Evaluation of Minn. Stat. § 62A.30, Subd. 4

Report to the Minnesota Legislature Pursuant to Laws of Minnesota 2023, Chapter 57, Article 2, Section 65

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Executive Summary

Minn. Stat. § 62A.30, Subd. 4 requires a health carrier to provide health insurance coverage for breast cancer screenings using three-dimensional (3D) mammograms, also known as digital breast tomosynthesis, for enrollees at high risk for breast cancer. The Minnesota Legislature clarified existing state law such that 3D mammograms for breast cancer screening were covered as a preventive service and therefore prohibited cost-sharing (e.g., co-payment, deductible, or coinsurance). This health benefit mandate was enacted in the 91st Legislature (2019-2020) and took effect on January 1, 2020.

Public comments indicated that some health insurance plans provided various coverage for 3D mammograms prior to January 1, 2020. After the mandate went into effect, utilization rates and costs for 3D mammograms increased. It is unclear if this rise in utilization rates is directly related to the law. Respondents noted that increased premiums tied to 3D mammograms may be offset by the corresponding downstream savings of early and accurate detection of breast cancer, but that has not yet been determined.

The Patient Protection and Affordable Care Act (ACA) requires coverage of women's preventive health care, including screening mammograms, as an essential health benefit requirement. 3D mammograms are not specifically required as a preventive screening under the ACA. Several states have added coverage for 3D mammogram screenings with no cost-sharing. Of states that require medical necessity criteria for 3D mammogram screening coverage, the required criteria align with those in Minn. Stat. § 62A.30, Subd. 4.

Recommendations for 3D mammograms are inconsistent across clinical practice guidelines for breast cancer screenings, but some clinical practice guidelines include 3D mammograms as a recommended screening for individuals at high risk for breast cancer. This mandate's medical necessity criteria include the same high-risk factors that are associated with a lifetime risk of developing breast cancer, developing more aggressive cancer types, and poorer prognosis. The clinical effectiveness literature on 3D mammograms is mixed and varies considerably by study design and population. However, it is most consistent in demonstrating that 3D mammograms may result in fewer false positives compared to standard mammograms. 3D mammograms may also improve detection of advanced cancers when compared to standard mammograms, but there is inconsistent evidence on whether this applies to individuals with dense breast tissue.

For Minnesotans with commercial health insurance, the total amount spent on breast cancer screenings for standard mammograms and 3D mammograms was $56.7 million in 2018, which increased to $60.1 million by 2022, an increase of approximately 6.0% over this period. During this same period, 3D mammograms increased as a proportion of all screening mammograms from 50% of screening mammograms to 82% of screening mammograms. The analysis found that the costs per procedure for 3D mammograms increased from $431 in 2018 to $476 in 2022, a net increase of 10.4%. By comparison, the cost per procedure for standard mammograms increased from $330 to $342, with a net increase of only 3.6% during this same time period.

A more comprehensive analysis to assess the cost-effectiveness of 3D mammograms was limited by several factors, including a reduction in breast cancer screenings as a result of the COVID-19 public health emergency, which occurred during the time period of analysis. The current literature is mixed as to the cost-effectiveness of 3D mammograms, but some studies suggest that 3D mammograms' improved cancer detection and reduced false negatives compared to standard mammograms may result in reduced unnecessary testing and improved health outcomes for breast cancer secondary to early detection. The cost-effectiveness of 3D mammograms cannot be comprehensively assessed, as coverage that reduces disparities in screenings may improve rates of early detection and reduce delays in treatment for underserved populations. However, no study has evaluated the impact of coverage for 3D mammogram screenings on disparities in health outcome related to breast cancer screening.

Introduction

Minn. Stat. § 62J.26 requires the Minnesota Department of Commerce (Commerce)—in coordination with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB)—to evaluate mandated health benefit proposals for potential fiscal, economic, and public health impacts. In 2023, the Minnesota Legislature passed legislation directing Commerce to conduct an evaluation of the economic cost and health benefits of one existing state-required health benefit mandate each year for the next five years. Commerce is evaluating Minn. Stat. § 62A.30, Subd. 4, an existing state-required health benefit mandate which expands coverage requirements for breast cancer screenings to include three-dimensional (3D) mammograms for individuals with a high risk of developing breast cancer.

For evaluation criteria and required evaluation components, please review the Retrospective Evaluation Report Methodology, available at https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Bill Requirements

Minn. Stat. § 62A.30, Subd. 4 was passed by the 91st Legislature (2019-2020) and took effect on January 1, 2020. This law requires a health carrier to provide health insurance coverage for breast cancer screenings using 3D mammograms, also known as digital breast tomosynthesis, for enrollees at high-risk for breast cancer. The bill requires these screenings to be covered as a preventive service and therefore prohibits cost-sharing (e.g., co-payment, deductible, or coinsurance) as described under Minn. Stat. § 62Q.46.

This mandate applies to fully insured small and large group commercial health plans, individual market plans, Medicare supplemental policies, and the State Employee Group Insurance Program (SEGIP). It does not apply to self-insured employer plans, grandfathered plans, Medicare, and Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare).

Related Health Conditions and Services

Associated Services. A mammogram is a breast X-ray that is used to detect breast cancer.[1] A screening mammogram aims to detect breast cancer in the absence of signs or symptoms, whereas a diagnostic mammogram checks for breast cancer when a sign or symptom of breast cancer is present. Standard mammograms may be referred to as “two-dimensional (2D) mammograms” or “digital mammograms”. A 3D mammogram expands on the visual images provided by a standard mammogram using a series of cross-sectional digital 3D images of breast tissue from different angles. This procedure is used to detect breast cancer, as well as other changes in the breast, both in the presence and absence of signs or symptoms of breast cancer. It is used for both screening and diagnostic purposes.

