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Evaluation of Eliminating Cost-Sharing for Cancer Genetic Testing

PREPARED FOR THE MARYLAND HEALTH CARE COMMISSION

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Highlights

The following is a summary of the comprehensive report on the evaluation of the medical, social, and financial impact of eliminating cost–sharing for genetic testing for inherited gene mutations for individuals with a personal or family history of cancer, and the follow–up, evidenced–based, screenings for individuals with an increased risk of cancer as recommended by clinical practice guidelines. Lewis & Ellis, LLC (L&E) was engaged by the Maryland Health Care Commission to perform this evaluation.

MEDICAL IMPACT

- Although genetic testing is highly accurate in identifying genetic variations, detecting a variation associated with an increased risk of cancer does not guarantee that the patient will develop the disease. Only about 10% of all cancers may be caused by genetic inheritance.
- For example, it is estimated that 55-65% of women with the BRCA1 gene variation and 45% of women with the BRCA2 gene variation will develop breast cancer by age 70. By contrast, the average risk of a woman developing breast cancer is about 13%. However, overall, fewer than 10% of women diagnosed with breast cancer carry a BRCA mutation.
- A 2020 National Trends Survey (NTS) found that approximately a quarter of genetic tests completed were for cancer gene testing purposes. The most common type of cancer gene tests utilized are for detecting genes associated with breast cancer, ovarian cancer, and colorectal cancer.
- Direct-to-consumer (DTC) genetic testing, which allows individuals to order tests without a doctor's prescription, is widely available to the public. However, DTC tests are generally less accurate compared to those conducted through a healthcare provider.
- During provider interviews, a key piece of feedback emphasized the importance of clearly defining clinical guidelines for what qualifies as 'an individual with a personal or family history of cancer,' should legislation regarding genetic testing coverage or cost-sharing be introduced. This clarity is essential to ensure that testing is efficiently targeted, minimizing undue patient anxiety and preventing unnecessary overutilization.

SOCIAL IMPACT

- A 2020 National Trends Survey (NTS) found that while approximately 35% of people were aware of cancer genetic testing, only about 5% had undergone such testing.
- Most private health insurers cover genetic counseling and testing at little to no out-of-pocket cost for individuals who meet specific personal or family cancer history criteria.
- The NTS also revealed that individuals with an income of less than $50K per year are about 25% less likely to be aware of genetic testing and nearly half as likely to have utilized it.
- Clinical guidelines advise that women at high risk of breast cancer, for example, should consider a range of risk-management options (incl. genetic counseling, genetic

testing, etc.), yet these options remain significantly underutilized. Inductive analyses have identified three main categories of health-related financial constraints: (a) lack of insurance, (b) underinsurance, and (c) other financial burdens such as medical debt, raising children, and managing comorbidities.

FINANCIAL IMPACT

- L&E utilized data from provider interviews and publicly available sources to estimate variables influencing cost and utilization, categorizing them into low, mid, and high-end assumptions. These ranges are not limited to the three scenarios illustrated but are intended to capture the uncertainties inherent in each assumption, offering a spectrum of potential outcomes.
- L&E estimated that the financial impact ranges from 0.00%-0.06% of premium. The following report provides a detailed discussion of the data used to inform each assumption evaluated by L&E. The table below summarizes the calculation of the financial impact.
- Cost impact estimates for similar genetic testing coverage changes in two states ranged from 0.01%-0.15%. While there are differences in each state and each proposed coverage change, L&E took these estimates under consideration.

SUMMARY OF THE CALCULATION OF THE FINANCIAL IMPACT

Assumption	Low	Mid	High
Cancer Genetic Testing Utilization % Post- Coverage Change (a)	0.20%	0.71%	1.24%
Unit Cost per Cancer Genetic Test (b)	$750	$1,000	$1,250
% of Cancer Genetic Testing Cost Paid by Insurer Pre- Coverage Change (c)	85%	75%	65%
% of Cancer Genetic Testing Cost Paid by Insurer Post- Coverage Change (d)	100%	100%	100%
Cancer Genetic Testing Coverage Change Unit Cost Impact (e)= [(d)-(c)]*(b)	$112.50	$250.00	$437.50
Cancer Genetic Testing Coverage Change Cost PMPY (f)=(e)*(a)	$0.23	$1.78	$5.41
Maryland Estimated 2025 Claims Costs PMPM (g)	$738.70	$738.70	$738.70
Maryland Estimated Loss Ratio (h)	85%	85%	85%
Premium Cost PMPY (i)=(f)/(h)	**$0.26**	**$2.09**	**$6.36**
Premium Cost PMPM (j)=(i)/12	**$0.02**	**$0.17**	**$0.53**
Maryland Estimated 2025 Premium PMPM (k)=(g)/(h)	$869.06	$869.06	$869.06
% Impact Premium (l)=(j)/(k)	**0.00%**	**0.02%**	**0.06%**

