

Evaluation of HF447-1E and HF2414

Report to the Minnesota Legislature pursuant to Minn. Stat. §62J.26

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Executive Summary

House Files 447-1E and 2414 require health plans to provide additional coverage for diagnostic services recommended following breast cancer screenings. Commerce has determined that neither would be considered a new state mandated benefit under the Affordable Care Act (ACA) requiring defrayal of costs, as the bills clarify existing benefits under health plans by requiring them to be covered at a zero-cost preventive level. Each bill would carry a cost to the state, however, based on MMB estimates of fiscal impact to SEGIP.

Introduction and Policy Context

Pursuant to Minn. Stat. § 62J.26, subd. 3, the Minnesota Department of Commerce (Commerce) has been requested to perform an evaluation of HF447-1E and HF2414. The purpose of the evaluation is to provide the legislature with a detailed analysis of the potential impacts of any mandated health benefit proposal. Because the two bills are similar in subject matter, Commerce has combined its analysis of both bills into a single report.

House Files 447-1E and 2414 were first introduced during the 2021-2022 legislative session and meet the definition of a mandated health benefit proposal under Minn. Stat. §62J.26, which indicates the following criteria regarding the definition of a mandated health benefit proposal:

A mandated health benefit proposal or "proposal" means a proposal that would statutorily require a health plan company to do the following:

- (i) provide coverage or increase the amount of coverage for the treatment of a particular disease, condition, or other health care need;
- (ii) provide coverage or increase the amount of coverage of a particular type of health care treatment or service or of equipment, supplies, or drugs used in connection with a health care treatment or service;
- (iii) provide coverage for care delivered by a specific type of provider;
- (iv) require a particular benefit design or impose conditions on cost-sharing for:
 - (A) the treatment of a particular disease, condition, or other health care need;
 - (B) a particular type of health care treatment or service; or
 - (C) the provision of medical equipment, supplies, or a prescription drug used in connection with treating a particular disease, condition, or other health care need; or
- (v) impose limits or conditions on a contract between a health plan company and a health care provider.

"Mandated health benefit proposal" does not include health benefit proposals amending the scope of practice of a licensed health care professional.

Commerce is required to consult with the Departments of Health (MDH) and Management and Budget (MMB). Per statute, evaluations must focus on the following areas:

- Scientific and medical information regarding the proposal, including potential for benefit and harm
- Overall public health and economic impact
- Background on the extent to which services/items in the proposal are utilized by the population
- Information on the extent to which service/items in the proposal are already covered by health plans, and to which health plans the proposal would impact
- Cost considerations regarding the potential of the proposal to increase cost of care, as well as its potential to increase enrollee premiums in impacted health plans
- The cost to the State if the proposal is determined to be a mandated benefit under the Affordable Care Act (ACA)

Bill Requirements and Impact

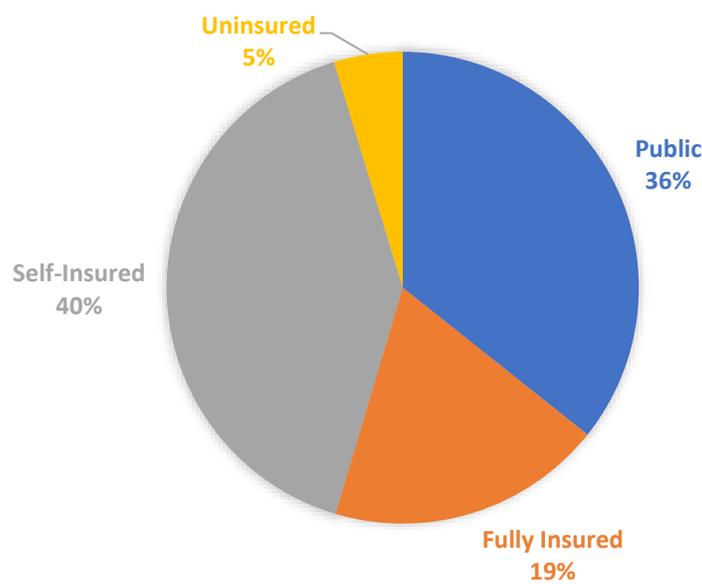
House File 447-1E and HF2414 would both require regulated health plans in Minnesota to provide additional coverage for breast cancer screening follow-up services. Specifically, HF447-1E requires health plans to provide coverage for all post-screening mammography diagnostic services recommended by a physician at zero cost to the enrollee. The bill does not list any specific services that are required to be covered. House File 2414 includes coverage requirements for testing, more advanced imaging, and biopsies recommended following a screening.