Associated Health Conditions. Breast cancer is defined as cancer occurring in the tissue of the breast.[1] Breast cancer primarily affects women, with only 0.2% of breast cancer cases occurring in men. According to the most current statistics in Minnesota, there are roughly 4,500 new cases of breast cancer per year, with 650 associated deaths in 2019.[2]

The mandate requires coverage for 3D mammograms for enrollees who are at risk for breast cancer, which is defined by the following factors:

- a family history with one or more first- or second-degree relatives with breast cancer;
- a positive test for BRCA1 or BRCA2 mutations;
- heterogeneously dense breasts or extremely dense breasts based on the Breast Imaging Reporting and Data System established by the American College of Radiology (ACR); or
- a previous diagnosis of breast cancer.

The law states that this coverage requirement does not prohibit 3D mammogram coverage for an enrollee without one of the above high-risk factors for breast cancer.

Related State and Federal Laws

This section provides an overview of state and federal laws related to the enacted mandate and any external factors that provide context on current policy trends related to this topic.

Related Federal Laws

The Patient Protection and Affordable Care Act (ACA) includes coverage of women's preventive health care, including screening mammograms, as an essential health benefit (EHB) requirement.[3] The ACA does not explicitly include 3D mammograms as a screening procedure, so coverage is not presently required for this service under federal law.[4] In order for 3D mammogram screening to be required for coverage by private insurers under the ACA, the United States Preventive Services Task Force (USPSTF) must give the procedure an A or B recommendation.[5] Currently, the USPSTF concludes that the existing evidence is insufficient to assess the benefits and harms of 3D mammograms as a primary screening method for breast cancer.[6]

Medicare Parts B and C (Medicare Advantage) provide coverage for 3D mammogram screenings at no cost-sharing once every 12 months for women over the age of 40.[7,8]

Related Minnesota Laws

Several relevant Minnesota laws provide coverage determinations for the use of 3D mammograms for breast cancer screening. Minn. Stat. § 62Q.46 requires that a health plan company provide coverage for preventive items and services without imposing cost-sharing requirements, including a deductible, coinsurance, or co-payment.[9] 3D mammogram screenings fall under "preventive items and services" for individuals at risk for breast cancer and therefore are covered for enrollees with no cost-sharing.

According to Minn. Stat. § 62Q.46, preventive items and services covered in Minnesota must align with the ACA unless otherwise noted. Under Minnesota law, "preventive items and services" means evidence-based items or services that have a rating of A or B in the current recommendations of the USPSTF. Preventive items and services specific to women's health may also be covered in Minnesota if they are listed in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).[9]

Minn. Stat. § 62A.30, Subd. 5, which was enacted in 2022, requires coverage for additional diagnostic services or testing following a mammogram if a health care provider determines them to be medically necessary. While cost-sharing was already prohibited for 3D mammogram screenings under Minn. Stat. § 62Q.46, this subdivision expands coverage without cost-sharing to follow-up tests and services if determined medically necessary by a health care provider.

State Comparison

Coverage for 3D mammograms for breast cancer screening varies across states, from no coverage for 3D mammogram screening to full coverage without cost-sharing.[5,10] States that have added coverage for 3D mammogram screenings have done so using a variety of approaches. One of the most common approaches is expanding the state definition of "mammogram" or "mammography" to digital mammography including digital breast tomosynthesis (e.g., Kentucky,[11] Louisiana,[12] Missouri,[13] Oklahoma,[14] Texas[15]). Other states have expanded coverage by enacting statutes that specifically add 3D mammograms as a type of screening mammogram (e.g., Arizona,[16] Connecticut,[17] Nebraska[18]). Because these methods of coverage typically fall under states' definitions of preventive items or services, states that cover 3D mammograms as a type of screening do so at no cost-sharing (e.g., coinsurance, copayment, or deductible). State coverage for 3D mammogram screening is typically focused on commercial insurers, but Washington D.C. has also expanded this coverage to their Medicaid program.[19]

For states that provide coverage for 3D mammogram screenings, some require medical necessity criteria to be met in order for beneficiaries to receive coverage (e.g., Arizona, Nebraska) while others only impose age limitations in alignment with national guidelines (e.g., Louisiana, Washington D.C.). Of states that impose age limitations, a few will waive the limitations upon physician recommendation if the individual is at high-risk of developing breast cancer (e.g., Arkansas,[20] Connecticut). The most common risk factors cited by states for individuals at high-risk of developing breast cancer are a family history of breast cancer, a personal history of breast cancer, positive genetic testing (e.g., BRCA 1 or BRCA 2), and dense breast tissue.

Two of the most recent states to add coverage are Arizona (2023) and Nebraska (2024). Arizona added coverage for 3D mammogram screening by enacting legislation stating that a contract that provides coverage for surgical services for a mastectomy shall also provide coverage for preventive mammography screening including but not limited to 3D mammograms, following recommendations by the National Comprehensive Cancer Network (NCCN). This includes individuals at risk for breast cancer due to family history, a prior diagnosis of breast cancer, positive testing for hereditary gene mutations, or heterogeneously dense breast tissue based on breast imaging reporting and data systems of the ACR. Starting in 2024, Nebraska expanded coverage for women who have an increased risk of breast cancer due to a family or personal history of breast cancer, a prior atypical breast biopsy, positive genetic testing, or dense breast tissue based on a breast image to one digital breast tomosynthesis per year. These medical necessity criteria are based on the NCCN Guidelines for Breast Cancer Screening and Diagnosis version 1.2022 and the recommendation of a health care provider.[21]

Public Comments Summary

Commerce solicited public input on the health benefit mandate through a request for information (RFI) posted to Commerce's website and the Minnesota State Register. The summary below represents only the opinions and input of the individuals and/or organizations who responded to the RFI.

