

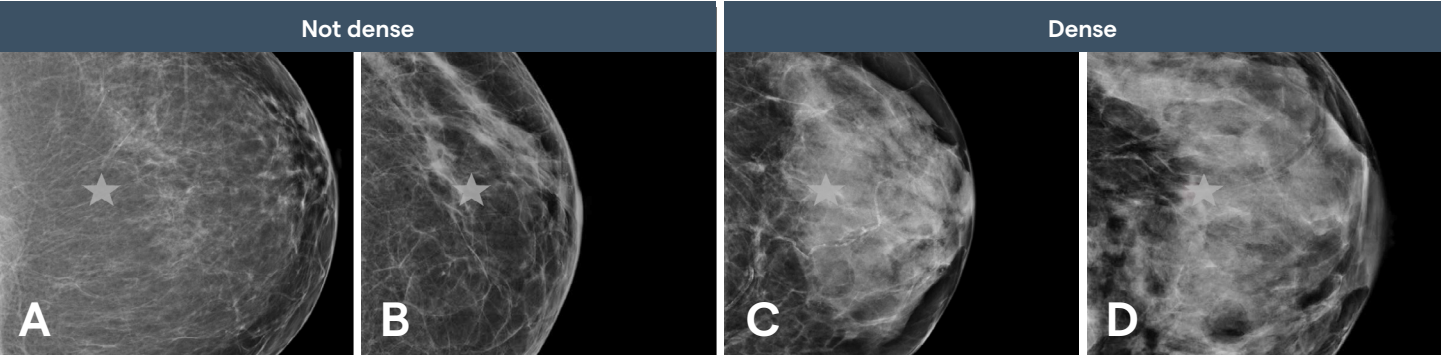
FDA national breast density notification requirement



[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	Your checklist
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.”	☐ 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
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 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.	

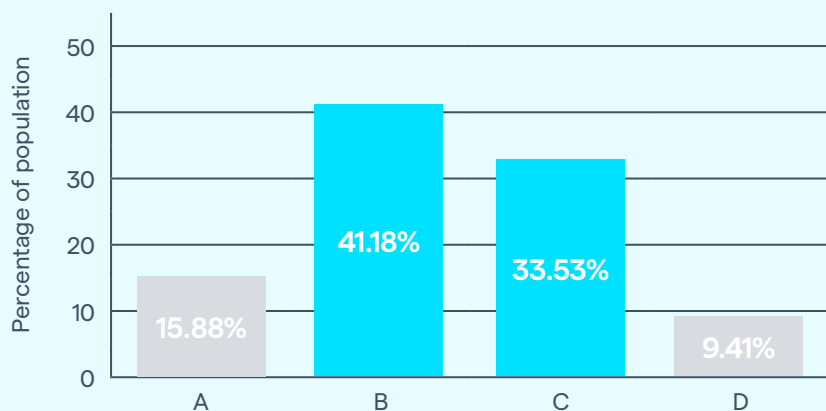


*The star in the images represents how cancer may be hidden on a mammogram.

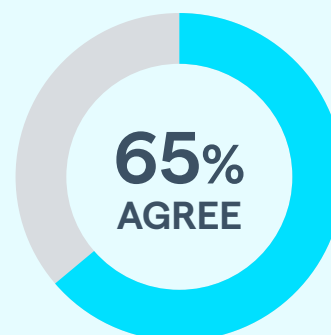
Getting non-dense vs. dense right

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.



