

MQSA Legislative Updates: Part One

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Personal Disclosures: None

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Patient Journey

Ate healthy
Exercised daily
No strong family history
Years of "normal" mammograms

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Dense Breast Tissue Categories



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Mammogram of a Fatty Breast
A small cancer is easy to see

Mammogram of a Dense Breast
Even a large cancer is hard to see

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Cancer Detection in Dense Breasts

Is there a chance I can have cancer even when my doctor said my mammogram was normal?

Category of Breast Density	Percent of Cancers That Will <u>Not</u> Show on a Mammogram
Extremely dense	40%
Heterogeneously dense	25%
Scattered fibroglandular	15%
Fatty breasts	10%

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Rev. March 2022

Wanders et al., Breast Cancer Res, 2017;
Destounis et al., AJR, 2017;
Kerlikowske et al., Ann Intern Med, 2015

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Double Whammy

✓ HIDES CANCER
✓ INCREASES RISK

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Dear Ms. Pushkin,

We wish to report the following on your mammography examination.

Normal/Negative. No evidence of cancer.

*Interpreting Radiologist:
XX, M.D.*

- **NOT** told of density
- **NOT** told density could drastically compromise mammogram
- **NOT** told of increased risk
- **NOT** referred on for further screening

Courtesy JoAnn Pushkin

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“My radiologist knew I had dense breasts.
 My referring doctor knew I had dense breasts.
 The only one that *didn't* know was the one with
 dense breasts.”

JoAnn Pushkin, FDA / NMQAAC testimony, November 4, 2011

STATE INFORM LAWS

STATE INSURANCE LAWS

FEDERAL - INFORM AND
 INSURANCE EFFORTS

EDUCATIONAL
 RESOURCES



World's Leading Website About Dense Breasts

How a cancer would show in breast density categories on a mammogram

A. Fatty	B. Scattered	C. Heterogeneously Dense	D. Extremely Dense

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Breasts that are (C) heterogeneously dense, or (D) extremely dense, are considered “dense breasts.”

DENSE BREASTS: 5 FACTS YOU SHOULD KNOW

LEGISLATION TAB

Map Legend

- Some density notification required (38 states)
- Effort for inform/education; notification not required
- Active bill
- Inactive bill/no notification enacted
- Expanded insurance coverage for breast imaging

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By Data Point / State Inform Law Requirements

Data Points Mentioned	Yes	No
Informs Woman Her Breasts are Dense	AL, AZ, CA, CO, DC, DE, FL, GA, HI, IA, IL, KY, MA, ME, MI, MN, NC, NE, NM, NV, NY, OH, OK, OR (extremely dense only), PA, RI, SC, SD, TN, UT, VA, VT, WA, WI	CT, LA, MD, MO, NJ, TX,
Masking Effect*	AL, AZ, CT, DC, DE, FL, GA, HI, IL, KY, LA, MA, MD, ME, MI, MN, MO, NC, NE, NJ, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VA, VT, WI	CA, CO, NM, NV, SC, WA,
"Supplemental Screening" Consideration	AL, CT, DC, DE, GA, HI, LA, MA, ME, MI, MO, NY, OH, OR, RI, SD, TN, TX, VA,	AZ, CA, CO, FL, IA, IL, KY, MD, MN, NC, NE, NJ, NM, NV, OK, PA, SC, UT, VT, WA, WI

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NEWS! FDA ANNOUNCES DENSE BREAST REPORTING STANDARD

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New FDA national requirement for density inform.
Effective date: 09/10/24

Effective Sept 10, 2024

ALL imaging centers must comply

More info in DBI "Legislation Tab"

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Patient Letter Language

“Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. +

+ if NOT dense:
Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.”

+ IF dense:
Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.”

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Reporting to Referring Providers

Written report must include assessment of breast density, classified:

- (A) “The breasts are almost entirely fatty.”
- (B) “There are scattered areas of fibroglandular density.”
- (C) “The breasts are heterogeneously dense, which may obscure small masses.”
- (D) “The breasts are extremely dense, which lowers the sensitivity of mammography.”

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If there IS a state insurance law, are all women covered?