House Files 447-1E and 2414 have very similar requirements in that both bills require full coverage (zero cost-sharing to enrollees) for routine breast cancer screenings. The primary difference between the bills is based on what services following a breast cancer screening should be covered. House File 2414 specifically identifies genetic testing, breast examination, mammography, MRIs, digital breast tomosynthesis, ultrasound, thermography, biopsies, and any other diagnostic/preventive services identified by the federal Food and Drug Research Administration as needing to be covered with zero cost-sharing to the enrollee. Additionally, HF2414 prohibits health plans from imposing age or annual or lifetime testing limitations on these procedures. The full text of each bill is available in the Appendix of this document.

House File 447-1E indicates that additional physician-recommended diagnostic services following a mammogram must be covered. The bill does not specify any specific diagnostic services, but it is reasonable to assume that all services identified under HF2414 would be included as part of the requirement for coverage.

Requirements under both bills would apply to all fully insured health plans regulated in Minnesota, as well as the State Employee Group Insurance Program (SEGIP). Requirements in each bill would not apply to self-insured employer plans, grandfathered plans, or public plans such as medical assistance and MinnesotaCare, and Medicare and Medicare supplemental policies. Figure 1 shows a breakdown of health insurance coverage in Minnesota by type (including uninsured).

Figure 1. Minnesota Insurance Coverage 2019



Source: Minnesota Department of Health. Chartbook Section 2. Trends and Variations in Health Insurance Coverage. Accessed at <https://www.health.state.mn.us/data/economics/chartbook/docs/section2.pdf>.

Regulatory authority over the fully insured market is shared with the Department of Health (MDH) which regulates health maintenance organizations (HMOs) in the state.

State and Federal Law

This evaluation considers the interaction between state and federal law—specifically as it pertains to the potential for the bill to be considered a state benefit mandate understood under Section 1311(d)(3) of the ACA ([45 CFR § 155.170](#)), which indicates that new mandates related to specific care, treatment, or services not offered under the general essential health benefits (EHB) package in the state prior to January 1, 2012 must have associated costs defrayed by the state. The state is only required to defray associated costs that would not have been provided by the health carrier without the requirements of the new mandate. ¹ Per the EHB final rule², costs associated with benefit mandates passed prior to or on December 31, 2011 do not need to be defrayed by the state.

Evaluation of Mandated Health Benefit Proposal

The Department's evaluation of HF447-1E and HF2414 included the following elements in order to meet criteria under Minn. Stat. §62J.26:

- Solicitation of feedback from potential stakeholders by publishing a request for information notice in the State Register

¹ 45 CFR Parts 147, 155, and 156 Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule. Accessed at <https://www.govinfo.gov/content/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

² 45 CFR Parts 147, 155, and 156 Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule. Accessed at <https://www.govinfo.gov/content/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

- Scoping review of available literature in PubMed
- Hybrid umbrella/systematic literature review of available resources
- Consultation with the Department of Health and MMB
- Solicitation of comments from health plans, including request for actuarial analysis
- Internal actuarial analysis

Additional information regarding the Department’s literature review may be found in the Appendix.

In the Department’s evaluation, the coverage requirements under HF447-1E and HF2414 do not constitute benefit mandates requiring state defrayal of costs. All of the explicitly indicated coverage requirements under HF2414 have been, and currently are, covered under the state’s benchmark plan. Under HF447-1E, which does not indicate any specific diagnostic service to be covered following a breast cancer screening, if passed, Commerce assumes that the diagnostic services utilized would generally mirror those listed under HF2414.

Commerce assumes the requirements of both bills to be cost-sharing alterations versus a new benefit mandate. Commerce notes that the requirements of HF447-1E remain open-ended, and that there are cancer screening services that may not be covered by health plans or the state’s benchmark plan. Without any specific requirements in the bill that establish coverage outside the scope of general standards of practice, however, Commerce assumes that post-mammogram diagnostic care includes services that are already covered by the benchmark plan and other regulated health plans.

Commerce’s conclusion regarding the status of HF447-1E and HF2414 as new state mandated benefits under the ACA is consistent with previous analyses. Senate File 1038, which has required health plans to provide coverage for 3-D mammography services the same as other screening and preventive services, was determined not be a state mandated benefit under the ACA. The rationale for SF1038 not constituting a benefit mandate was based on the bill clarifying an existing benefit that was covered for policyholders and an alteration of cost-sharing for enrollees rather than mandating an entirely new benefit that were not previously covered.

Scientific and Medical Analysis

Scientific and Medical Background

Under Minn. Stat. §62J.26 Commerce must provide scientific and medical analysis of each proposed health benefit mandate. Specifically, evaluations must include scientific and medical information on the mandated health benefit proposal, as well as the potential for harm or benefit to the patient. The latter requires an analysis of the comparative benefit or harm from alternative forms of treatment, including the results of at least one professionally accepted and controlled trial comparing the medical consequences of the proposed therapy, alternative therapy, and no therapy.

Breast cancer is the most common cancer among women, making up 1 in 10 new cancer diagnoses each year. Early detection of breast cancer is crucial to improved survival rate. The incidence of breast cancer is 125 in 100,000 for females and 1 in 100,000 for males.

