FDA national breast density notification requirement

Volpara HEALTH

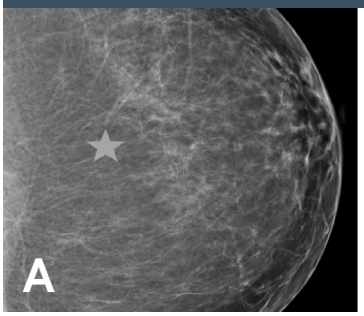
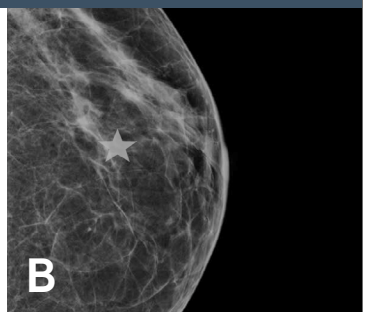
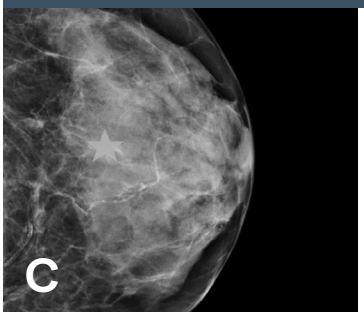
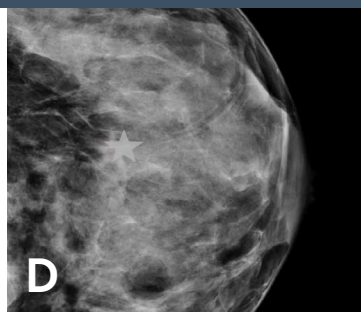
Dense breast tissue is common but has been linked to an increased risk for breast cancer and can also dramatically impact early detection. In the United States, nearly half of all women over 40 years old have dense breasts. As breast density increases, the accuracy of mammography decreases.

The FDA recently announced changes to the Mammography Quality Standards Act (MQSA), making breast density notification a federal requirement, **effective September 10, 2024**.

What you need to know	New patient standard language
The mammography report summary that is provided to patients must identify whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density.	**The lay letter must include one of the following statements:** **NOT DENSE:** "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. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." **DENSE:** "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. 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."
	New referrer standard language
Reports for healthcare providers must include an assessment of breast density using the BI-RADS® 5th Edition categories	Four classifications include: **A** The breasts are almost entirely fatty. **B** There are scattered areas of fibrograndular density. **C** The breasts are heterogeneously dense, which may obscure small masses. **D** The breasts are extremely dense, which lowers the sensitivity of mammography.

Your checklist

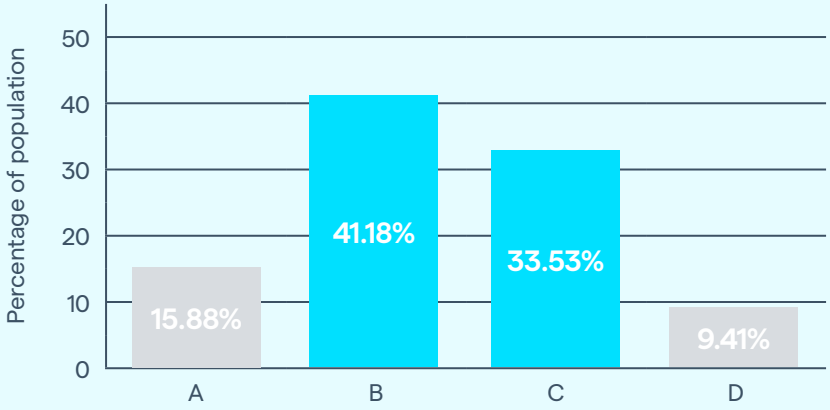
- ☐ Review MQSA Rule Update
- ☐ Consider your state-level language for insurance coverage
- ☐ Contact the MQSA program for assistance if needed
- ☐ Request letter content review from your legal team
- ☐ Update results letter template(s) and referrer reports in mammography reporting and tracking software
- ☐ Prepare/distribute referrer communication regarding report language changes
- ☐ Prepare/train patient-facing staff on new language
- ☐ Evaluate available educational content
- ☐ Work with vendor to optimize education and dense breast screening program