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If there is NO state insurance law, or if a plan is EXEMPT, might additional tests be covered?

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STATES WITH EXPANDED INSURANCE LAWS

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States with insurance law(s)* for:
 ■ Ultrasound only (2)
 ■ Ultrasound, MBI (20 plus DC); + other tests in some states
 ■ Diagnostic breast imaging only (1)
 ■ No law for expanded breast imaging

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 *Copay/deductible may still apply. Some plans exempt from state laws.

Check DenseBreast-info.org for updates.

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FIND IT EARLY ACT

Federal Insurance Bill


Would ensure insurance coverage for **no** cost-sharing screening or diagnostic breast imaging for women with dense breasts or increased risk for breast cancer.

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FindItEarlyAct.org




LEARN MORE / SUPPORT THE BILL

- Bill information
- Lobbying-101

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Providers Home

CME/CE, "Dense Breasts and Supplemental Screening"

Flow Chart: Who Needs More Screening?

Health Care Provider FAQs

Risk Model Tutorial

Table: Screening Guideline Comparison


DB-I Research

Patient Resources


DenseBreast-info.org Website About Dense Breasts

How to Interpret Breast Density Categories on a Mammogram

How to Interpret Breast Density Categories on a Mammogram

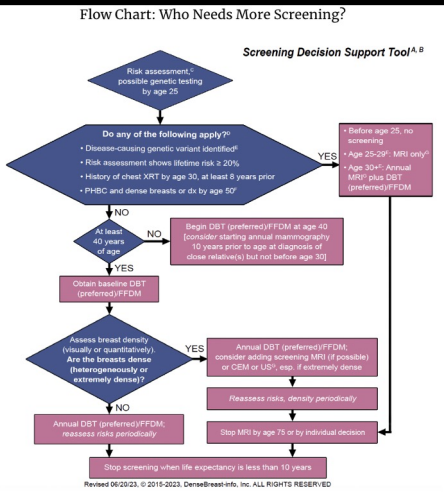


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Flow Chart: Who Needs More Screening?


Screening Decision Support Tool^{A,B}




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HEALTH CARE PROVIDER RESOURCE

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CME/CE, "Dense Breasts and Supplemental Screening"



A certified educational program for physicians, midlevel providers, and nurses practicing in obstetrics and gynecology, internal medicine, family medicine, radiology, and surgery; and radiologic technologists.

Provider	Access Course	Credits/Tuition
MD, DO, NP, PA Nurse	AMA Credits*	1.5 AMA PRA Cat 1 Tuition: FREE
RT	ASRT Credits**	1.5 ASRT Cat A Tuition: FREE

HEALTH CARE PROVIDER RESOURCE

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Join us for World Dense Breast Day, September 27th. Learn more [HERE](#).

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Patients Home

Dense Breasts: 5 Facts You Should Know

Patient Questions and Answers

Website About Dense Breasts

Let's Talk About Dense Breasts, Video Series

breast density categories on a mammogram

A. Fatty Is My Mammogram Enough?

C. Heterogeneously Dense **D. Extremely Dense**

Print: Patient Brochure

Print: Patient Fact Sheet

Print: Patient Risk Checklist

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PATIENT RESOURCE

Video Series: Let's Talk About Dense Breasts

Let's talk about

What is Breast Density? Video 1 3:18

Let's talk about

Why Does Breast Density Matter? Video 2 4:47

Let's talk about

Is My Mammogram Enough? Video 3 3:40

"What is Breast Density?" topics:

- How is breast density determined?
- Does having dense breasts increase my risk factor for getting breast cancer?
- How do I know if I have dense breasts?

"Why Does Breast Density Matter?" topics:

- Can dense tissue hide cancer on a mammogram?
- What have women with dense tissue experienced?
- If I have a normal mammogram, does that mean I do not have breast cancer?

"Is My Mammogram Enough?" topics:

- What breast screening technologies are available?
- How will I know what screening tool is best for me?
- How can I determine my risk for developing breast cancer?