The United States Preventive Services Task Force (USPSTF) has identified that breast cancer screening is most advantageous or has the most evidence of success for women aged 50-74. Evidence to support screening at earlier ages or greater frequency is insufficient.³

A review of evidence indicates that incidence of breast cancer for both females and males rises with age, and that risk factors are also similar for both, despite the difference in overall incidence. Genetics play a large part in breast cancer risk factors for both females and males. Specifically, inherited mutations to the BRCA1/2 genes (which typically help fight cancer) are indicators of breast cancer risk.⁴

Screening is performed through digital exam, x-ray, ultrasound, magnetic resonance imaging (MRI) and sometimes digital breast tomosynthesis (3-D mammography). Follow-ups to these screenings generally include biopsy of tissue or hematological profiling (looking for cancer markers or any other evidence of breast cancer in blood or tissue).

Potential for Harm or Benefit

Overall, the potential for harm resulting from the passage of HF447-1E and HF2414 is low. Both bills require coverage for services that would generally otherwise be subject to enrollee cost-sharing. By eliminating that barrier, patients may be able to obtain additional services and receive earlier diagnoses for cancer. The potential for benefit is therefore assessed as moderate. It is important to note that higher utilization of screenings and subsequently post-screening follow-up services can result in higher false positive rates.

Public Health, Economic, and Fiscal Impact

For the purposes of this and subsequent sections, the following definitions apply:

Public Health: The science and practice of protecting and improving the health and wellbeing of people and their communities. The field of public health includes many disciplines, including medicine, public policy, biology, sociology, psychology and behavioral sciences, and economics and business.

Economic Impact: The general financial impact of a drug, service, or item on the population prescribing or utilizing a particular drug, service or item for a particular health condition.

Fiscal Impact: The quantifiable dollar amount associated with the implementation of the mandated health benefit proposal. The areas of potential fiscal impact that the Department reviews for are the cost of defrayal of benefit mandates as understood under the ACA, the cost to SEGIP, and the cost to other state public programs. The fiscal impact is expressed in number of dollars required for the state to implement a proposal.

The impact of HF447-1E and HF2414 on public health generally, as well as its overall economic and fiscal impact, are contingent on understanding the utilization of breast cancer screening generally and understanding the number of false positives and average utilization of follow-up diagnostics.

³ While screening mammography in women aged 40 to 49 years may reduce the risk for breast cancer death, the number of deaths averted is smaller than that in older women and the number of false-positive results and unnecessary biopsies is larger. The balance of benefits and harms is likely to improve as women move from their early to late 40s.
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening>

⁴ Gradishar, WJ, Ruddy, Kathryn. Breast cancer in men. In: UpToDate. 2022.

Public Health

The public health impact for both bills can be generally seen as a net positive, overall. Follow-up care for breast cancer screening is generally not covered at the preventive level by health plans and can be a barrier to care for individuals requiring such follow-up.⁵ The net positive is mirrored by patient advocates responding to the Commerce's RFI. Increasing follow-up services, while important, also comes with the risk of increasing numbers of false positives for breast cancer.⁶

Economic Impact

Both bills are similar in requiring health plan coverage for follow-up services for routine cancer screenings and requiring them to be covered at the preventive level (meaning zero cost-sharing for enrollees). Diagnostic and testing services following a screening mammogram are not considered to be a preventive service as understood under 45 CFR § 147.130 and the ACA.

It is unlikely that there would be an expected increase in total cost of services based on the passage of either HF447-1E or HF2414. Because both bills expand the definition of a preventive service, and therefore expand the level of reimbursement for screening and diagnostic services for breast cancer, Commerce assumes that there could potentially be an increase in use of screening techniques that are more expensive.

Follow-up diagnostic services are specifically identified in HF2414 whereas HF447-1E indicates that services ordered by an attending physician to be covered without regard to what those services will be. Consequently, the economic impact on price of services of HF447-1E, as well as the potential increase in enrollee premiums, is difficult to determine. Without any specific indication of what certain follow-up screening services might entail, Commerce concludes that the full range should be considered.

Fiscal

Services required to be covered under HF2414 are understood to be already covered by health plans operating in the state albeit at a non-preventive level of reimbursement. Commerce assumes that post-screening mammography diagnostic services under HF447-1E would be for the most part similar, with the possibility that there may be additional services eligible for coverage not explicitly identified under HF2414. The requirements under HF447-1E and HF2414 do not mandate coverage of previously uncovered diagnostic and screening services; rather, the requirements alter the cost-sharing of these services only. Commerce does not interpret cost-sharing alterations for already covered services to be considered a new state benefit mandate under the ACA. Thus, because HF447-1E and HF2414 are not benefit mandates under the ACA, they would not require defrayal of cost by the state if enacted. The bill does not apply to public programs.