Not dense		Dense	
			
A	B	C	D

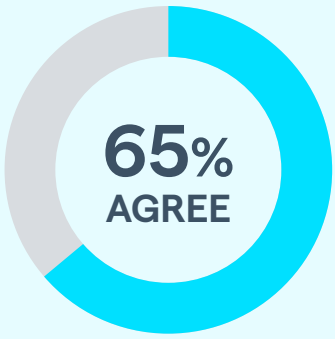
*The star in the images represents how cancer may be hidden on a mammogram.

Getting non-dense vs. dense right

Nearly 75% of patients will be assessed in either the B or C density categories.
Accurate classification between a BI-RADS B and C is essential.



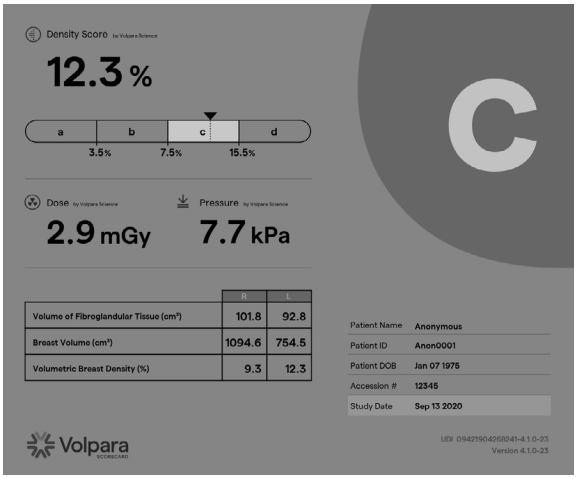
BI-RADS classification of breast density by categories A to D[1]



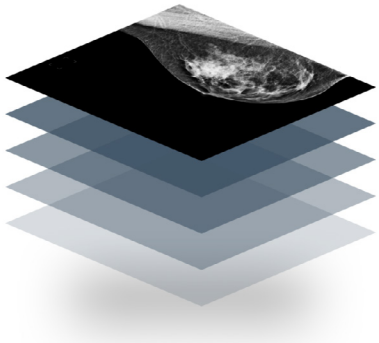
Two experts agreed about 65% of the time on a BI-RADS density category in a blind study.[2]

Volpara Scorecard: #1 tool for automated breast density assessment

Research has shown that radiologists who assess breast density visually assign density categories inconsistently.[3] The objective TruDensity® algorithm in Volpara® Scorecard™ is proven to reduce reader variability. TruDensity automatically assesses the volumetric breast density percentage (VBD%) of each mammogram on a continuous scale. This differentiates each woman on a continuum of density—whether her density is a "high B" or a "low C." This gives the radiologist important insight to evaluate patients on the dense, non-dense threshold more precisely.



Radiologists typically agree with Volpara's assessment of non-dense (A or B) or dense (C or D) 96% of the time.[4]



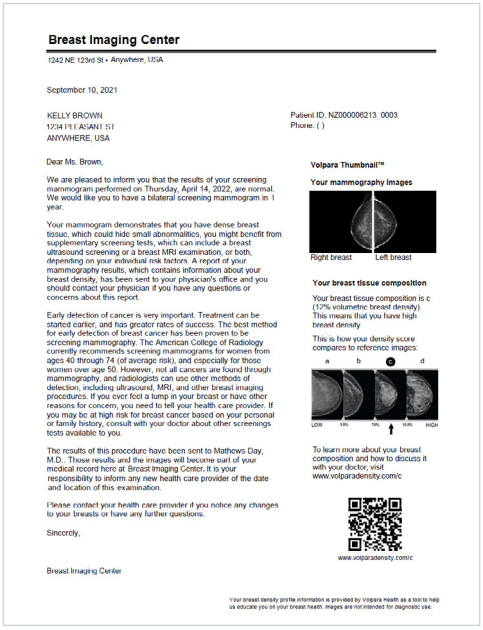
Volpara's software is used to assess breast density for more than 6 million women annually.