Key Public Comment Themes

For this mandate, Commerce received limited public comments. RFI responses indicated that some health insurance plans already provided some form of coverage for 3D mammograms before the mandate took effect in 2020. After enactment of the mandate, carriers experienced increased utilization rates and costs for 3D mammograms. Respondents indicated it is unclear whether the cost increase for 3D mammograms was due to the mandate or other external factors, such as changing practice patterns related to breast cancer screenings. Respondents noted that while 3D mammograms are more expensive than standard mammograms, they may result in downstream savings due to earlier and more accurate cancer detection and reduced call back imaging. These respondents noted that it is unclear whether potential savings associated with 3D mammograms would be offset by the associated increase in premiums. Based on information submitted by carriers and SEGIP, per member per month (PMPM) costs increased by less than $1, on average. Given the limited number of respondents to the RFI, Commerce is unable to share additional data related to changes in utilization and PMPM costs.

Evaluation of Enacted Statute

Methodology

The following section includes an overview of the current literature examining the clinical effectiveness of 3D mammograms, current standards of care for breast cancer screening, and the economic and public health impact of the enacted mandate. The literature review of key terms (see Appendix B) includes moderate- to high-quality relevant peer-reviewed literature and/or independently conducted domestic research that was published within the last 10 years and is relevant to the enacted health benefit mandate. For further information on the literature review methodology, please reference: https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Standards of Care

Evolution in Breast Cancer Guidelines. Clinical practice guidelines, used by health care providers for breast cancer screening recommendations, generally cover who should receive screening (e.g., age ranges, gender), the frequency at which screenings should occur (e.g., annual versus biennial), what type of screening procedure should be used, and what risk factors should be considered. The clinical practice guidelines have evolved over the last 10 years, related to risk factors, age, and frequency of screening, in addition to technological updates. The USPSTF notes that the risk of screening, not specific to 3D mammograms, includes false-positives and false-negatives resulting from screening, overdiagnosis, and radiation from mammogram technology as reasons to continue revisiting the guidelines to weigh benefits and harms. Overdiagnosis, resulting from diagnosis of breast cancer that may otherwise be asymptomatic, is one driver for variation and revisions in screening clinical guidelines.[5,22] Current breast cancer screening guidelines seek to balance the harms of delayed diagnosis and supplemental testing with the potential harms of overdiagnosis. No studies identified for this evaluation assessed the impact of 3D mammograms on overdiagnosis.

Clinical Guidelines and Populations Impacted. The American Cancer Society (ACS), NCCN, and American College of Obstetrics and Gynecology (ACOG) broadly indicate that women with average[a] risk of breast cancer, starting around age 40, should receive annual or biennial mammograms, with some guidelines recommending reduced frequency beginning between the ages of 75-79. [23,24,25] While the previously published USPSTF guidelines recommended that annual mammogram screenings for women of average risk begin at 50, the 2024 updates to the USPSTF guidelines recommend annual mammogram screening begin at 40.[6] A recent study conducted modeling estimates on screenings and found that screenings beginning at age 40 confer the most benefit in outcomes, compared to screenings beginning after age 50, weighing current estimates of false positives and the impact of screening on life expectancy.[26] This study was not specific to 3D mammograms. Another study concurred with the findings in the modeling estimates, noting that women between the ages of 40-49 may have unique risk factors, with more aggressive cancers and late-stage detection than individuals 50 and above.[27] For individuals at high risk for breast cancer, some guidelines indicate that screening may be warranted as early as age 30.[24,25]

Clinical Guidelines and 3D Mammograms. Recommendations for 3D mammograms are inconsistent across clinical practice guidelines. Currently, the NCCN guidelines recommend that at age 40, individuals at high risk for breast cancer should be prescribed 3D mammograms for breast cancer screenings, although screenings may begin as early as age 30.[25] NCCN guidelines attribute this recommendation to the "improved detection" of 3D mammogram screenings compared to standard mammograms, as well as reduced call-back rates (e.g., subsequent testing resulting from incomplete test results or false positives). The ACS guidelines cite that 3D and standard mammograms should both be available to patients whose doctor has determined that one screening method is more appropriate than another, but recommend that magnetic resonance imaging (MRI), not 3D mammograms, be considered for high-risk individuals.[24] The ACOG and USPSTF concluded that the evidence for 3D mammograms compared to standard mammograms, particularly for those with dense breast tissue, is insufficient to recommend 3D mammograms as a routine screening modality for women, including women with dense breast tissue.[28,29]

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[a] The ACS defines average risk for screening as individuals without "a personal history of breast cancer, a strong family history of breast cancer, or a genetic mutation known to increase risk of breast cancer (such as in a BRCA gene), and have not had chest radiation therapy before the age of 30". They define high-risk as a 20-25% lifetime risk of breast cancer in the presence of any of these factors.

Table 1. Variations in Clinical Practice Guidelines

Organization	Includes Age-Based Recommendations for Women at Average Risk for Breast Cancer	Includes Age-Based Recommendations for Women at High-Risk for Breast Cancer	Cites Insufficient Evidence to Recommend 3D Mammograms for Screenings	Includes Recommendations for 3D Mammograms for Individuals at High-Risk for Breast Cancer
ACOG	x		x	
ACS	x	x		
NCCN	x	x		x
USPSTF	x		x	

Clinical Efficacy of 3D Mammograms

The literature on the clinical effectiveness of 3D mammograms considers the accuracy of the test and the associated impact on health outcomes for breast cancer. There are different factors used to evaluate the accuracy of a screening intervention, such as the ability of a test to detect cancer and the ability for a test to differentiate between cancerous and non-cancerous tissue. The literature also discusses the accuracy and clinical benefit of 3D mammograms compared to standard mammograms. It should be noted that differences across populations studied, variation in radiographic interpretation, and methodological challenges to control for all high-risk factors in treatment groups contribute to variation in findings across the current literature.