According to MMB, both bills would carry a cost to SEGIP based on the extension of zero cost-sharing to services traditionally subject to enrollee cost-sharing. For HF447-1E, MMB estimated a possible increase of \$0.17 per member per month (PMPM) in premiums in SEGIP impact. For HF2414, MMB estimated a possible increase of \$0.04 PMPM. Total projected state fiscal impact over the next several years are listed below for each bill:

⁵ Baicker K, Congdon WJ, Mullainathan S. Health insurance coverage and take-up: Lessons from behavioral economics. *Milbank Quarterly*. 2012;90(1):107–134. doi: 10.1111/j.1468-0009.2011.00656.x.

⁶ Marmot MG, Altman DG, Cameron DA, Dewar JA, Thompson SG, Wilcox M. The benefits and harms of breast cancer screening: an independent review. *Br J Cancer*. 2013;108:2205-40.

Table 1 – Projected Fiscal Impact of HF447-1E

Fiscal Year	2022	2023	2024	2025
State Fiscal Impact (SEGIP) ⁷	\$115,581	\$242,721	\$254,857	\$267,600

Table 2 – Projected Fiscal Impact of HF2414

Fiscal Year	2022	2023	2024	2025
State Fiscal Impact (SEGIP) ⁸	\$0	\$27,196	\$57,111	\$59,966

Current Utilization

MDH estimated utilization of services and paid prices in 2019 based on available data from the Minnesota All Payer Claims Database (MN APCD). Data from 2019 from the APCD indicated 143,874 (out of 1,487,165; or 10%) Minnesotans covered by commercial insurance plans that report data to the MN APCD had both an ICD-10 diagnosis code and a CPT procedure code for a screening mammogram. In narrowing focus to the individual or small group market, 42,952 (out of 431,140; or 10%) Minnesotans covered by commercial insurance plans that report data to the MN APCD had both an ICD-10 diagnosis code and a CPT procedure code for a screening mammogram. Note that these estimates are based on all enrollees and are not limited to a specific gender or age group.

⁷ Figures in this table represent the cost to the state from SEGIP impact. The total cost impact to the SEGIP plan—specifically, adding in the employee share of the overall premium—will be higher.

⁸ See above footnote

Table 3 - Claims and Paid Amounts for Breast Cancer Screening and Follow-Up Services among Commercially Insured Minnesotans, 2019, Among 143,874 Minnesotans with an ICD-10 Code and a CPT Code for a Screening Mammogram

Type of Service	Codes	Total Claims	Total Patient Paid	Total Plan Paid	Total Paid (plan + patient)	Patient Paid per Unit	Plan Paid per Unit	Total Paid (plan + patient) per Unit
Screening mammography	77067	145,287	\$311,330.93	\$45,479,931.28	\$45,791,262.21	\$2.14	\$313.04	\$315.18
Diagnostic mammography, including computer-aided detection (CAD), unilateral	77065	10,508	\$1,218,279.53	\$2,109,236.89	\$3,327,516.42	\$115.94	\$200.73	\$316.67
Diagnostic mammography, including computer-aided detection (CAD), bilateral	77066	935	\$117,767.24	\$232,685.48	\$350,452.72	\$125.95	\$248.86	\$374.82
Breast MRI (w/o contrast material; bilateral)	77047	87	\$19,112.98	\$52,196.66	\$71,309.64	\$219.69	\$599.96	\$819.65
Digital breast tomosynthesis	77063	83,979	\$300,286.89	\$10,467,812.30	\$10,768,099.19	\$3.58	\$124.65	\$128.22

BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis	81162	536	\$32,967.60	\$572,665.24	\$605,632.84	\$61.51	\$1,068.41	\$1,129.91
Breast Biopsy (first lesion, including ultrasound guidance)	19083	1,433	\$1,143,553.62	\$1,922,549.29	\$3,066,102.91	\$798.01	\$1,341.63	\$2,139.64
Breast Biopsy (each additional lesion, inc. ultrasound guidance)	19084	160	\$37,882.29	\$96,843.94	\$134,726.23	\$236.76	\$605.27	\$842.04
Breast Biopsy (first lesion, including ultrasound magnetic resonance guidance)	19085	99	\$42,737.58	\$271,095.07	\$313,832.65	\$431.69	\$2,738.33	\$3,170.03

Source: Health Economics Program (MDH) analysis of data in the Minnesota All Payer Claims Database (MN APCD). Note that commercial plans covered by ERISA are not required to report data to the MN APCD.

Note: There was insufficient data (< 11 observations) for the following: unilateral breast MRI (CPT code 77046); some genetic testing codes (CPT codes 81163, 81164, 81216, 81432, 81433); temperature gradient studies (CPT code 93740. No claims for CPT codes 81165-81167 [BRCA testing] were found in the analysis for CPT units and costs after limiting the analysis to those with a screening mammogram.