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DENSE BREAST-info **Patient Fact Sheet**

Why a Conversation About Your Breast Density Matters

Breast density is seen on a mammogram and described as one of four categories:

(A) Fatty; (B) Scattered fibroglandular density; (C) Heterogeneously dense; or (D) Extremely dense

(C) Heterogeneously dense or (D) Extremely dense are "dense breasts"

Dense breasts are normal. Almost half of women over age 40 have dense breasts.

Although normal, dense breasts make it harder to see cancer on a mammogram. Cancers can be hidden and missed until they are larger and more likely to have spread.

Dense breasts increase the risk of getting breast cancer. The denser the breasts, the greater the risk.

After a mammogram, other screening tests, such as Ultrasound, or especially MRI, find more early-stage cancers in dense breasts.

Talk to your doctor or health professional about what additional screening tests may be recommended for you based on your risk factors, including breast density.

DenseBreast-info.org is the world's leading website on the topic.

PATIENT RESOURCES

Resources by Language

- English
- Arabic
- Bulgarian
- Chinese
- Croatian
- Czech
- Danish
- Dutch
- French
- German
- Greek
- Hungarian
- Italian
- Japanese
- Korean
- Lithuanian
- Polish
- Portuguese
- Russian
- Serbian
- Slovenian
- Spanish
- Turkish
- Vietnamese

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World's Leading Website About Dense Breasts

How a cancer would show in breast density categories on a mammogram

A. Fatty **B. Scattered** **C. Heterogeneously Dense** **D. Extremely Dense**

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Breasts that are (C) heterogeneously dense, or (D) extremely dense, are considered "dense breasts."

Español página web/Web Page

Senos densos: 5 datos a saber

Preguntas y respuestas de los pacientes/Patient Questions and Answers

Lista de riesgos de cáncer de mama/Breast Cancer Risk Checklist

Videos educativos/Educational Videos

¿Es mi mamografía suficiente?

Folleto del paciente/Patient Brochure

Hoja informativa para pacientes/Patient Fact Sheet

Facebook

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Senos Densos: 5 Datos para saber

Senos densos: 5 datos a saber

Preguntas y Respuestas de los Pacientes/Patient Questions and Answers

Lista de Riesgos de Cancer de Mama/Breast Cancer Risk Checklist

La densidad de los senos y el Cáncer de Mama

Videos Educativos/Educational Videos

¿Es mi mamografía suficiente?

Folleto del Paciente/Patient Brochure

Hoja Informativa Para Pacientes/Patient Fact Sheet

Facebook

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Utilize DenseBreast-info.org

- ❖ Include DBI as a resource in patient reports
- ❖ Share/run patient education video series
- ❖ Print DBI patient materials: Fact Sheet, Brochures, Risk Checklist
- ❖ Recommend as staff and referring community resource
- ❖ Share FREE staff and referring community CME/CE opportunity

Radiologist reads the mammogram

Patient determined to have dense breasts

Patient receives notification

Physician receives report

A RESOURCE IS AVAILABLE

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Supplemental Screening

- ▶ Tomosynthesis (“3D mammography”), *now becoming standard of care*
- ▶ Ultrasound
- ▶ Molecular breast imaging (MBI)
- ▶ Contrast-enhanced digital mammography (CEM, CEDM)
- ▶ MRI

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Expected Added Cancer Detection and change in false positive recall rates after Standard Mammography by Screening Modality

Method	Breast Density	Added Cancer Detection (from 2D 2-7 per 1000)	Projected change in False Positive Recall Rate (from 2D 100-120 per 1000)
Tomosynthesis (3D mammography)	Heterogeneously or Extremely dense	Average 1 per 1000	-16 per 1000
Ultrasound (first round)	Heterogeneously or Extremely dense	2-3 per 1000	+75 to 117 per 1000
Ultrasound (subsequent rounds)	Heterogeneously or Extremely dense	3-4 per 1000	+70 to 98 per 1000
Ultrasound after tomosynthesis (first round)	Heterogeneously or Extremely dense	1-3 per 1000	+45 per 1000
Ultrasound after tomosynthesis (subsequent rounds)	Heterogeneously or Extremely dense	1 per 1000	+37 per 1000
MBI	Heterogeneously or Extremely dense	7-9 per 1000	+54 to 77 per 1000
Contrast-Enhanced Mammography	Heterogeneously or Extremely dense	Average 10 per 1000	+65 per 1000
MRI/Ab MRI (first round)	Heterogeneously or Extremely dense	Average 16 per 1000	+103 per 1000
	All densities	Average 17 per 1000	+87 per 1000
MRI (subsequent rounds)	All densities	Average 6 per 1000	+23 per 1000