Introduction

PROCESS

Lewis & Ellis, LLC (L&E) was engaged by the Maryland Health Care Commission (MHCC) to conduct an analysis of eliminating cost–sharing for genetic testing for inherited gene mutations for individuals with a personal or family history of cancer, and the follow–up, evidenced–based, screenings for individuals with an increased risk of cancer as recommended by clinical practice guidelines. Maryland Statute requires the Commission to assess the social, medical, and financial impact of eliminating cost sharing for genetic testing (as required under §15–1501 of the Insurance Article).

Insurance Article §15–1501, Annotated Code of Maryland, requires that the MHCC annually assess the medical, social, and financial impact of proposed mandated health insurance services that failed to pass, or as otherwise requested, during the preceding legislative session or as requested by a Legislator or Legislative Committee by July 1 of each year. The assessment reports are due to the General Assembly annually by December 31. L&E reviewed literature, gathered statistics from public sources[a], interviewed providers[b], conducted insurer surveys[c], and gathered data from the Maryland All-Payer Claims Database (APCD). Each of these components have been considered in the evaluation performed.

Medical Evaluation

BACKGROUND ON GENETIC TESTING

The National Human Genome Research Institute (NHGRI) defines genetic testing as the use of a laboratory test to examine an individual's DNA for variations, typically performed in the context of medical care, ancestry studies, or forensics. Genomic variation simply refers to DNA sequence differences among an individual or a population. Certain gene variations can indicate higher risk of certain diseases, such as cancer, or can be used to diagnose certain conditions such as cystic fibrosis.[1] Genetic tests use a blood or saliva sample, and results are usually ready in a few weeks.

The history of genetic testing began in the 1950s with the discovery of DNA itself in 1953 by James Watson and Francis Crick. Their groundbreaking work unveiled the double-helix structure of DNA. Then in the 1980s, Dr. Alec Jeffreys at the University of Leicester, established the technique known as DNA fingerprinting, which enabled the identification and comparison of unique DNA profiles.[2,3] Genome-wide association studies (GWAS) began in the 1990s. A GWAS involves scanning markers across many sets of DNA, or genomes, to find genetic variations associated with a particular disease. Since these studies began, there have been more than 60,000 genetic associations identified across thousands of diseases.[4,5]

[a]Including reports for other states who have considered or passed similar legislation.

[b]The interview was on October 9, 2024, with various providers spanning the medical genetics, oncology, hematology, and family medicine fields.

[c]Five carriers were surveyed, three responded: Aetna, CareFirst, and Kaiser.

While there are many types of genetic testing, the type relevant to this analysis is known as presymptomatic or predictive testing. The Mayo Clinic defines this type of testing as genetic testing before symptoms are present that may show if an individual is at risk of developing a certain condition, typically utilized if there is a family history of the condition. The standard method involves multigene (or panel) tests. Based on the patient's personal and family history, as well as the amount of information they wish to receive, a healthcare provider may order a panel test targeting genes associated with a specific type of cancer or a broader panel test that examines genes linked to various common cancers. If a gene variant is already known to be present in the family, the entire gene may be tested for changes, or the testing may focus solely on the specific known variant. [6]

MEDICAL EFFECTIVENESS

While genetic testing is highly accurate in identifying genetic variations, if a genetic variation associated with higher cancer risk is detected it does not mean that the patient will develop cancer. This is because only about 10% of all cancers may be caused by genetic inheritance.[7] So, for example, it is estimated that 55-65% of women with the BRCA1 gene variation and 45% of women with the BRCA2 gene variation will develop breast cancer by age 70.[8] In comparison, the average risk of a woman developing breast cancer is about 13%.[9] However, overall, less than 10% of women diagnosed with breast cancer have a BRCA mutation.