Current Health Insurance Coverage

The coverage requirements in HF2414 specifically identify certain post-mammography diagnostic services, which are generally covered by regulated health plans in Minnesota. Some services identified—specifically genetic testing—may be subject to utilization management or not covered by health plans. The state benchmark plan’s coverage policy for genetic testing for cancer susceptibility identifies a number of genetic tests that will not be covered by their plans (including the state benchmark plan).⁹

Commerce assumes that all specifically identified services in HF2414 would apply to HF447-1E. Given the open-endedness of HF447-1E and the assumption that HF2414 is an appropriate reference point for levels of coverage, Commerce assumes that there would also be a lack of coverage for a number of genetic tests prior to implementation of HF447-1E.

As a consideration, follow-up services are not identified as preventive under Section 223(c)(2)(A) of the Internal Revenue Service (IRS). The lack of identification under the IRS for the services being required to be covered as preventive may have an impact on Minnesotans enrolled in High Deductible Health Plans (HDHP). HDHPs may not provide benefits for any service until the minimum deductible for that year is satisfied, unless for preventive services as understood under the ACA or the IRS. Because the services required to be covered under these bills are not identified here, they would technically not be eligible for preventive coverage immediately.

Coverage of services that are ineligible for full coverage prior to meeting a plan deductible may jeopardize enrollment in the HDHP, which is a prerequisite to enroll in a Health Savings Account (HSA) or Health Reimbursement Arrangement (HRA).

Impact on Insurance Benefits

Requirements under HF447-1E and HF2414 apply to all fully insured health plans, including individual health plans, group health plans, health carriers, health maintenance organizations (HMOs) and health service plan corporations defined under Minn. Stat. §62A.011. House File 447-1E and HF2414 also apply to health plan companies defined under Minn. Stat. §62Q.01.

Requirements under HF447-1E and HF2414 do not apply to self-insured employer plans, Medicaid, MinnesotaCare, Medicare, or Medicare supplemental policies.

Impact on Health Insurance Premiums

In its Request for Information published in November 2021, Commerce requested feedback regarding potential impact on health insurance premiums. Commerce also performed its own analysis with the following assumptions utilizing APCD data provided by MDH.

⁹ https://www.healthpartners.com/public/coverage-criteria/policy.html?contentid=ENTRY_232707

Commerce considered the potential increase in utilization of diagnostic services, the increase in plan cost-sharing, and the potential for a shift in enrollee utilization to higher cost diagnostic services. Commerce estimates a range of \$0.25 to 0.63 PMPM between both HF447-1E and HF2414.

Health insurance carriers responding to Commerce's RFI concurred with the assessment that HF447's broadness precludes the ability to make a more specific assessment of premium increases. Commerce notes that the estimation of premium increases should be the same or similar for each bill, with the understanding that HF447-1E would require coverage of services explicitly identified in HF2414.

Summary of Comments Received

Commerce placed a request for information in the November 22, 2021 publication of the [State Register](#), requesting comments regarding all mandated health benefit proposals, including HF447-1E and HF2414. The Department received feedback from health plans, generally, and from patient advocates.

In summary, comments received from health plans affirmed the Commerce's analysis regarding the overall economic and fiscal impact of the bills.

Comments from patient advocates were supportive of passing legislation that would reduce consumer costs associated with follow-up diagnostic services.

ACA Benefit Mandate Impact and Analysis

The ACA requires states to defray the cost of benefit mandates passed after December 31, 2011. According to the ACA, a benefit mandate is one passed by the state that imposes requirements of health plans to cover new services or items related to specific care or treatment. Under the ACA, a state may enact requirements unrelated to specific care, treatment, or services and not be responsible for defraying the cost, generally falling into the following:

1. *Provider Types*. Mandates that require a covered service to be covered by additional health care provider types.
2. *Cost-Sharing*. Mandates that require or change cost-sharing amounts for covered services, including deductibles, copayments, and coinsurance.
3. *Delivery Methods*. Mandates that require health carriers to cover new methods of delivering covered services (telehealth for example).
4. *Reimbursement Methods*. Mandates that require health carriers to reimburse health care providers for covered services provided in new ways.
5. *Dependent-Coverage*. Mandates that require health carriers to define dependents in a certain way or to cover dependents under specific circumstances.
6. *ACA Conforming Coverage*. Mandates required to comply with ACA requirements.

All explicitly identified screening and diagnostic procedures for breast cancer detection listed in HF2414 are covered under regulated health plans, but at a non-preventive level. The requirements of HF2414 do not add new benefits under the benchmark or any other EHB-compliant plan; rather, the requirements merely alter the cost-sharing of previously covered benefits.

Similarly, the requirements of HF447-1E establish zero-cost sharing for physician recommended diagnostic services following a mammogram. While there are no explicitly indicated services mentioned in the bill, Commerce assumes that follow-up services would mirror those specifically identified in HF2414 based on standards of care.

As both bills primarily alter cost-sharing for already covered services, Commerce concludes that neither bill represents a new state mandated benefit as understood under the ACA.