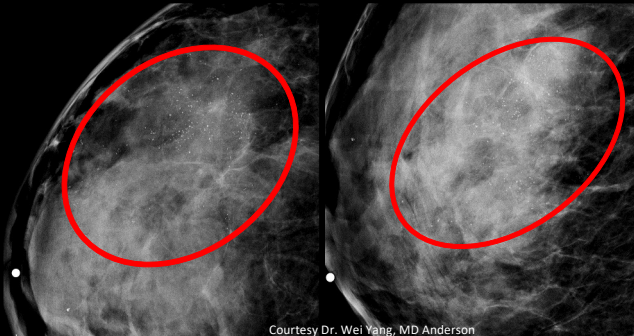
© DenseBreast-info.org, Dr. Wendie Berg, Dr. Robin Seitzman

References available at <https://densebreast-info.org/screening-technologies/cancer-detection-by-screening-method/>

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Value of Mammography in Dense Breasts



Courtesy Dr. Wei Yang, MD Anderson

48F with suspicious calcifications, dense breasts; extensive high grade DCIS with microinvasion, ER/PR(-), HER2(+)

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Supplemental Screening Should Not Replace Mammography

- Supplemental screening in women with dense breasts should be done as an adjunct – **not a replacement** for mammography in women with dense breasts
 - **Exception:** high-risk women < age 30, MRI alone is recommended. Add annual mammography to annual MRI at age 30+ (same visit or alternating 6-month intervals)

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What is Tomosynthesis ("3D")?

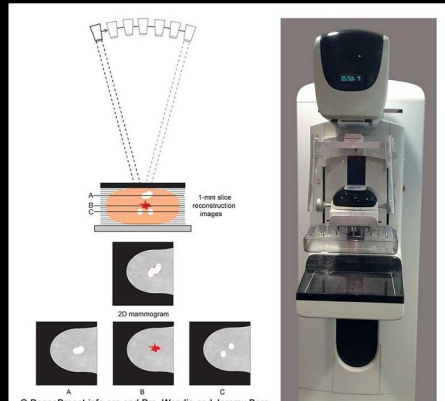


Figure 1




Figure 2

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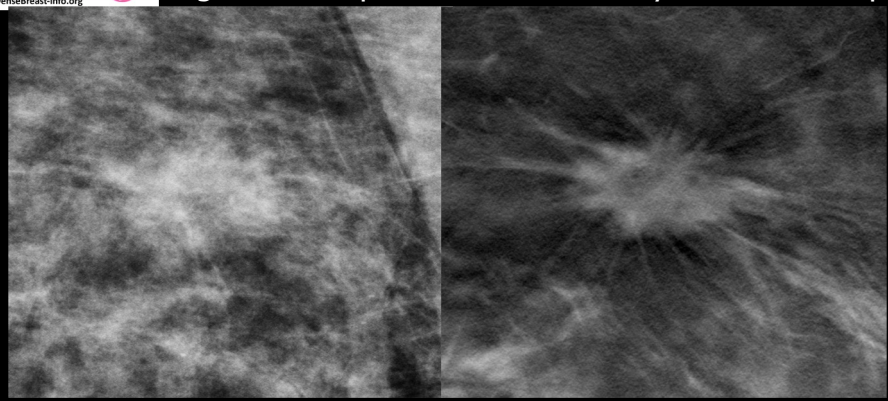
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Digital close up

3D Tomosynthesis close up



Invasive Ductal CA


Rafferty EA et al. Radiology 2013, 266:104-113

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Ultrasound



Courtesy Dr. Dianne Georgian-Smith

PROS:

- No injection, minimal pressure, ~comfortable
- No ionizing radiation
- Easy to guide biopsy
- Reduced interval cancer rate
- Mostly invasive cancers: 1-3/1000 (after tomo)
- Widely available, relatively inexpensive