During provider interviews, a key piece of feedback emphasized the importance of clearly defining clinical guidelines for what qualifies as 'an individual with a personal or family history of cancer,' should legislation regarding genetic testing coverage or cost-sharing be introduced. In this way, testing should be efficiently targeted to avoid undue anxiety on patients and unnecessary overutilization. It was also noted that the best practice for patients who test positive for a genetic variation is to refer them to a genetic counselor, though genetic counseling services are not always covered by insurance.

Providers also noted that the percentage of individuals that will test positive for a cancer genetic variation are in the minority. For example, prevalence of harmful BRCA gene changes in the general population is about 0.2-0.3%.[10] If a cancer gene variation is detected, follow-up care typically includes more frequent cancer screenings and/or starting screenings at a younger age than recommended for the general population. Since individuals who test positive for a genetic variation represent a small percentage of the population, and cancer screenings are generally (though not always) covered by insurers as a preventive service, L&E did not assume any specific additional costs for 'evidence-based follow-up screenings for individuals with an increased risk of cancer, as recommended by clinical practice guidelines.' However, L&E believes that the selected range of assumptions accounts for scenarios where additional follow-up screening costs could arise, even though these costs were not explicitly included.

AVAILABILITY AND USAGE OF SERVICES

Several types of healthcare providers are qualified to complete genetic testing for cancer risk including a genetic counselor, oncologist, or medical geneticist. A study of genetic counselors

in a sample of states, published in 2019, placed Maryland in the top one third of states with the highest number of genetic counselors per capita, with 1.7 per 100,000 people.[11] Similarly, based on Kaiser Family Foundation (KFF) data, Maryland is in the top 10% of states with the highest number of oncologists per capita, with 13.1 per 100,000 people.[12,13] It should be noted that an insurer's participating network consists of a subset of the total number of providers. However, insurer survey responses indicated that Maryland insurers do not experience difficulty contracting with these types of services providers.

In recent years, there has been a significant and remarkable increase in genetic testing. Now that genetic testing is commercially available, an individual has the means to access their results through direct-to-consumer (DTC) genetic testing, which are comprised of genetic tests that customers can order themselves without a doctor's order. Today, more than 25 global companies offer DTC services to the public.[2] However, DTC testing is materially less accurate than testing done through a healthcare provider.

A 2020 National Trends Survey (NTS) found that approximately a quarter of genetic tests completed were for cancer gene testing purposes.[14] The most common type of cancer gene tests utilized are for detecting genes associated with breast cancer, ovarian cancer, and colorectal cancer.

Based on insurer survey data, approximately 10% of claims for cancer genetic testing are denied due to lack of evidence of medical necessity. Nothing in the language of this analysis suggests that L&E should assume any changes to the practice of denying claims due to lack of evidence of medical necessity (e.g., absence of a personal or family history of cancer). Therefore, no changes to this practice were assumed in L&E's evaluation.

Social Evaluation

POPULATION UTILIZATION

The previously mentioned NTS found that about 75% of the people were aware of genetic testing. However, the most common type of genetic testing awareness was ancestry testing and only about 20% of people ever had any kind of genetic testing done. In particular, the study showed that about 35% of people were aware of cancer genetic testing and only about 5% of people had ever had cancer genetic testing completed.[14]

L&E performed an analysis of Maryland APCD which showed that from 2019-2023 approximately 0.2%-1.2% of insured members in Maryland utilized cancer genetic testing.

INSURANCE COVERAGE

Research showed that private health insurers cover genetic counseling and testing with low- or no out-of-pocket costs for people who meet certain personal or family cancer history criteria.[15] This is consistent with responses received from surveyed Maryland insurers. This is a vast difference compared to just 30 years ago, when coverage or reimbursement for genetic testing was much more expensive and highly variable.[15]

L&E's analysis of the Maryland APCD revealed that approximately 70%-90% of cancer genetic testing claims are paid by the insurer.

Regarding self-funded employer groups who employ at least five hundred employees, Maryland insurer survey responses indicated that coverage for cancer genetic testing is generally similar to the fully insurance market. That is, most plans cover the benefit with low- or no out of pocket costs.