Appendix

Bill Text – HF447-1E

1.1 A bill for an act

1.2 relating to health insurance; requiring no-cost diagnostic services and testing

1.3 following a mammogram;amending Minnesota Statutes 2020, section 62A.30, by

1.4 adding a subdivision.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. Minnesota Statutes 2020, section 62A.30, is amended by adding a subdivision

1.7 to read:

1.8 Subd. 5.Mammogram; diagnostic services and testing. (a) If a health care provider

1.9 determines an enrollee requires additional diagnostic services or testing after a mammogram,

1.10 a health plan must provide coverage for the additional diagnostic services or testing with

1.11 no cost sharing, including co-pay, deductible, or coinsurance.

1.12 (b) This subdivision does not apply to Medical Assistance under chapter 256B and

1.13 MinnesotaCare under chapter 256L.

1.14 EFFECTIVE DATE. This section is effective January 1, 2022, and applies to health

1.15 plans offered, issued, or sold on or after that date.

Bill Text – HF2414

1.1 A bill for an act

1.2 relating to health insurance; increasing availability and coverage for testing and

1.3 diagnostic services related to breast cancer; amending Minnesota Statutes 2020,

1.4 sections 62A.30, subdivisions 2, 4; 256B.0625, subdivision 14.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. Minnesota Statutes 2020, section 62A.30, subdivision 2, is amended to read:

1.7 Subd. 2. Required coverage. (a) Every policy, plan, certificate, or contract referred to

1.8 in subdivision 1 that provides coverage to a Minnesota resident must provide coverage for

1.9 routine screening procedures for cancer and the office or facility visit, including

1.10 mammograms, surveillance tests for ovarian cancer for women who are at risk for ovarian

1.11 cancer as defined in subdivision 3, pap smears, and colorectal screening tests for men and

1.12 women, when ordered or provided by a physician in accordance with the standard practice

1.13 of medicine.

1.14 (b) Every policy, plan, certificate, or contract referred to in subdivision 1 that provides

1.15 coverage to a Minnesota resident must provide coverage for all diagnostic and preventive

1.16 screenings and tests related to breast cancer, including but not limited to genetic testing,

1.17 breast examination, mammography, magnetic resonance imaging, digital breast

1.18 tomosynthesis, ultrasound, thermography, biopsy, and other breast cancer screening tests

1.19 currently being evaluated by the federal Food and Drug Breast Cancer Research Foundation.

1.20 (c) A health carrier is prohibited from placing age limitations or annual or lifetime testing

1.21 limitations on the screenings and tests described in paragraph (b).

1.22 EFFECTIVE DATE. This section is effective January 1, 2022, and applies to health

1.23 plans offered, issued, or renewed on or after that date.

2.1 Sec. 2. Minnesota Statutes 2020, section 62A.30, subdivision 4, is amended to read:

2.2 Subd. 4. Mammograms. (a) For purposes of subdivision 2, paragraph (a), coverage for

2.3 a preventive mammogram screening (1) includes digital breast tomosynthesis for enrollees

2.4 at risk for breast cancer, and (2) is covered as a preventive item or service, as described

2.5 under section 62Q.46.

2.6 (b) For purposes of this subdivision, "digital breast tomosynthesis" means a radiologic

2.7 procedure that involves the acquisition of projection images over the stationary breast to

2.8 produce cross-sectional digital three-dimensional images of the breast. "At risk for breast

2.9 cancer" means:

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

2.11 cancer;
2.12 (2) testing positive for BRCA1 or BRCA2 mutations;
2.13 (3) having heterogeneously dense breasts or extremely dense breasts based on the Breast
2.14 Imaging Reporting and Data System established by the American College of Radiology; or
2.15 (4) having a previous diagnosis of breast cancer.
2.16 (c) This subdivision does not apply to coverage provided through a public health care
2.17 program under chapter 256B or 256L.
2.18 (d) Nothing in this subdivision limits the coverage of digital breast tomosynthesis in a
2.19 policy, plan, certificate, or contract referred to in subdivision 1 that is in effect prior to
2.20 January 1, 2020.
2.21 (e) Nothing in this subdivision prohibits a policy, plan, certificate, or contract referred
2.22 to in subdivision 1 from covering digital breast tomosynthesis for an enrollee who is not at
2.23 risk for breast cancer.

2.24 EFFECTIVE DATE. This section is effective January 1, 2022, and applies to health
2.25 plans offered, issued, or renewed on or after that date.

2.26 Sec. 3. Minnesota Statutes 2020, section 256B.0625, subdivision 14, is amended to read:

2.27 Subd. 14. Diagnostic, screening, and preventive services. (a) Medical assistance covers
2.28 diagnostic, screening, and preventive services.