3D Mammograms and Cancer Detection Rates, False Positives, and Recall Rates. 3D mammograms may be more effective than standard mammograms in detecting tumors by differentiating between cancerous and non-cancerous tissue, which may mitigate the challenge of interpreting overlapping breast images.[30,31] Several studies, including two meta-analyses, found improved cancer detection rates for 3D mammograms compared to standard mammograms across international and U.S. studies included in the respective analyses.[30,32,33] One of these studies found that 3D mammograms may be more effective than standard mammograms in detecting invasive cancer cells without increased detection in precancerous/abnormal cells.[31] This may be an important factor for concerns of overdiagnosis, where 3D mammograms may offer improved detection for cancers most likely to impact morbidity and mortality without contributing to overdiagnosis or potentially unnecessary invasive follow-up testing. However, the long-term outcomes for screening with 3D mammograms compared to standard mammograms have not been fully evaluated.

In addition to improved cancer detection rates, some studies found lower rates of false positives for screenings with 3D mammograms compared to standard mammograms.[31,34] From a review of retrospective studies, one study found that the false positive rate of 3D mammograms were between 1.6-3.6% compared to the false positive rate of standard mammograms, which ranged from 8.7-16.2%.[33] Women who were screened with 3D mammograms and called back for subsequent screening were more likely to have a diagnosis of breast cancer than those who were called back following standard mammograms. Overall, 3D mammograms may be associated with lower recall rates compared to standard screening, referring to call backs for additional screening when testing indicates abnormal findings.[30,32,35,36] However, one study evaluating the results across several screening sites found that 3D mammograms were associated with higher rates of biopsy compared to standard mammograms.[35] This finding may be related to the higher-risk factors associated with those who received 3D mammograms compared to standard mammograms.

3D Mammograms and Dense Breast Tissue. Given considerable variation in breast density classification, evolution in radiographic guidance, and study populations, there is significant variation in current literature on the comparative effectiveness of 3D mammograms for women with dense breast tissue. Several studies have found comparative benefits for the use of 3D mammograms compared to standard mammograms for women with dense breast tissue, such as improved cancer detection rates,[31,33] reduced false positives,[33] and reduced risk of advanced cancer.[37] For some studies, this has varied by rating of breast density (e.g. "extremely dense", "scattered breast density").[38]

Some studies found limited differences between the comparative advantage of 3D mammograms in women with dense breast tissue.[31,39] One study found that for women with non-dense breasts, 3D mammograms may be more beneficial than standard mammograms for early-stage cancer detection, reduced screening failures for interval and advanced cancer, reduced false positives, and unnecessary biopsy recommendations.[31] However, this same study found that these findings did not extend to women with dense breast tissue.

Public Health Impact

High-Risk Factors and Breast Cancer Outcomes. The mandate's medical necessity criteria for 3D mammograms align with high-risk factors that are associated with a higher lifetime risk of developing breast cancer, developing more aggressive cancer types, and poorer prognosis. For example, individuals with BRCA1 and BRCA2, two inherited genetic mutations carried by 0.2%–0.3% of the general population and indicated in the medical necessity criteria of the mandate, are on average four times as likely to develop breast cancer by age 70 compared to those without these inherited biomarkers.[40, 41]

Breast density, another medical necessity criteria indicated by the mandate, may be associated with a two- to six-fold risk of breast cancer compared to non-dense breast tissue.[31,38] One study found a lower breast cancer risk associated with increased breast density compared to older studies, which the authors hypothesize may be related to increased use of 3D mammograms and/or changes in breast density ratings.[38] No additional studies evaluated the long term impact of 3D mammograms for individuals with high risk factors other than dense breast tissue.

Population estimates for 2022 indicate that there are 1.27 million women between the ages of 40-79 in the state of Minnesota, who would broadly fall under the recommended average risk age category for annual breast cancer screenings (standard or 3D mammograms) in the current clinical practice guidelines.[42] As previously mentioned, some clinical practice guidelines indicate that women at high-risk of breast cancer may begin screening as early as age 30, and there are approximately 381,000 women between the ages of 30-39 in the state of Minnesota. It is unknown what percentage of this population has one or more of the high-risk factors indicated by the mandate's medical necessity criteria or would be prescribed a 3D mammogram versus a standard mammogram. The mandate does not specify an age-criteria for 3D mammograms, but women within the age ranges specified by the clinical practice guidelines would be most impacted by coverage for 3D mammograms.

Health Equity Considerations. Disparities exist in breast cancer screening uptake, as well as cancer risk and outcomes for underserved populations.[43,44,45] Specific to 3D mammograms, one study found that, during the early stages of the technology's adoption (around 2005), 3D mammograms were prescribed at a lower rate to black women versus white women, although the gap in prescription rates reduced in subsequent years.[46] This study found that reimbursement rates and coverage of 3D mammograms may have been a primary driver for these disparities, as well as technological availability across facilities. Black women may be at higher risk for developing breast cancer and, on average, experience more late-stage diagnoses and poor health outcomes compared to their white counterparts.[47]

Black individuals are also less likely than their White counterparts to be prescribed or engage in genetic testing, which identifies the BRCA1 and BRCA2 mutations that are linked to more aggressive cancers and are among the criteria for use of 3D mammograms. Black women have a higher incidence of breast cancer prior to the age of 50, as well as aggressive triple-negative breast cancer.[48] Hispanic women also present with more aggressive cancer subtypes at earlier ages. Both Black and Hispanic women are less likely to receive 3D mammograms than their White counterparts.[49]

Coverage that reduces disparities in screenings may improve rates of early detection and reduce delays in treatment for underserved populations.[48] A qualitative study found that fear of cost, both associated with mammograms and for follow-up testing for abnormal findings, is the most commonly perceived barrier to mammogram screening.[50] With multifactorial elements that account for breast cancer risk, breast cancer outcomes, and disparities, coverage for advanced mammogram technology may play some role in mediating disparities. However, no study has evaluated the impact of coverage for 3D mammogram screenings on disparities in health outcomes related to breast cancer screening.