BARRIERS AND DISPARITIES

In an evaluation of the Maryland APCD, L&E found that the average cost per cancer genetic testing service was approximately $950 (i.e., claim amount paid by the insurer and insured in total).

The NTS identified that individuals with an income of less than $50K per year are about 25% less likely to be aware of genetic testing and almost half as likely to utilize genetic testing. Another study found significant financial barriers to genetic testing, particularly for individuals considered to be of low socioeconomic status (SES).[16] The study stated that, to ensure genetic testing for hereditary cancers becomes a cornerstone of preventative medicine, it must first be made more accessible to low-SES individuals. This is crucial, as those in low-SES groups experience higher cancer incidence and mortality rates.

Clinical guidelines advise that women at high risk of breast cancer, for example, should consider a range of risk-management options, yet these options remain significantly underutilized. Inductive analyses have identified three main categories of health-related financial constraints: (a) lack of insurance, (b) underinsurance, and (c) other financial burdens such as medical debt, raising children, and managing comorbidities.[17] These financial constraints limit access to various breast cancer risk-management actions, including genetic counseling, genetic testing, enhanced screening, and prophylactic surgeries.

Financial Evaluation

To estimate the financial impact of genetic testing, L&E evaluated data from the Maryland All-Payer Claims Database (APCD), insurer survey responses, provider interview responses, and publicly available sources. L&E used the collected information and data to estimate low-end, high-end, and mid-range assumptions for each variable that could impact cost or utilization. The ranges for each variable were then used to calculate the final estimated aggregate range for the financial impact.

While L&E selected specific assumptions to develop a range of estimated fiscal impact, the range is not intended to represent only the three low-, mid-, and high- scenarios illustrated. Each range is intended to capture the various uncertainties inherent in each assumption and to provide an estimated range of potential outcomes. Therefore, the final estimated range captures many scenarios and sets of assumptions.

Each of the following sections discuss the data used to inform each assumption evaluated by L&E.

GENETIC TESTING UTILIZATION PRE- COVERAGE CHANGE

Claimant and member data was provided to L&E from the Maryland APCD from 2019-2023.[d] Based on the APCD data, L&E selected the following range for the genetic testing utilization percentage pre-coverage change, determined by the upper, middle, and lower values of the utilization percentage by year:

Genetic Testing Utilization Pre- Coverage Change			
	Low	Mid	High
Cancer Genetic Testing Utilization % Pre- Coverage Change	0.20%	0.70%	1.20%

COVERAGE CHANGE INDUCED UTILIZATION

There is little data available regarding induced utilization[e] because of eliminating cost sharing for genetic testing. However, it would be unreasonable to assume that there is no potential for increased utilization because of the overall decrease in cost to the insured that would occur if cost sharing were eliminated. Based on L&E's similar experience with cost-sharing eliminations, the following range was selected for the induced utilization assumption:

Assumed Genetic Testing Coverage Change Induced Utilization		
Low	Mid	High
0.0%	1.5%	3.0%

GENETIC TESTING UNIT COST

Based on the information available from the APCD data, publicly available research, and feedback from providers interviewed, L&E selected the following assumptions for the total cost per genetic test.

Genetic Testing Unit Cost			
	Low	Mid	High
Unit Cost per Cancer Genetic Test	$750	$1,000	$1,250

INSURER COST-SHARING PRE- AND POST-COVERAGE CHANGE

Based on the APCD data, the average insurer-paid claims costs as a percentage of total cancer genetic testing claims costs were determined to be between 70 and 90 percent. Additionally, feedback from providers interviewed indicated some patients pay up to $500 for cancer

[d] Includes the fully insured individual and group markets, as well as the State Health Plan.

[e] An increase in demand for and utilization of health care services caused by a decrease in the level of cost-sharing that insured's are required to pay under their insurance coverage.

genetic testing. This amount would imply an insurer paid portion of the claim of around 50-60%.

Based on the information available, L&E selected the following assumptions for the Insurer Cost-Sharing Pre- and Post- Coverage Chage:

Assumed Insurer Cost-Sharing	Low	Mid	High
Cancer Genetic Testing Insurer Cost-Share Pre-Coverage Change	85%	75%	65%
Cancer Genetic Testing Insurer Cost-Share Post-Coverage Change	100%	100%	100%

L&E notes that a higher level of pre-coverage change insurer cost-share results in a lower financial impact. Therefore, the higher pre-coverage change cost-share percentages are listed for the mid- and low- scenarios.