2.29 (b) "Preventive services" include services related to pregnancy, including:

2.30 (1) services for those conditions which may complicate a pregnancy and which may be
2.31 available to a pregnant woman determined to be at risk of poor pregnancy outcome;

3.1 (2) prenatal HIV risk assessment, education, counseling, and testing; and

3.2 (3) alcohol abuse assessment, education, and counseling on the effects of alcohol usage

3.3 while pregnant. Preventive services available to a woman at risk of poor pregnancy outcome

3.4 may differ in an amount, duration, or scope from those available to other individuals eligible

3.5 for medical assistance.

3.6 (c) "Screening services" include, but are not limited to, blood lead tests.

3.7 (d) Coverage of diagnostic screenings and tests under this subdivision must comply with

3.8 section 62A.30.

3.9 (d)(e) The commissioner shall encourage, at the time of the child and teen checkup or

3.10 at an episodic care visit, the primary care health care provider to perform primary caries

3.11 preventive services. Primary caries preventive services include, at a minimum:

3.12 (1) a general visual examination of the child's mouth without using probes or other dental

3.13 equipment or taking radiographs;

3.14 (2) a risk assessment using the factors established by the American Academies of

3.15 Pediatrics and Pediatric Dentistry; and

3.16 (3) the application of a fluoride varnish beginning at age one to those children assessed
3.17 by the provider as being high risk in accordance with best practices as defined by the
3.18 Department of Human Services. The provider must obtain parental or legal guardian consent
3.19 before a fluoride varnish is applied to a minor child's teeth.
3.20 At each checkup, if primary caries preventive services are provided, the provider must
3.21 provide to the child's parent or legal guardian: information on caries etiology and prevention;
3.22 and information on the importance of finding a dental home for their child by the age of
3.23 one. The provider must also advise the parent or legal guardian to contact the child's managed
3.24 care plan or the Department of Human Services in order to secure a dental appointment
3.25 with a dentist. The provider must indicate in the child's medical record that the parent or
3.26 legal guardian was provided with this information and document any primary caries
3.27 prevention services provided to the child.

3.28 EFFECTIVE DATE. This section is effective January 1, 2022.

Codes Utilized in Assumptions

Diagnosis (ICD-10) Code(s):

V76.11 – Screening mammogram for high risk patient

V76.12 – Screening mammogram

Z12.31 - Encounter for screening mammogram for malignant neoplasm of breast

Z80.3 – Family history of malignant neoplasm of the breast

Z85.3 – Personal history of malignant neoplasm of the breast

CPT Code(s):

77046 through 77047 – Breast MRI

77063 – Digital breast tomosynthesis

77065 through 77066 - Diagnostic mammography, including computer-aided detection (CAD)

77067 – Screening mammography

76498 – Unlisted magnetic resonance procedure

81162 through 81167 – BRCA Testing

81216 – BRCA Testing

81432 through 81433 – Genomic analysis for hereditary breast and other cancers

93740 – Temperature gradient studies

19803 through 19805 – Biopsy of breast

HCPCS Code(s):

N/A

NDC Code(s):

N/A*

*It is possible that drugs such as tamoxifen and raloxifene may be prescribed as a preventive measure for breast cancer; however, the USPSTF has already identified these drugs as preventive and they should be subject to no cost to the enrollee.

Description of Review

Commerce performed an umbrella review of available information related to breast cancer screening. An umbrella review is similar to a systematic literature review, but with a focus on reviewing relevant information or studies that are essentially other systematic reviews and/or meta-analyses. This approach allows for gathering of significant high-level, but pertinent, information regarding the topic being researched.

The Department searched PubMed utilizing combinations of the terms “breast cancer,” “screening,” “diagnostic,” “standard of care,” “experimental,” “investigative,” “accepted methodology,” and “alternative treatment.” The search limited these terms to peer-reviewed articles published in the last 10 years.

Bibliography

Berg WA, Bandos AI, Mendelson EB, Lehrer D, Jong RA, Pisano ED. Ultrasound as the Primary Screening Test for Breast Cancer: Analysis From ACRIN 6666. *J Natl Cancer Inst.* 2015 Dec 28;108(4):djv367. doi: 10.1093/jnci/djv367. PMID:26712110; PMCID: PMC5943835.

Berg WA, Zhang Z, Lehrer D, Jong RA, Pisano ED, Barr RG, Böhm-Vélez M, Mahoney MC, Evans WP 3rd, Larsen LH, Morton MJ, Mendelson EB, Farria DM, Cormack JB, Marques HS, Adams A, Yeh NM, Gabrielli G; ACRIN 6666 Investigators. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. *JAMA.* 2012 Apr 4;307(13):1394-404. doi: 10.1001/jama.2012.388. PMID: 22474203; PMCID: PMC3891886.

Carbine NE, Lostumbo L, Wallace J, Ko H. Risk-reducing mastectomy for the prevention of primary breast cancer. *Cochrane Database Syst Rev.* 2018 Apr 5;4(4):CD002748. doi: 10.1002/14651858.CD002748.pub4. PMID: 29620792; PMCID: PMC6494635.