Cost of Care and Utilization

Objective. This analysis assesses trends in the utilization and cost of mammographic screening in Minnesota over the last 5 years, covering periods pre- and post- mandate enactment, to better understand how the mandate adoption may have affected mammography usage and costs to issuers and consumers.

Methodology. To evaluate the mandate's coverage requirement for breast cancer screenings using 3D mammograms, MDH provided data on the cost for 3D mammograms and alternative screening procedures along with utilization rates. This data was obtained from the Minnesota All Payer Claims Database (MN APCD) from 2018-2022, for 3D mammograms, standard mammograms, and MRI procedures, which are all used for screening patients at high-risk of breast cancer.[24] MDH estimates that the MN APCD includes 40% of the total commercial health insurance market in Minnesota.

The MN APCD data used in this report represent claims paid by insurance companies for members in fully insured commercial health insurance plans (employer-based and individual market plans) and do not include most self-insured plans or any public health insurance programs (See Table 2).

Table 2. Number of Commercial Members Included in MN APCD between 2018 and 2022

Year	Number of Members
2018	1,294,587
2019	1,215,876
2020	1,207,259
2021	1,148,493
2022	1,121,860

Claims were included for members of all ages and any gender who received one of the following Current Procedural Terminology (CPT) procedure codes:

- 77063 - Screening digital breast tomosynthesis, both breasts
- 77067 - Screening mammography, including computer-aided detection; bilateral
- 77047 - Breast MRI (w/o contrast material; bilateral)

The CPT code 77063 for 3D mammograms is coded as an add-on procedure to standard mammogram (77067), therefore CPT code 77063 occurring on the same day as 77067 are considered a screening 3D mammogram rather than a diagnostic 3D mammogram. Data were also tabulated for CPT codes that were co-occurring with International Classification of Diseases (ICD-10) codes indicating medical necessity for breast cancer screening, including Z-diagnosis codes which indicate a screening encounter. Z-diagnosis codes for a screening encounter were missing from 1% of the 3D mammogram procedures included in the claims analysis, which may reflect either an error in omitting the code or that this data captured some diagnostic 3D mammogram claims. For a complete list of codes used in this analysis, see Appendix C. Less than 1% of claims for 3D mammograms included a co-occurring medical necessity code, such as family or personal history of cancer, which is likely associated with coding practices. As such, an analysis of co-occurring high-risk criteria was not feasible with the available data.

A trend analysis was conducted to identify changes in utilization and cost in the periods before and after the mandate became effective. Due to the limited number of claims for Breast MRI for preventive breast cancer screenings, this analysis focused on a comparison of utilization and cost for screening 3D mammograms and standard mammograms pre- and post-mandate.

Utilization. The overall percentage of members receiving breast cancer screening of any type (3D or standard mammogram) has remained stable at 11-12% across all years of analysis, with the exception of 2020 when the number dropped to 10% during the COVID-19 pandemic. The rate of breast cancer screenings returned to 2019 percentages by 2022 (see Figure 1). Excepting the 2020 data period, the percentage of members receiving mammogram screenings of either 3D mammograms or standard mammograms has not changed in pre- or post-enactment periods.

Figure 1. Percentage of Members Screened with 3D or Standard Mammogram

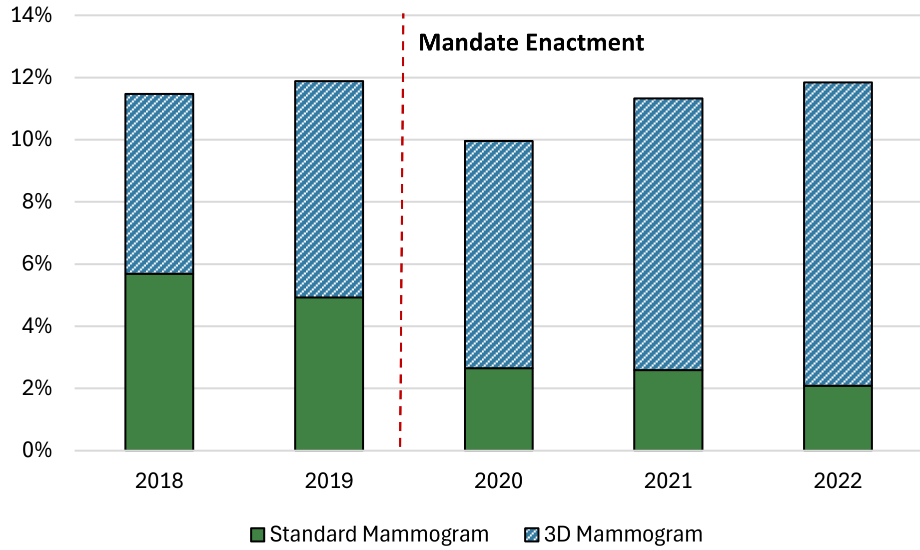


Table 3 shows the total number of screenings, including both 3D mammograms and standard mammograms, associated with the percentages shown in Figure 1. The relative consistency in the total percentages in Figure 1, despite a drop in screenings between 2018 and 2022, corresponds to the drop in the number of commercial enrollees associated with claims in the MN APCD (see Table 2).