CONS:


- 2-5% rate of biopsy for benign masses
- Quality can vary

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Automated US



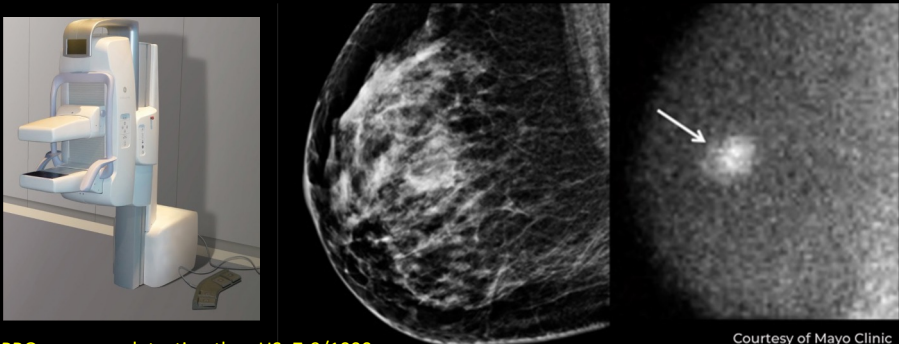
Curved array 15-6 MHz transducer, 15 cm width
Typically 3 acquisitions per breast
3D dataset, transverse acquisition with coronal reconstruction

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Molecular Breast Imaging (MBI)



Courtesy of Mayo Clinic

PRO: > cancer detection than US: 7-9/1000

CON: Whole body radiation; Minimum 40 minute exam; Not widely available

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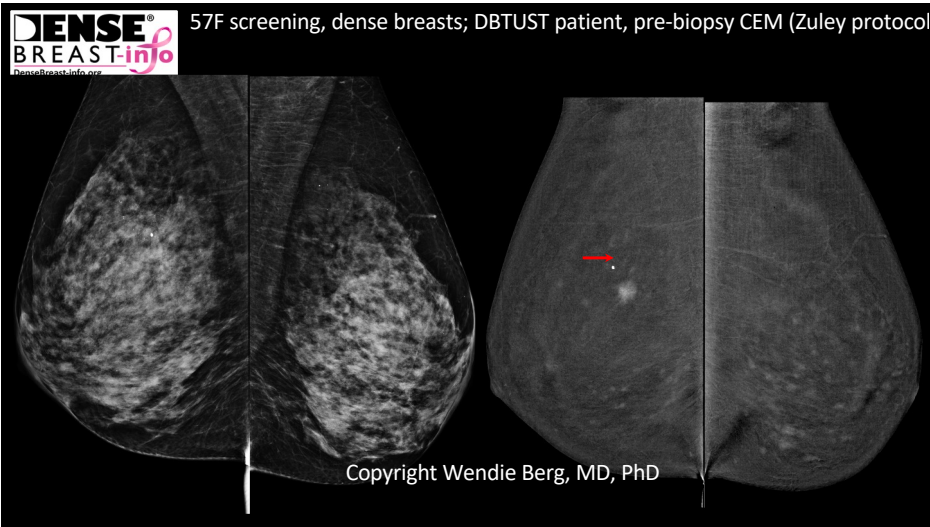
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Contrast-Enhanced Digital Mammography