> "We have found Volpara to decrease inter- and intra-observer variation in breast density determination, thereby optimizing the care of our patients."
>
> —Dr. Kathy Schilling, Lynn Women's Health Institute at Boca Raton Regional Hospital, Baptist Health

The Volpara TruDensity physics-based AI algorithm is cleared by the FDA, Health Canada, and TGA (Australia); is CE marked; and has been validated in more than 400 articles and research abstracts.

Going beyond density inform to understanding + action

Volpara® Thumbnail™ empowers patients to understand their breast density with image-enhanced mammography results letters. Patients are shown two non-diagnostic images of their breasts and an explanation of what their density category means in simple-to-understand terms and visuals.



Breast Imaging Center

1242 NE 123rd St • Anywhere, USA

September 10, 2021

KELLY BROWN
1234 1ST ASANI ST
ANYWHERE, USA

Patient ID: NZ000006213_0003
Phone: ( )

Dear Ms. Brown,

We are pleased to inform you that the results of your screening mammogram performed on Thursday, April 14, 2022, are normal. We would like you to have a bilateral screening mammogram in 1 year.

Your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report.

Early detection of cancer is very important. Treatment can be started earlier, and has greater rates of success. The best method for early detection of breast cancer has been proven to be screening mammography. The American College of Radiology currently recommends screening mammograms for women from ages 40 through 74 (of average risk), and especially for those women over age 50. However, not all cancers are found through mammography, and radiologists can use other methods of detection, including ultrasound, MRI, and other breast imaging procedures. If you ever feel a lump in your breast or have other reasons for concern, you need to tell your health care provider. If you may be at high risk for breast cancer based on your personal or family history, consult with your doctor about other screenings tests available to you.

The results of this procedure have been sent to Mathews Day, M.D.. Those results and the images will become part of your medical record here at Breast Imaging Center. It is your responsibility to inform any new health care provider of the date and location of this examination.

Please contact your health care provider if you notice any changes to your breasts or have any further questions.

Sincerely,

Breast Imaging Center

Volpara Thumbnail™

Your mammography images

Right breast Left breast

Your breast tissue composition

Your breast tissue composition is c (12% volumetric breast density). This means that you have high breast density.

This is how your density score compares to reference images:

a b c d

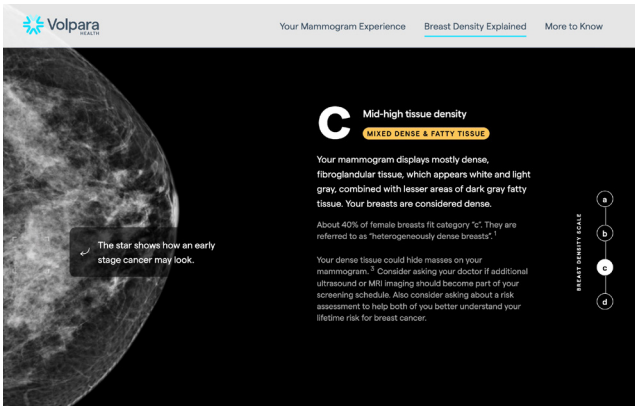
LOW HIGH

To learn more about your breast composition and how to discuss it with your doctor, visit www.volparadensity.com/c

www.volparadensity.com/c

Your breast density profile information is provided by Volpara Health as a tool to help us educate you on your breast health. Images are not intended for diagnostic use.

Scan this QR code with the camera app on your cell phone for more about breast density.



Professional Services to lower your burden and unlock success

Volpara experts are available to help breast imaging centers educate referrers and patients, and to maximize the value of dense breast screening programs.

New dense breast screening program development

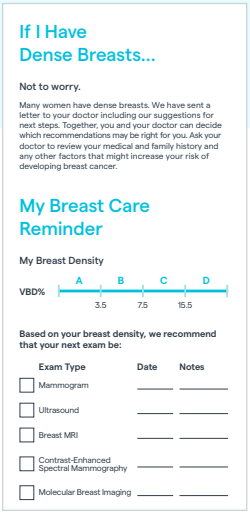
Project services include:

- Audit workflow, resources, and potential volume
- Goals and KPI identification
- Referrer and patient education
- Quarterly program audits/optimization

Breast density awareness and education services

Project services include:

- Referrer Lunch & Learns
- Ready to use patient education presentations
- Branded, customized digital and printed collateral
- Technologist and front desk scripts/training



If I Have Dense Breasts...