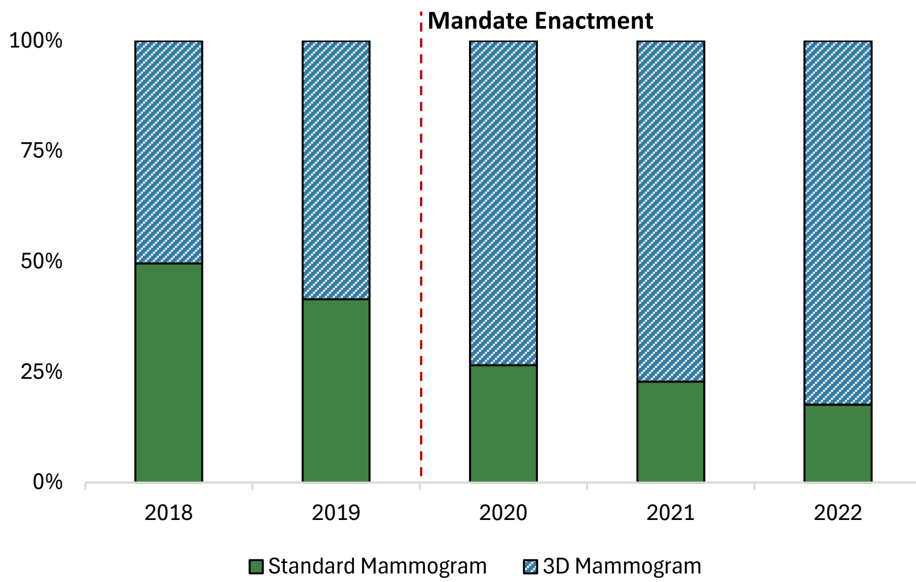
Table 3. Total Number of Annual Screenings for 3D and Standard Mammograms

Year	Number of Screenings
2018	148,658
2019	144,607
2020	120,362
2021	130,226
2022	132,903

Between the years of 2018 and 2022, 3D mammograms accounted for more breast cancer screenings than standard mammograms. While there was not an increase in the overall percentage of members receiving breast cancer screenings between 2018 and 2022, as seen in Figure 1, the proportion of members receiving 3D mammograms compared to standard mammograms increased across the period of analysis. As shown in Figure 2, in 2018 there was an approximately 50%-50% split in usage of 3D mammograms and standard mammograms, but by 2022 approximately 82% of breast cancer screenings were 3D mammograms compared to standard mammograms. When considering year over year changes, the data indicates a 47% decrease in standard mammograms after the mandate was enacted between 2019 and 2020, and a further 21% decrease in standard mammogram procedures between 2021 and 2022. While the data show a small increase in use of 3D mammograms compared to standard mammograms prior to the mandate, the rate has its largest shift from 2019 to 2020 following the mandate's enactment. The degree to which this trend relates to updates in the clinical practice guidelines, broader adoption of 3D mammograms in provider practice patterns, and the mandate becoming effective, is unknown.

These findings are echoed in the literature, which indicates an increasing shift in the use of 3D mammograms for breast cancer screenings.[33,51] Whether or not this shift is associated with changing standards of care which better identify high-risk individuals, such as an increased use of genetic testing, or other states' enactment of similar mandates, is unknown.

Figure 2. 3D and Standard Mammogram Utilization Percentages



Economic Impact

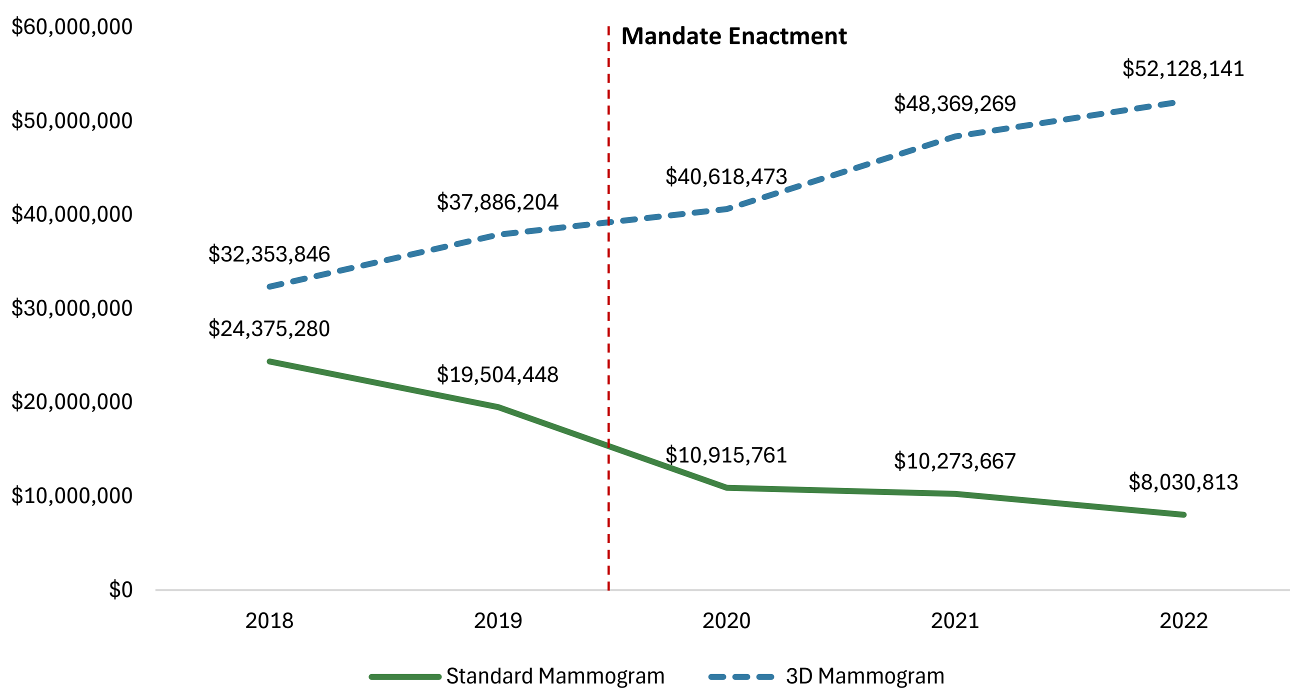
Total Costs. In 2018, the total amount spent on breast cancer screenings for 3D mammograms and standard mammograms was $56.7 million, which increased to $60.1 million by 2022. This represents a 6.0% increase over this period. Total issuer cost for both 3D mammograms and standard mammograms was $55.7 million in 2018, increasing to $59.8 million in 2022, which represents an increase of 7.4%. Total cost sharing for enrollees for both 3D mammograms and standard mammograms was approximately $978,000 in 2018, rising to $1.2 million in 2021, before decreasing to $354,000 in 2022. Subdivision 5 of Minn. Stat. § 62A.30, which became effective in 2022 and prohibits cost-sharing for follow-up testing from breast cancer screening, may account for the reduction in enrollee cost-sharing between 2021 and 2022.