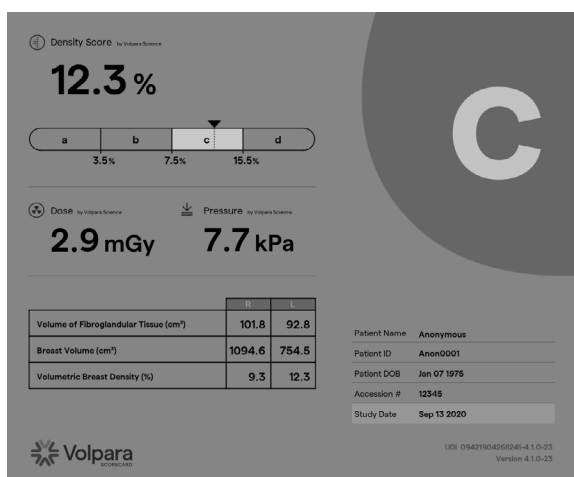
BI-RADS classification of breast density by categories A to D¹



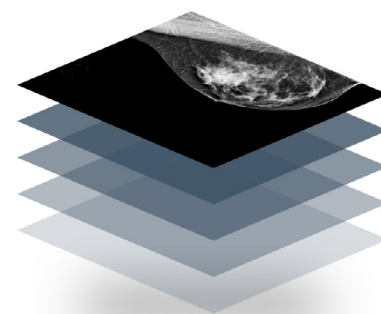
Two experts agreed about 65% of the time on a BI-RADS density category in a blind study.²

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.

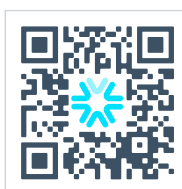
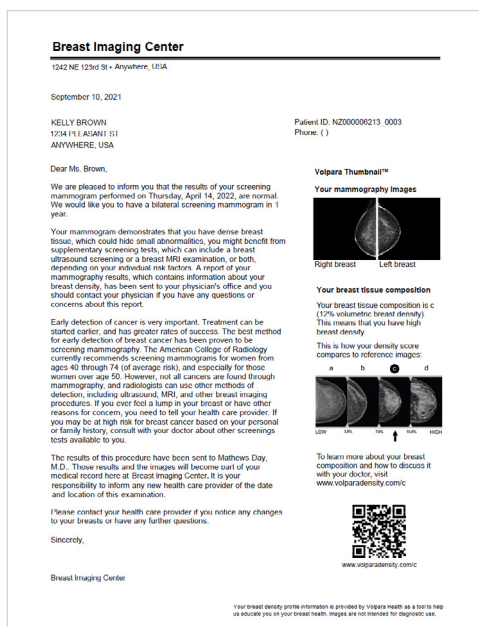
“We have found Volpara to decrease inter- and intra-observer variation in breast density determination, thereby optimizing the care of our patients.”

—Dr. Kathy Schilling, Lynn Women’s Health Institute at Boca Raton Regional Hospital, Baptist Health

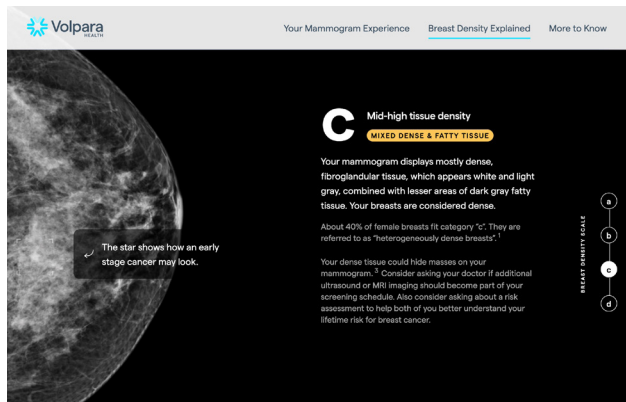
The Volpara TruDensity physics-based AI algorithm is cleared by the FDA, Health Canada, and TGA (Australia); is CE marked; and has been validated in more than [400 articles and research abstracts](#).

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.