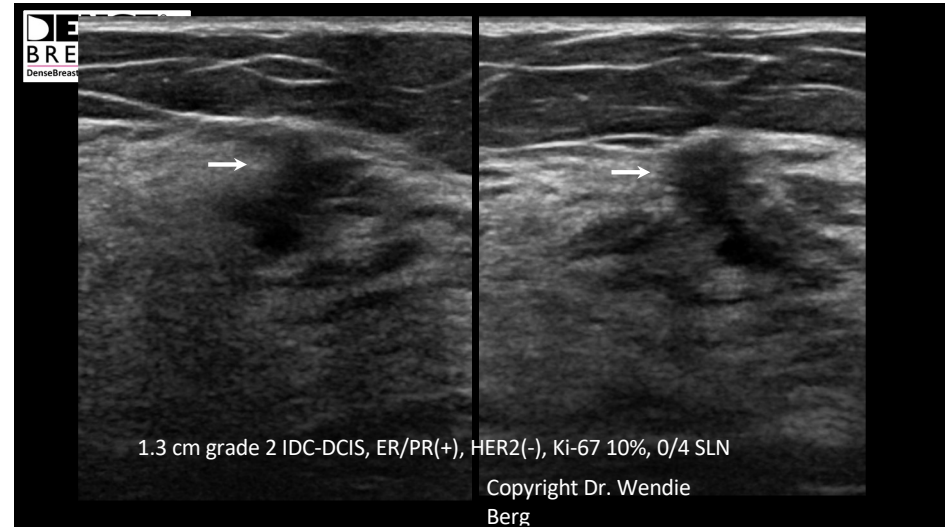
- ▶ Requires i.v. injection of iodinated contrast (the same as used in CT scanning)
- ▶ Low-energy and high-energy mammogram images obtained; exam time ~10 minutes
- ▶ Subtraction to show areas of enhancement
- ▶ Cancers are seen because of increased vascularity and leaky vessels (as on MRI)
- ▶ Radiation dose is ~2X that of standard mammogram
- ▶ Hx kidney disease, DM, HTN: check kidney function first

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Contrast-Enhanced Breast MRI

PROS:

- Highest cancer detection 8-16 per 1000 first round
- No ionizing radiation
- Reduced interval cancers
- Reduced late-stage disease
- Includes axillary nodes

CONS:

- Requires i.v. contrast
- Gd accumulates in the brain
 - Unknown effects
- Claustrophobia, pacemaker
- Cost, availability

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Abbreviated MRI

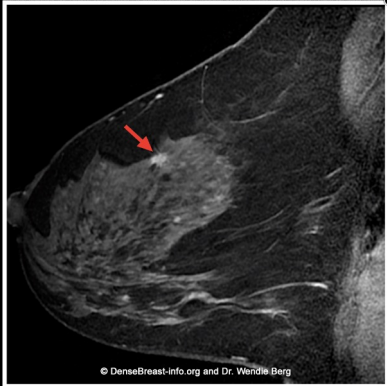
- Nearly comparable added cancer detection
- May address barriers
 - Better tolerated
 - More cost effective
- Becoming more available: Timetobeseen.org
- No CPT code
 - direct to patient billing \$250-\$850
 - Add "-52" limited modifier to MRI CPT code 77049

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T1-weighted fat suppressed MRI image, 53 y.o, dense breasts and family history



0.9 cm grade 1 invasive ductal carcinoma. Not visible on tomosynthesis, even in retrospect

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High-Risk Women Should Have Screening MRI Regardless of Breast Density

- Pathogenic mutation carrier or untested 1st degree relative
- Calculated lifetime risk of $\geq 20\%$ by risk models based largely on family history
- Chest/mantle radiation therapy ages 10-30 and at least 8 years prior
- Personal history of breast cancer and dense breasts (treated conservatively) OR diagnosed by age 50
- Personal history of breast cancer diagnosed $>$ age 50, not dense [consider MRI]
- History of LCIS/ADH on prior biopsy [consider MRI]

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Screening for Dense Breasts and not Previously Identified as High Risk

Often qualify for annual MRI due to lifetime risk $\geq 20\%$, especially with other risk factors present

- Extremely dense/no other risks [EUSOBI (every 2-4 years)]
- Dense (Extremely or heterogeneously)/ no other risks (ACR, "if desired")
- Extremely dense plus 1 first degree relative OR 2 second degree relatives OR prior benign biopsy with proliferative change (ACS, NCCN)
- Heterogeneously dense plus 1st or 2nd degree relative with breast cancer (any age) and prior benign biopsy with proliferative change OR ≥ 2 relatives (same side of family) diagnosed by 50 (ACS, NCCN, ACR, EUSOBI)
- Heterogeneously without other risks [MRI or CEM may be appropriate; US may be appropriate (ACR - disagreement)]

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Screening for those who qualify but cannot undergo MRI

- NCCN guidelines (6/19/23): "Consider CEM or MBI for those who qualify for but cannot undergo MRI. Whole breast ultrasound may be done if contrast-enhanced imaging or functional imaging is not available/accessible"
- ACR guidelines (5/19/23): "For those who qualify for but cannot undergo breast MRI, CEM or ultrasound could be considered".

