D reconstruction, allow breast tomosynthesis exams to be performed with a radiation dose similar to conventional digital mammography."

FDA Clearances: The Selenia® Dimensions® system provides the platform for digital breast tomosynthesis. The Dimensions system was originally approved by the U.S. Food and Drug Administration (FDA), for breast tomosynthesis mammography in 2011. While the majority of clinical evidence was obtained using the Selenia Dimensions system, other manufacturers, including General Electric and Siemens, have recently obtained FDA approval for breast tomosynthesis systems.

Rationale: While more than 100 previous publications demonstrate that breast tomosynthesis increases cancer detection while reducing false positive recalls[1-8], recent manuscripts further validate the performance characteristics[9-12] of tomosynthesis and demonstrate favorable cost effectiveness[13-15], and 2015 conference presentations report favorable outcomes with respect to interval cancer rates[16-18], the use of tomosynthesis in a rural population[19] and the use of tomosynthesis with low dose synthesized 2-D mammograms[20-22].

Table A: NCCN Centers Currently Using Breast Tomosynthesis Systems for Screening

Member Institution	Uses Breast Tomosynthesis for Screening
Fred & Pamela Buffett Cancer Center, Omaha, NE	Yes
Case Comprehensive Cancer Center/University Hospitals Seidman Cancer Center and Cleveland Clinic Taussig Cancer Institute, Cleveland, OH	Yes
City of Hope Comprehensive Cancer Center, Los Angeles, CA	Yes
Dana-Farber/Brigham and Women's Cancer Center | Massachusetts General Hospital Cancer Center, Boston, MA	Yes
Duke Cancer Institute, Durham, NC	Yes
Fox Chase Cancer Center, Philadelphia, PA	Yes
Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT	Yes
Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance, Seattle, WA	Yes
The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD	Yes
Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL	Yes
Mayo Clinic Cancer Center, Phoenix/Scottsdale, AZ; Jacksonville, FL; and Rochester, MN	Yes
Memorial Sloan Kettering Cancer Center, New York, NY	Yes
Moffitt Cancer Center, Tampa, FL	Yes

The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute, Columbus, OH	Yes
Roswell Park Cancer Institute, Buffalo, NY	Yes
Siteman Cancer Center at Barnes-Jewish Hospital and Washington University, St. Louis, MO	Yes
St. Jude Children's Research Hospital/The University of Tennessee Health Science Center, Memphis, TN	N/A
Stanford Cancer Institute, Stanford, CA	Yes
University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, AL	Yes
UC San Diego Moores Cancer Center, La Jolla, CA	N/A
UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA	N/A
University of Colorado Cancer Center, Aurora, CO	Yes
University of Michigan Comprehensive Cancer Center, Ann Arbor, MI	Yes
The University of Texas MD Anderson Cancer Center, Houston, TX	Yes
Vanderbilt-Ingram Cancer Center, Nashville, TN	Yes
Yale Cancer Center/Smilow Cancer Hospital, New Haven, CT	Yes

Institutions with "NA" do not offer mammography services.

Table B: Summary of Cited References

		Recall/False Positive Rate/Specificity			Cancer Detection Rate/Sensitivity		
Study	Exams	DM+BT	DM	% Change	DM+BT	DM	% Change
Skaane 2013	12,631	5.3%	6.1%	-13%*	8.0	6.1	+31%*
Ciatto 2013	7,292	4.3%	5.0%	-14%*	8.1	5.3	+53%*
Friedewald 2014	454,850	9.1%	10.7%	-15%*	5.4	4.2	+29%*
Lourenco 2014	25,498	6.4%	9.3%	-31%*	4.6	5.4	NS
Rose 2014	10,878	5.4%	8.2%	-34%*	5.4	3.5	+54%*
Destounis 2014	1,048	4.2%	11.5%	-63%*	5.7	3.8	NS
Margolies 2014	996	Not Reported		-8% to -25%	18	15	NS
Lång 2015	7,500	3.8%	2.6%**	+46%**	6.3	8.9	+43%*
Gilbert 2015	7,060	Spec 70%	Spec 57%	p<0.001	Sens 89%	Sens 87%	NS
Sharpe 2015	85,852	6.1%	7.5%	-19%*	5.4	3.5	+54%*
McDonald 2015	26,299	8.8%	10.4%	-15%*	5.5	4.6	NS
Reisenauer RSNA 2015	5,387	6.7%	8.2%	-18%	9.3	4.7	+98%
Salem RSNA 2014	The addition of DBT to 2D mammography reduced the interval cancer rate by 38%.						
Conant RSNA 2015	Interval cancer rate decreased from 0.9/1000 for DM to 0.5 for DBT yr 1 and 0.1 for DBT yr 2.						
Skaane RSNA 2015	Implementing DBT increased the cancer detection rate. The interval cancer rate remained stable.						
Choi RSNA 2015	Diagnostic performance of synthetic mammograms and FFDM are comparable for calcifications.						
Zuckerman RSNA 2015	Overall recall rate for synthetic 2D/DBT was 8.3% compared to 8.8% for DM/DBT (p=0.45).						
Mariscotti RSNA 2015	Synthetic DM is comparable to DM, demonstrating a similar SE, SP and AUC values.						

NS = Not statistically Significant, NR= Not reported.

False positive rates for Skaane and Ciatto estimated based on the percentage of cases recommended for arbitration by a single reader.

*Statistically Significant (p<0.01)

**The post-arbitration recall rate for the DM population in Lang 2015 was biased because BT information was used during arbitration.

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