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November 1, 2024

Dr. Dora Hughes
CMO and Director of the Center for
Clinical Standards and Quality (CCSQ)

Tamara Syrek Jensen
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality

Dr. Martin Mendoza
Chief Health Equity Officer and Director
Office of Minority Health

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Ensuring Equitable and Appropriate Access to Breast Cancer Screening

Dear Dr. Hughes, Ms. Jensen, and Dr. Mendoza:

On behalf of the Advanced Medical Technology Association (AdvaMed), and in recognition of Breast Cancer Awareness Month, we are writing to highlight ongoing challenges that women face in accessing the technologies necessary to screen for, detect, and diagnose breast cancer, specifically for women with dense breasts. This is especially relevant given the recently implemented requirements under the Mammography Quality Standards Act (MQSA)[1] that providers notify women whether they have dense or non-dense breast tissue and explain the significance of breast density.

To ensure appropriate patient access and uptake for breast cancer screening and diagnosis, we would like to work with CMS and other relevant Agencies to:

1. Ensure Medicare coverage policies include breast density, defined as patients with mammographically demonstrated category C (heterogeneously dense) or category D (extremely dense) breast tissue as an indication for coverage of supplemental breast imaging in addition to screening mammography,
2. Reduce or eliminate potentially prohibitive cost sharing for patients whose providers have recommended supplemental breast imaging,
3. Promote health equity via increased access to appropriate breast imaging modalities.

[1] https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program/important-information-final-rule-amend-mammography-quality-standards-act-mqsa

AdvaMed member companies produce medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate setting.

Dense Breast Tissue

Breast cancer is the most commonly diagnosed cancer among women in the U.S. and constitutes 15% of all new cancer diagnoses.[2] Seven out of ten cases of breast cancer are diagnosed in women aged 55 years and older.[3] Screening with mammography has been proven to reduce mortality and therefore, equitable access to screening is of critical importance to female Medicare beneficiaries.

Breast tissue density is an indicator of the amount of glandular and connective tissue relative to fatty tissue measured during a mammogram. Breast tissue is categorized according to a standardized system developed by the American College of Radiology called the Breast Imaging-Reporting and Data System (BI-RADS). The categories include A) almost entirely fatty; B) scattered areas of fibroglandular density; C) heterogeneously dense; and D) extremely dense. Women with breasts classified as BI-RADS C or D are referred to as having "mammographically dense breasts."[4] The risk of breast cancer increases with mammographic breast density, and women with BI-RADS C or D have a 1.5 to 2-fold higher risk of breast cancer compared to those with average density (BI-RADS B).[5]

Nearly half of all women 40 and older and one third of women in their 70s have mammographically dense breast tissue.[6,7,8] Dense tissue can make it more difficult to identify breast cancer on a mammogram. Mammography is less sensitive in dense tissue and may miss up to 25% of breast cancers in women with heterogeneously dense breasts and 40% of breast cancers in women with extremely dense breasts.[9, 10, 11] This can result in later staging of the disease at diagnosis and more advanced disease progression. Compared to digital mammography, digital breast tomosynthesis (DBT) can improve detection in women with dense breasts and studies have shown that the

[2] https://seer.cancer.gov/statfacts/html/breast.html
[3] https://www.kff.org/womens-health-policy/fact-sheet/coverage-of-breast-cancer-screening-and-prevention-services/
[4] https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2022-2024-breast-cancer-fact-figures-acs.pdf
[5] Bertrand KA, Tamimi RM, Scott CG, et al. Mammographic density and risk of breast cancer by age and tumor characteristics. Breast Cancer Res. 2013;15:R104
[6] https://www.cancer.gov/types/breast/breast-changes/dense-breasts
[7] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#bcei-recommendation-title-area
8 https://ajronline.org/doi/10.2214/AJR.10.6049
[9] https://www.breastcancer.org/research-news/dense-breasts-mri-supplemental
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5638217/
[11] https://www.cancer.gov/types/breast/breast-changes/dense-breasts

combination of DBT with supplemental imaging results in even higher cancer detection than either test alone.[12,13,14,15]

Women with dense breast tissue can benefit from receiving supplemental imaging exams such as ultrasound, MRI imaging, or contrast-enhanced mammography. In fact, a recent study published in JAMA Internal Medicine estimates that the use of supplemental MRI, in addition to DBT or digital mammography, lowered the number of deaths in women with heterogeneously and extremely dense breasts.[16]

Density Notification Requirements

New requirements have recently been enacted requiring healthcare providers to notify women about their breast density. A final rule issued by the FDA on March 10, 2023, under the MQSA, requires healthcare providers to provide a written lay summary of the results of a mammogram. Beginning September 10, 2024, the summary provided to patients identifies whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density. Numerous states have passed similar notification laws in recent years.

While notification about the presence and risks of dense breast tissue is an important first step in empowering women to make informed decisions about their care, access to imaging tests in addition to mammography is limited. This issue is especially urgent given its potential to impact health equity. While the rate of breast cancer for women of color is similar to white women, Black women are often diagnosed with breast cancer at more advanced stages when treatment options are more limited, costly, and result in death rates 40% higher than white women.[17] Black women may face worse disease progression in part because of their increased likelihood of having dense breast tissue[18], and greater research is needed to improve screening efficacy and outcomes.