MARYLAND TOTAL CLAIMS COSTS PMPM AND PREMIUM PMPM

L&E utilized the 2023 APCD paid claims data as the base year and trended it to 2025 with an assumed paid claims trend of 9.5% per year. The 9.5% assumption is based on the average paid claims trend from 2019-2023. The projected 2025 paid claims per member per month (PMPM) is $738.70.

Further, L&E assumed a total loss ratio of 85% based on typical industry pricing practices. L&E does not expect the elimination of cost sharing for cancer genetic testing to have any material impact on retention (i.e., non-claims costs). Therefore, the projected 2025 premium PMPM is $869.06.

POTENTIAL FOR COST SAVINGS

To the extent that cancer gene testing results in early detection or prevention of cancer, there is potential for cost savings. However, the extent of cost saving is difficult to measure because it involves predicting what would have happened if testing and early intervention did not take place. For example, for someone electing a risk-reducing mastectomy due to cancer gene detection, the measure of cost savings depends on whether the person would have developed cancer or not without the risk-reducing mastectomy.

While L&E acknowledges the potential of long-term cost savings, L&E did not make an explicit cost savings assumption because:

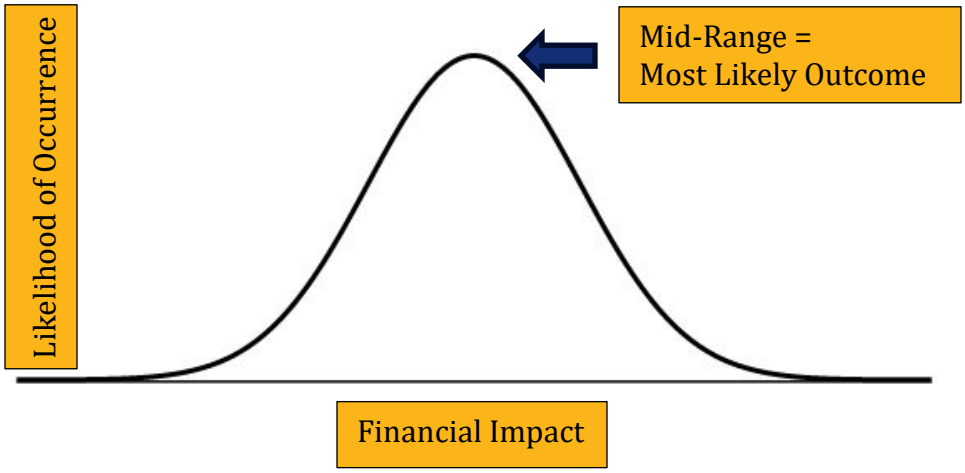
- There is little data on the magnitude of such cost savings, especially regarding the cost savings' relationship to incremental coverage increases.
- L&E believes that the selected range of assumptions captures scenarios in which marginal cost savings could be achieved even though cost savings was not explicitly assumed.

RESULTING FISCAL IMPACT ESTIMATE

The following table illustrates the range of assumptions selected by L&E and the resulting estimated fiscal impact range.

Assumption	Low	Mid	High
Genetic Testing Utilization % Pre- Coverage Change (a)	0.20%	0.70%	1.20%
Coverage Change Induced Utilization (b)	0.0%	1.5%	3.0%
Genetic Testing Utilization % Post- Coverage Change (c)=(a)*(b)	0.20%	0.71%	1.24%
Unit Cost per Cancer Genetic Test (d)	$750	$1,000	$1,250
% of Cancer Genetic Testing Cost Paid by Insurer Pre- Coverage Change (e)	85%	75%	65%
% of Cancer Genetic Testing Cost Paid by Insurer Post- Coverage Change (f)	100%	100%	100%
Cancer Genetic Testing Coverage Change Unit Cost Impact (g)= [(f)-(e)]*(d)	$112.50	$250.00	$437.50
Cancer Genetic Testing Coverage Change Cost PMPY (h)=(g)*(c)	$0.23	$1.78	$5.41
Cancer Genetic Testing Coverage Change Cost PMPM (i)=(h)/12	**$0.02**	**$0.15**	**$0.45**
Maryland Estimated 2025 Claims Costs PMPM (j)	$738.70	$738.70	$738.70
% Impact CCs (k)=(j)/(i)	0.00%	0.02%	0.06%
Maryland Estimated Loss Ratio (l)	85%	85%	85%
Premium Cost PMPY (m)=(l)/(h)	$0.26	$2.09	$6.36
Premium Cost PMPM (n)=(m)/12	**$0.02**	**$0.17**	**$0.53**
Maryland Estimated 2025 Premium PMPM (o)=(j)/(l)	$869.06	$869.06	$869.06
% Impact Premium (p)=(n)/(o)	**0.00%**	**0.02%**	**0.06%**