- **Comparative Procedure Costs and Cost Growth.** The literature scan and cost analysis are consistent in demonstrating that the cost for screening with 3D mammograms exceeds the cost of standard mammograms on a per-procedure basis. The MN APCD claims analysis found that the costs per procedure for 3D mammograms increased from $431 in 2018 to $476 in 2022, a net increase of 10.4%. The cost per procedure for standard mammograms increased from $330 to $342, with a net increase of

3.6% during this same time period. One study found that, nationally, the cost per 3D mammograms compared to standard mammograms has risen from $280.7 in 2015 to $315.6 in 2019, and attributed the cost increase with broader adoption of 3D mammograms compared to standard mammograms.[51] Another study found that while 3D mammograms are more expensive than standard mammograms, the cost for 3D mammograms on a year-to-year basis has remained level, or decreased, in states with mandates for 3D mammogram coverage. [5] As found in the analysis for Minnesota commercial claims between 2018-2022, the annual rate of growth between each year of commercial claims data for the 3D mammogram procedure was 3.7%, 2.6%, 4.7%, and -1%. The aforementioned study hypothesized that in states that mandate coverage of 3D mammograms, broader adoption of the technology across facilities allowed for improved negotiation for issuers for 3D mammogram reimbursements.[5]

Cost Drivers. Total costs for breast cancer screenings have shifted primarily due to the increased utilization of 3D mammograms compared to standard mammograms for breast cancer screenings. As seen in Figure 3, when utilization rates for 3D mammograms and standard mammograms were roughly equivalent in 2018, the difference in total costs for 3D mammograms compared to standard mammograms were $7.9 million. By 2022, when 3D mammograms accounted for 82% of procedures, the difference in total costs for 3D mammograms compared to standard mammograms were $44.1 million.

Figure 3. Total Costs for 3D Mammograms and Standard Mammograms in Minnesota



As the analysis indicates, change in utilization and member cost-sharing were the most significant drivers for increased costs to issuers for 3D mammograms. The member per-procedure cost sharing of standard mammograms and 3D mammograms were $2.77 and $10.62, respectively. In 2021, the average member-paid standard mammogram cost sharing decreased to $2.47 and the 3D mammogram cost sharing increased to

$11.58. In 2022 the average member-paid 3D mammogram cost dropped significantly to $2.69, just slightly higher than the standard mammogram cost of $2.54 per procedure.

Cost-Effectiveness. There were limited data available to conduct a reliable cost-effectiveness analysis for this mandate. This type of analysis would require linking longitudinal medical record and claims data to assess the impact of different types of breast cancer screenings on treatment and outcomes.

To assess the cost-effectiveness considerations of the mandate, we conducted a focused literature scan on this topic. Current literature is mixed on whether 3D mammograms are cost-effective, with variation in study results based on the extent to which downstream costs (e.g., need for subsequent testing, cost of treatment) were included for analysis. Some economic analyses have found that 3D mammograms are cost-effective due to the procedure's ability to detect cancer earlier than other modalities, resulting in improved health outcomes and reduced health expenditures, and that 3D mammograms may be most cost-effective among women between the ages of 40-49.[52] 3D mammograms may also be cost-effective due to their ability to reduce false-positives, compared to standard mammograms, and more accurately identifying cases where follow-up testing is warranted.[31,33]

One study using national data reported that 3D mammograms are not a cost-effective screening tool.[5] This was primarily driven by the imbalance between only "marginal" reductions in health expenditures for individuals prescribed 3D mammograms, compounded by the more substantial cost of 3D mammograms compared to standard mammograms.

No studies evaluated the use of 3D mammograms as the primary screening method for individuals with high-risk factors, as indicated by the medical necessity requirement of the mandate and the clinical practice guidelines. The cost-effectiveness of 3D mammograms may relate to individual risk factors (e.g., age, high-risk factors) among those who receive 3D mammograms.