Not to worry.

Many women have dense breasts. We have sent a letter to your doctor including our suggestions for next steps. Together, you and your doctor can decide which recommendations may be right for you. Ask your doctor to review your medical and family history and any other factors that might increase your risk of developing breast cancer.

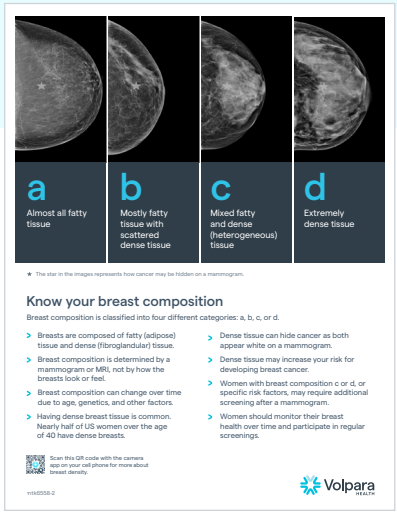
My Breast Care Reminder

My Breast Density

VBD% A 3.5 B 7.5 C 15.5 D

Based on your breast density, we recommend that your next exam be:

Exam Type	Date	Notes
☐ Mammogram		
☐ Ultrasound		
☐ Breast MRI		
☐ Contrast-Enhanced Spectral Mammography		
☐ Molecular Breast Imaging		



a Almost all fatty tissue

b Mostly fatty tissue with scattered dense tissue

c Mixed fatty and dense (heterogeneous) tissue

d Extremely dense tissue

★ The star in the images represents how cancer may be hidden on a mammogram.

Know your breast composition

Breast composition is classified into four different categories: a, b, c, or d.

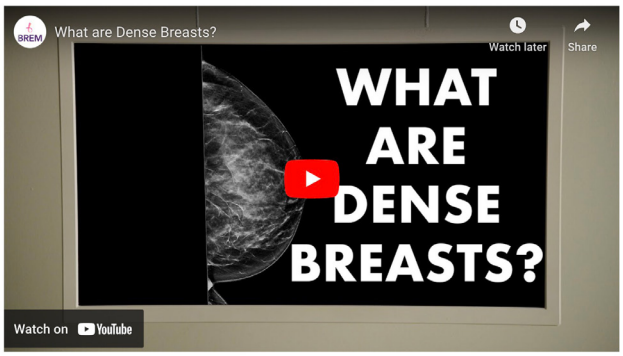
- Breasts are composed of fatty (adipose) tissue and dense (fibroglandular) tissue.
- Breast composition is determined by a mammogram or MRI, not by how the breasts look or feel.
- Breast composition can change over time due to age, genetics, and other factors.
- Having dense breast tissue is common. Nearly half of US women over the age of 40 have dense breasts.
- Dense tissue can hide cancer as both appear white on a mammogram.
- Dense tissue may increase your risk for developing breast cancer.
- Women with breast composition c or d, or specific risk factors, may require additional screening after a mammogram.
- Women should monitor their breast health over time and participate in regular screenings.

Scan this QR code with the camera app on your cell phone for more about breast density.