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12 Rafferty EA, Durand MA, Conant EF, et al. Breast Cancer Screening Using Tomosynthesis and Digital Mammography in Dense and Nondense Breasts. JAMA. 2016;315(16):1784–1786.
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14 Patel BK, Carnahan MB, Northfelt D, Anderson K, Mazza GL, Pizzitola VJ, Giurescu ME, Lorans R, Eversman WG, Sharpe RE Jr, Harper LK, Apsey H, Cronin P, Kling J, Ernst B, Palmieri J, Fraker J, Mina L, Batalini F, Pockaj B. Prospective Study of Supplemental Screening With Contrast-Enhanced Mammography in Women With Elevated Risk of Breast Cancer: Results of the Prevalence Round. J Clin Oncol. 2024 Jul 26. Epub ahead of print.
15 Berg WA, Zuley ML, Chang TS, Gizienski TA, Chough DM, Böhm-Vélez M, Sharek DE, Straka MR, Hakim CM, Hartman JY, Harnist KS, Tyma CS, Kelly AE, Waheed U, Houshmand G, Nair BE, Shinde DD, Lu AH, Bandos AI, Berg JM, Lettiere NB, Ganott MA. Prospective Multicenter Diagnostic Performance of Technologist-Performed Screening Breast Ultrasound After Tomosynthesis in Women With Dense Breasts (the DBTUST). J Clin Oncol. 2023 May 1;41(13):2403-2415.
[16] Stout NK, Miglioretti DL, Su Y, et al. Breast Cancer Screening Using Mammography, Digital Breast Tomosynthesis, and Magnetic Resonance Imaging by Breast Density. JAMA Intern Med. Published online August 26, 2024. doi:10.1001/jamainternmed.2024.4224
[17] https://www.komen.org/about-komen/our-impact/breast-cancer/stand-for-h-e-r/
[18] https://academic.oup.com/jnci/article/107/10/djv296/987327?login=false

Coverage for Supplemental Imaging

While supplemental imaging with advanced technologies increases the effectiveness of detecting breast cancer in women with dense breast tissue, cost, availability, and insurance coverage limit its use. As a result, beneficiaries may either forgo supplemental imaging or are surprised by bills, especially when those exams were recommended and ordered by their healthcare provider. In many cases, Medicare beneficiaries do not realize the costs associated with the imaging until it has already been performed. Medicare's lack of coverage of imaging technologies for women with dense breast tissue leaves Medicare beneficiaries, who lack gap coverage, to either pay out of pocket or to forgo critical, potentially life-saving additional testing. Only 23% of Medicare beneficiaries are enrolled in a Medigap plan[19] leaving most without coverage for these cost-sharing gaps. This is an unacceptable barrier, especially given recently enacted FDA requirements that women be notified about their breast density and the inherent risk of dense breast tissue.[20]

AdvaMed urges CMS to cover imaging, in addition to a mammogram, for women with heterogeneously or extremely dense breast tissue.

Burdensome Cost Sharing

Women referred for additional imaging after a determination of dense breast tissue face significant costs simply to access necessary testing, either from greater cost-sharing, co-pays or the need to pay for the entire cost of a service that is not fully covered by Medicare. Such additional payment can be a deterrent to women getting the follow-up imaging they may need to detect cancer.[21,22]

Waiving or capping cost sharing is a popular policy that has gained significant uptake in recent years. To date, 26 states have enacted legislation that waives or caps cost sharing for women who must undergo additional imaging following a screening mammogram.[23] Congress is also considering the Find it Early Act (S. 5141/H.R. 3086) which would expand health insurance coverage of breast imaging, with no out-of-pockets costs, for women with dense breasts or at higher risk for breast cancer.

We encourage CMS to work with Congress and other stakeholders to reduce the financial burden placed on women who require additional imaging following a screening mammogram.

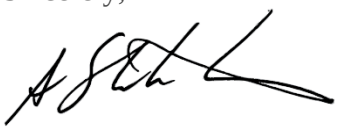
[19] https://crsreports.congress.gov/product/pdf/R/R47552
[20] https://www.federalregister.gov/documents/2023/03/10/2023-04550/mammography-quality-standards-act
[21] https://pubs.rsna.org/doi/10.1148/radiol.222952
[22] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802763
[23] https://www.komen.org/blog/center-for-public-policy-2024-midyear-update/

Conclusion

We appreciate the opportunity to bring to your attention issues of great importance to our members. Medicare beneficiaries with dense breast tissue deserve access to comprehensive breast cancer imaging. In the case of patients with heterogeneously or extremely dense breasts, this should include both primary and supplemental imaging exams.

We would welcome the opportunity to discuss any of these issues in more detail if helpful. Please do not hesitate to contact me at swhitaker@advamed.org if you have any questions or need any additional information.

Sincerely,



Scott Whitaker