National Comprehensive Cancer Network. NCCN Guidelines. Breast cancer screening and diagnosis v.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed July 24, 2023

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51-year-old with Extremely Dense Breasts and Right Breast Pain

A
2D mammogram:
no abnormality

B
3D mammogram:
no abnormality

C
Ultrasound: 1.6 cm irregular hypoechoic mass; grade 3 triple negative IDC

Courtesy Dr. Betty Rafferty in Berg WA et al, AJR epub Sept. 2020

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40F with Lump Noted After Fall on Bicycle

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Single Slices from Tomosynthesis

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Ultrasound

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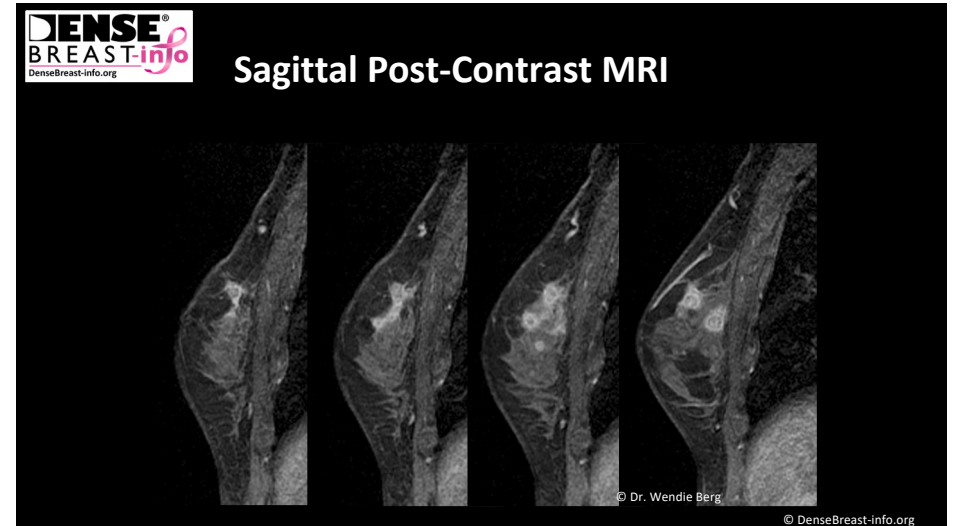
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Implementation

- Risk assessment: By age 25, repeat every 1-2 years
 - Formal: Risk models based largely on family history (e.g. Tyrer-Cuzick – not Gail)
 - Informal: dense breasts plus other risk factors
- Availability/feasibility
- Insurance coverage
 - Laws by state: DenseBreast-info.org or ask employer or health plan

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STATES WITH EXPANDED INSURANCE LAWS

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States with Insurance law(s) for:

- Ultrasound only (2)
- Ultrasound and MRI (20 plus DC)
- Diagnostic breast imaging only (1)
- No law for expanded breast imaging

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Implementation

- Insurance coverage (cont'd)
 - Plan ahead
 - Contact patient months before annual visit: introduce topic, suggest consideration of supplemental screening MRI based on breast density and risk factors
 - Ask about claustrophobia: Berg et al. found 157/222 (71%) women surveyed preferred CEM to MRI
 - Schedule mammogram/tomosynthesis and supplemental screening at same visit (alternatively at 6-month intervals)
 - Dedicated imaging center contact person to address questions prior to visit

Berg WA, Bandos AI, Siva MG. Analytic Hierarchy Process: Analysis of Patient Preferences for Contrast-Enhanced Mammography (CEM) versus MRI as Supplemental Screening Options for Breast Cancer. Journal of the American College of Radiology (2023). doi: <https://doi.org/10.1016/j.jacr.2023.03.014>

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DenseBreast-info.org World's Leading Resource on the Topic



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Thank you!

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info@mammographyeducators.com

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