L&E notes that the estimated impact range is considered to take on a normal curve, or bell curve, where the low- and high- estimates represent less likely impacts. This is illustrated visually below.



L&E also notes that the estimated impact applies to the Maryland insurance market as a whole, but individual insurers may not be affected equally. The impact for each insurer may vary depending on the characteristics of their underlying population, potentially leading to higher or lower effects compared to the overall average.

OTHER FISCAL IMPACT ESTIMATES CONSIDERED

When evaluating the cost impact of eliminating cost-sharing for cancer genetic testing, L&E considered estimates from two states. Although there are differences in each state and in each proposed coverage change, L&E took these estimates into consideration.

Estimated Cancer Genetic Testing Benefit Cost Impact	
California[18]	$0.23 PMPM
Kentucky[19]	0.01%-0.15%

Additionally, in response to the insurer survey, one insurer estimated a 0.05% cost impact.

ASOP 41 Disclosures

The Actuarial Standards Board (ASB), vested by the U.S.-based actuarial organizations[f], promulgates actuarial standards of practice (ASOPs) for use by actuaries when providing professional services in the United States.

Each of these organizations requires its members, through its Code of Professional Conduct[g], to observe the ASOPs of the ASB when practicing in the United States. ASOP 41 provides guidance to actuaries with respect to actuarial communications and requires certain disclosures which are contained in the following.

Identification of the Responsible Actuary

The responsible actuaries are:

- Traci Hughes, FSA, MAAA, Vice President & Principal
- David Dillon, FSA, MAAA, Senior Vice President & Principal

These actuaries are available to provide supplementary information and explanation.

Identification of Actuarial Documents

The date of this document is October 28, 2024. The date (a.k.a. "latest information date") through which data or other information has been considered in performing this analysis is October 28, 2024.

Disclosures in Actuarial Reports

- The contents of this report are intended for the use of the Maryland Health Care Commission. The authors of this report are aware that it may be distributed to third parties. Any third party with access to this report acknowledges, as a condition of receipt, that they cannot bring suit, claim, or action against L&E, under any theory of law, related in any way to this material.
- Lewis & Ellis, LLC is financially and organizationally independent from the health insurers and providers involved in this analysis. There is nothing that would impair or seem to impair the objectivity of the work.
- The purpose of this report is to assist the Maryland Health Care Commission in assessing the medical, social, and financial impact of required coverage for genetic testing.
- The responsible actuaries identified above are qualified as specified in the Qualification Standards of the American Academy of Actuaries.
- Lewis & Ellis has reviewed the data provided by the insurers and Maryland Health Care Commission for reasonableness, but the data has not been audited. L&E nor the responsible actuaries assume responsibility for these items that may have a material

[f] The American Academy of Actuaries (Academy), the American Society of Pension Professionals and Actuaries, the Casualty Actuarial Society, the Conference of Consulting Actuaries, and the Society of Actuaries.

[g] These organizations adopted identical *Codes of Professional Conduct* effective January 1, 2001.

impact on the analysis. To the extent that there are material inaccuracies in, misrepresentations in, or lack of adequate disclosure by the data, the results may be accordingly affected.

- Several of the assumptions made in this analysis are subject to uncertainty and it is not unexpected that actual results could differ from the calculated estimates.
- L&E is not aware of any subsequent events that may have a material effect on the findings.
- There are no other documents or files that accompany this report.

Actuarial Findings

The actuarial findings of the report can be found in the body of this report.

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