Volpara

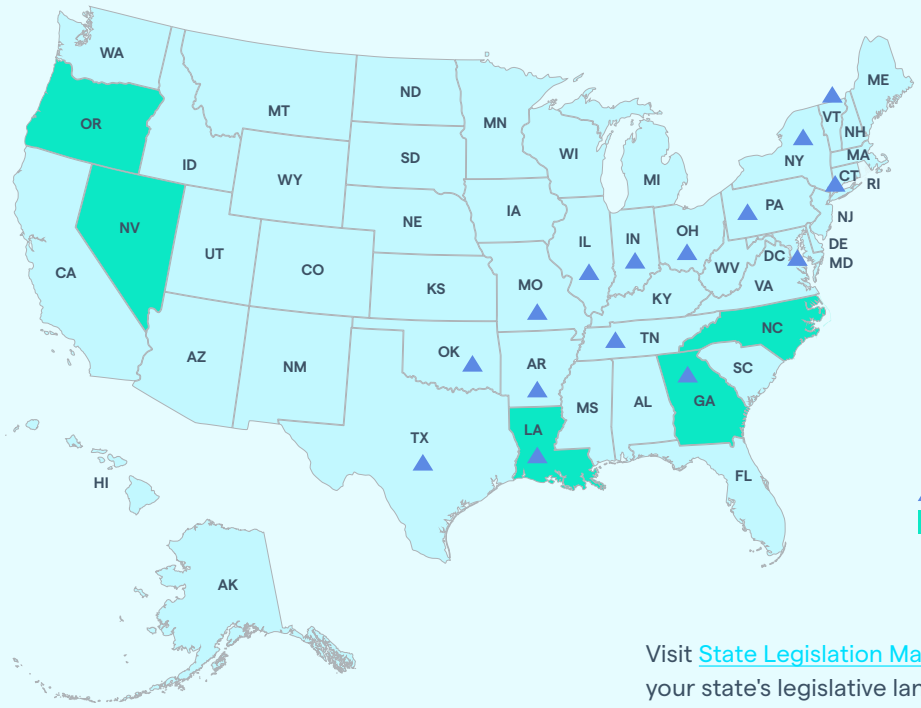
mrk6558-2

What are dense breasts? (Video from the Brem Foundation)



What's next? The Find It Early Act

The nationwide law for density inform did not address insurance coverage for additional lifesaving screenings. The Find It Early Act is a new federal bill that was introduced recently to ensure all health insurance plans cover screening and diagnostic breast imaging without out-of-pocket costs for women with dense breasts or higher risk for breast cancer. Sixteen states currently mandate coverage at the state level.



50 states + DC!
Federal density inform ruling effective 9/10/24

16 states + DC
Mandate supplemental imaging/ testing coverage and cap costs

5 states
Offer genetic testing as major population health initiatives

▲ State with insurance coverage
■ State-wide genetic testing program

Visit State Legislation Map | DenseBreast-info, Inc. to review your state's legislative language. Snapshot as of April 2023.

(for informational purposes only, please verify information)

Volpara Risk Pathways™ provides a smooth workflow for healthcare providers to assess hereditary and lifetime breast cancer risk. Volpara volumetric breast density assessment is the only automated, continuous measure validated for use with the Tyrer-Cuzick v8 (TC8) Risk Evaluation Tool.

Volpara interfaces with major genetics labs—including Ambry, Myriad, Natera, and Invitae—to offer the freedom to select a preferred lab or work with multiple labs as needs and/or patient insurance coverage requirements change.

> "The key improvement that Volpara brings to density reporting is an objective, reproducible density value that can be used in risk assessment models. These models are increasingly used to determine if a woman qualifies for MRI-based screening, and also to decide if the risk is high enough to warrant preventive therapy to reduce risk."
>
> —Professor Jack Cuzick, developer of TC8

1. Panta, Ritu & Shrestha, Shanta & Jha, Anamika. (2020). Glandular density distribution in digital mammography. *Grande Medical Journal*. 2. 5-9. 10.3126/gmj.v2i1.45080.
2. Ciatto et al, The Breast 2005.
3. Redondo A, Comas M, Macià F, Ferrer F, Murta-Nascimento C, Maristany MT, Molins E, Sala M, Castells X. Inter- and intraradiologist variability in the BI-RADS assessment and breast density categories for screening mammograms. *Br J Radiol*. 2012 Nov;85(1019):1465–70. doi: 10.1259/bjr/21256379. Epub 2012 Sep 19. PMID: 22993385; PMCID: PMC3500788.
4. Data on company file. Analysis from 36,642 cases across four clinics.

Volpara HEALTH

Contact

info@volparahealth.com
support@volparahealth.com

US +1 800 305 3865
AUS 1800 370 623
NZ 0800 444 148

Europe +44 203 051 1029
Global +64 4 499 6029

Connect

@VolparaHealth
@volpara
Volpara Health