Comstock CE, Gatsonis C, Newstead GM, Snyder BS, Gareen IF, Bergin JT, Rahbar H, Sung JS, Jacobs C, Harvey JA, Nicholson MH, Ward RC, Holt J, Prather A, Miller KD, Schnall MD, Kuhl CK. Comparison of Abbreviated Breast MRI vs Digital Breast Tomosynthesis for Breast Cancer Detection Among Women With Dense Breasts Undergoing Screening. *JAMA.* 2020 Feb 25;323(8):746-756. doi: 0.1001/jama.2020.0572. Erratum in: *JAMA.* 2020 Mar 24;323(12):1194. PMID: 32096852; PMCID: PMC7276668.

Cuzick J, Sestak I, Cawthorn S, Hamed H, Holli K, Howell A, Forbes JF; IBIS-I Investigators. Tamoxifen for prevention of breast cancer: extended long-term follow-up of the IBIS-I breast cancer prevention trial. *Lancet Oncol.* 2015 Jan;16(1):67-75. doi: 10.1016/S1470-2045(14)71171-4. Epub 2014 Dec 11. PMID: 25497694; PMCID: PMC4772450.

Gartlehner G, Thaler K, Chapman A, Kaminski-Hartenthaler A, Berzaczy D, Van Noord MG, Helbich TH. Mammography in combination with breast ultrasonography versus mammography for breast cancer screening in women at average risk. *Cochrane Database Syst Rev.* 2013 Apr 30;2013(4):CD009632. doi: 10.1002/14651858.CD009632.pub2. PMID: 23633376; PMCID: PMC6464804.

Jayasekera J, Mandelblatt JS. Systematic Review of the Cost Effectiveness of Breast Cancer Prevention, Screening, and Treatment Interventions. *J Clin Oncol.* 2020 Feb 1;38(4):332-350. doi: 10.1200/JCO.19.01525. Epub 2019 Dec 5. PMID: 31804858; PMCID: PMC6994253

Le TTT, Adler FR. Is mammography screening beneficial: An individual-based stochastic model for breast cancer incidence and mortality. *PLoS Comput Biol.* 2020 Jul 6;16(7):e1008036. doi: 10.1371/journal.pcbi.1008036. PMID: 32628726; PMCID: PMC7365474.

Melnikow J, Fenton JJ, Whitlock EP, Miglioretti DL, Weyrich MS, Thompson JH, Shah K. Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2016 Feb 16;164(4):268-78. doi: 10.7326/M15-1789. Epub 2016 Jan 12. PMID: 26757021; PMCID: PMC5100826.

Wöckel A, Albert US, Janni W, Scharl A, Kreienberg R, Stüber T. The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer. *Dtsch Arztebl Int.* 2018 May 4;115(18):316-323. doi: 10.3238/arztebl.2018.0316. PMID: 29807560; PMCID: PMC5987060.

van den Ende C, Oordt-Speets AM, Vroiling H, van Agt HME. Benefits and harms of breast cancer screening with mammography in women aged 40-49 years: A systematic review. *Int J Cancer.* 2017 Oct 1;141(7):1295-1306. doi: 10.1002/ijc.30794. Epub 2017 Jun 5. PMID: 28542784.

Nelson HD, Pappas M, Cantor A, Griffin J, Daeges M, Humphrey L. Harms of Breast Cancer Screening: Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation. *Ann Intern Med*. 2016 Feb 16;164(4):256-67. doi: 10.7326/M15-0970. Epub 2016 Jan 12. Erratum in: *Ann Intern Med*. 2018 Nov 20;169(10):740. PMID: 26756737.

Ruddy KJ, Winer EP. Male breast cancer: risk factors, biology, diagnosis, treatment, and survivorship. *Ann Oncol*. 2013 Jun;24(6):1434-43. doi: 10.1093/annonc/mdt025. Epub 2013 Feb 20. PMID: 23425944.

Román M, Sala M, Domingo L, Posso M, Louro J, Castells X. Personalized breast cancer screening strategies: A systematic review and quality assessment. *PLoS One*. 2019 Dec 16;14(12):e0226352. doi: 10.1371/journal.pone.0226352. PMID: 31841563; PMCID: PMC6913984.

Sharma R, Pannikottu J, Xu Y, Tung M, Nothelle S, Oakes AH, Segal JB. Factors Influencing Overuse of Breast Cancer Screening: A Systematic Review. *J Womens Health (Larchmt)*. 2018 Sep;27(9):1142-1151. doi: 10.1089/jwh.2017.6689. Epub 2018 Apr 30. PMID: 29708809; PMCID: PMC6148722.

Yuan WH, Hsu HC, Chen YY, Wu CH. Supplemental breast cancer-screening ultrasonography in women with dense breasts: a systematic review and meta- analysis. *Br J Cancer*. 2020 Aug;123(4):673-688. doi: 10.1038/s41416-020-0928-1. Epub 2020 Jun 12. PMID: 32528118; PMCID: PMC7434777.