Evaluation Limitations

Data Limitations. With the available MN APCD data and limited years since the mandate was enacted, a more comprehensive analysis assessing the specific impacts of this mandate on cost, utilization, and clinical outcomes was not feasible. As comorbidities and high-risk factors are inconsistently documented in breast cancer screening claims, our analysis was unable to capture the variations in follow-up testing, diagnoses, co-occurring high-risk criteria, comorbidities, or long-term outcomes between those receiving 3D mammograms versus standard mammograms. Most available data for 3D mammograms predates the mandate's enactment, which limits the evaluation in assessing the longer-term impact of the mandate.[b]

The timeframe for analysis also coincides with the height of the COVID-19 pandemic, a period that had significant changes in healthcare utilization patterns. As a result, the analysis is unable to control for important

[b] Data prior to 2018 is limited by the addition of the 3D mammogram code in 2017.

factors that may have altered utilization of 3D mammograms and breast cancer outcomes that are not specific to the impact of the mandate. Other factors, such as changing standards of care and provider adoption of 3D mammograms during the period of analysis, may have also altered utilization of 3D mammograms and breast cancer outcomes. It is suspected that the significant drop in screenings, diagnosis, and treatment during the COVID-19 pandemic are likely to impact cancer outcomes longitudinally, particularly for underserved groups most significantly impacted during this time and with the highest rates of breast cancer risk.[49]

Literature Review Limitations. The current literature varies in its findings related to the comparative effectiveness, public health impact, cost, and potential cost-effectiveness of 3D mammograms, with results that vary by study design (e.g., how a study defines harms, analytical methodology, populations studied). Most studies were limited due to critical confounding variables (e.g., multiple high-risk factors in study populations), as well as the limited study timeframes for longitudinal assessment of the impact of 3D mammograms on health outcomes. Some studies acknowledged methodological challenges to weigh cost, benefit, and harm for 3D mammograms, particularly with advancements in systemic treatments for breast cancer that have occurred simultaneously to technological advancements in screening.[22,53]

Summary and Future Considerations

This evaluation found that while the literature on 3D mammograms varies by study design and some of the associated findings, many studies found that 3D mammograms may be more effective than standard mammograms based on the reduced false positive rates and increased detection of advanced cancers compared with standard mammograms. Economically, this may result in downstream savings from reducing unnecessary follow-up diagnostic testing and improved breast cancer outcomes with early detection.

No study to date has assessed whether these savings outweigh the increased cost and utilization of 3D mammograms compared to standard mammograms for breast cancer screening. In Minnesota, 3D mammograms have increased as a proportion of all screening mammograms since the enactment of Minn. Stat. § 62A.30, Subd. 4. Given the data limitations and recency of the mandate, it cannot yet be determined whether this has impacted rates of early detection of breast cancer or any corresponding treatment implications.

While some components of this analysis were limited by the aforementioned challenges, future research may expand on the clinical effectiveness of 3D mammograms when used for screening and the longitudinal impacts on public health and health care costs. Evolution in breast cancer prevention and screening, such as broader adoption and implementation of genetic testing and efforts to increase annual breast cancer screenings, and longitudinal studies examining the comparative effectiveness of 3D mammograms for breast cancer screenings, may provide further insight into the impact of coverage of 3D mammograms.

Appendix A. Bill Text

Minn. Stat. § 62A.30, Subd. 4. Mammograms.

(a) For purposes of subdivision 2, coverage for a preventive mammogram screening (1) includes digital breast tomosynthesis for enrollees at risk for breast cancer, and (2) is covered as a preventive item or service, as described under section 62Q.46.

(b) For purposes of this subdivision, "digital breast tomosynthesis" means a radiologic procedure that involves the acquisition of projection images over the stationary breast to produce cross-sectional digital three-dimensional images of the breast. "At risk for breast cancer" means:

(1) having a family history with one or more first- or second-degree relatives with breast cancer;

(2) testing positive for BRCA1 or BRCA2 mutations;

(3) having heterogeneously dense breasts or extremely dense breasts based on the Breast Imaging Reporting and Data System established by the American College of Radiology; or

(4) having a previous diagnosis of breast cancer.

(c) This subdivision does not apply to coverage provided through a public health care program under chapter 256B or 256L.

(d) Nothing in this subdivision limits the coverage of digital breast tomosynthesis in a policy, plan, certificate, or contract referred to in subdivision 1 that is in effect prior to January 1, 2020.

(e) Nothing in this subdivision prohibits a policy, plan, certificate, or contract referred to in subdivision 1 from covering digital breast tomosynthesis for an enrollee who is not at risk for breast cancer.

Appendix B. Key Terms

3D Mammogram

Breast Cancer

Breast Neoplasm

Cost-Effective

Comparative Effectiveness

Dense Breast

Diagnostic Errors

Digital Breast Tomosynthesis

Digital Mammogram

Early Detection of Cancer

Early Diagnosis

False Negative

False Positive

Follow-up Testing

Guidelines

High-Risk

Mammogram

Mass Screening

Overdiagnosis

Overtreatment

Predictive Value of Tests

Preventive

Sensitivity

Specificity

Appendix C. Associated Codes

International Classification of Diseases (ICD-10) Code(s) Z codes:

Name	Code
Encounter for screening mammogram for malignant neoplasm of breast	Z12.31

International Classification of Diseases (ICD-10) Code(s) for High-Risk Factors:

Name	Code
Neoplasm of unspecified behavior of breast	D49.3
Inconclusive mammogram	R92.2
Genetic susceptibility – malignant neoplasm breast	Z15.01
Family history – malignant neoplasm breast	Z80.3
Personal history – malignant neoplasm breast	Z85.3

Current Procedural Terminology (CPT®) codes:

Name	Code
Screening digital breast tomosynthesis, both breasts	77063
Screening mammography, including computer-aided detection; bilateral	77067
Breast MRI (w/o contrast material; bilateral)	77047

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