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

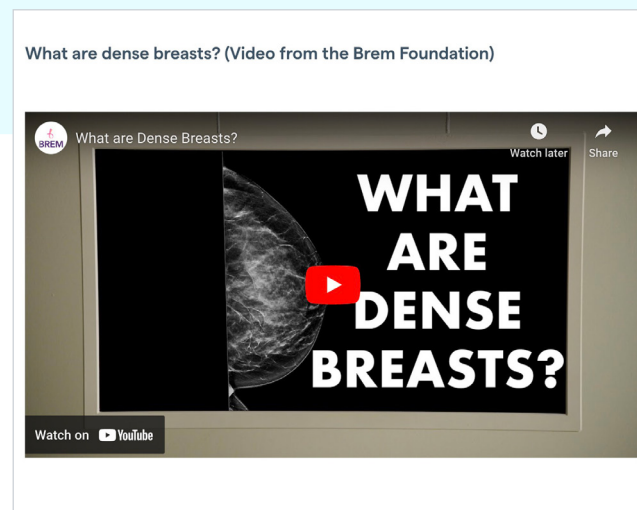
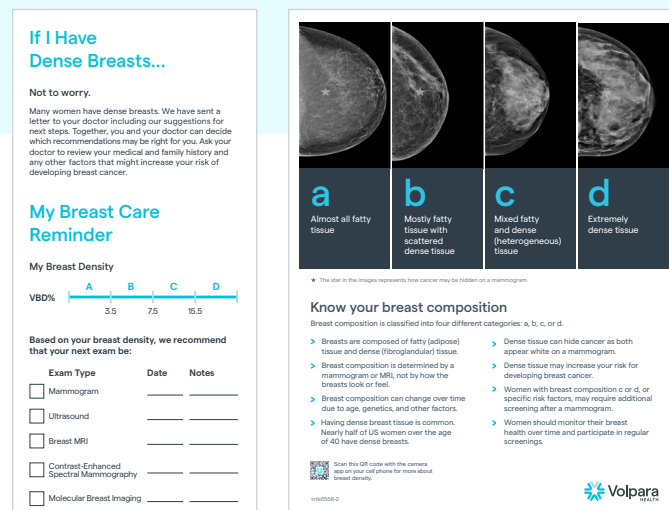
Project services include:

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

Breast density awareness and education services

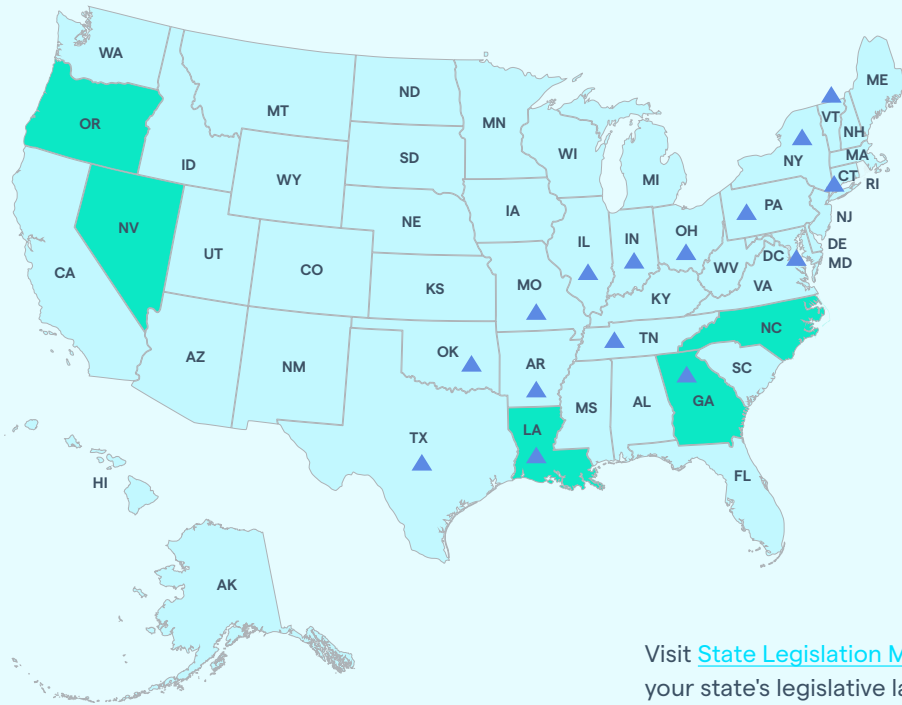
Project services include:

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



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.



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