Testimony on Opposition to Executive Budget Proposals Affecting Medicaid Coverage of Biomarker Testing

New York State Senate and Assembly Health & Finance Committees, Joint Legislative Budget Hearing on Health & Medicaid, February 10, 2026

Submitted by Alec Lewis, Regional Manager of Government Affairs at Natera Genetics

Chairpersons Krueger, Pretlow, Rivera, and Paulin, and Honorable Members of the Senate and Assembly Health and Finance Committees:

Thank you for the opportunity to submit testimony regarding the proposed changes to New York Medicaid's coverage policy for biomarker testing included in the Governor's Executive Budget.

My name is Alec Lewis, and I serve as Regional Manager of Government Affairs for Natera Genetics. I submit this testimony on behalf of Natera Genetics in strong opposition to the proposed Medicaid coverage rollbacks for biomarker testing (HMH Article VII, Part M, Subsection 12), and respectfully urge that these provisions not be included in the one-house or final budgets.

Biomarker testing is essential to matching patients with the most effective treatments for cancer and other serious diseases. It is a cornerstone of evidence-based, precision medicine and a critical tool for improving patient outcomes, quality of life, and survival. Recognizing this, the Legislature enacted biomarker testing coverage requirements with overwhelming bipartisan support to ensure equitable access for patients enrolled in Medicaid and those covered by state-regulated private insurance plans, consistent with the National Council of Insurance Legislators Model Act.

The Executive Budget proposal would reverse this important step forward for health equity. By rolling back established Medicaid coverage criteria while leaving private insurance coverage intact, the proposal would create a two-tiered system of access based solely on payer status. This disparity would disproportionately impact Medicaid beneficiaries and risks exacerbating existing inequities in health outcomes associated with race, ethnicity, income, and geography.

Consistent coverage standards across Medicaid and private plans are critical for providers to deliver equitable care. When coverage criteria are aligned, clinicians can order appropriate biomarker tests based on clinical need rather than insurance type. Removing this consistency introduces confusion, administrative burden, and the real risk that patients who would benefit from biomarker testing will not receive it.

The proposed rollback is particularly concerning given ongoing implementation challenges within the Medicaid program under current law. Medicaid has not consistently added biomarker tests to its fee schedule in a timely manner, even when those tests are explicitly covered under

New York's biomarker statute, including tests that are subject to an applicable Medicare Local Coverage Determination. As a result, patients and providers already face barriers to accessing tests the Legislature clearly intended to be covered. Rather than addressing these compliance and operational gaps, the Executive Budget proposal would further restrict access and move the program in the wrong direction.

From a fiscal perspective, reducing access to proven biomarker testing is a shortsighted approach to cost containment. Biomarker testing helps avoid unnecessary or ineffective treatments, reduces trial-and-error care, and can prevent disease progression that leads to significantly higher downstream costs. Upfront investment in appropriate diagnostic testing supports more efficient use of Medicaid dollars while improving patient outcomes.

An accompanying white paper submitted with this testimony outlines the actual annual savings achievable if New York fully implemented and enforced its existing biomarker testing law. The findings make clear that weakening coverage standards undermines both patient outcomes and fiscal efficiency, while full implementation delivers measurable savings by avoiding unnecessary and ineffective care, preventable complications, and disease progression.

Additionally, the fiscal estimate in proposed savings underlying the Executive Budget proposal raises serious concerns. The projected costs associated with biomarker testing appear out of line with reputable studies and with fiscal estimates and real-world experience from other states that have implemented similar coverage policies. Other state Medicaid programs have not observed the level of immediate cost increases assumed in the Executive Budget, particularly when testing is appropriately targeted and aligned with evidence-based clinical guidelines. Overstating short-term costs risks driving policy decisions that ultimately increase long-term spending and worsen patient outcomes.

Research demonstrates that biomarker-informed treatment decisions can improve health outcomes, increase quality of life, and extend survival. In chronic and degenerative diseases, delays in identifying effective treatments allow disease progression and irreversible harm, increasing long-term health care utilization. In oncology and certain autoimmune conditions, the time required to identify an effective therapy can be a matter of life or death. In all cases, ineffective treatment exacerbates the physical, emotional, and economic burdens of disease, with costs borne by both patients and the Medicaid program.

It is also important to view this proposal in a broader national context. New York would stand alone in moving backward by reintroducing restrictive eligibility criteria and removing access protections, including the elimination of NCOIL-based standards that many states have embraced. At the same time, states across the country are moving in the opposite direction. States from California to Florida are actively updating their Medicaid fee schedules to reflect biomarker coverage requirements. Arizona, Colorado, Georgia, Louisiana, Oklahoma, and neighboring New Jersey have issued bulletins or adopted regulatory guidance through their insurance departments emphasizing the importance of compliance with biomarker testing coverage laws. Just last month, the Mississippi House passed legislation to establish biomarker testing coverage using the same NCOIL-based standards the Executive Budget now seeks to

remove from New York's Medicaid program. In this context, the proposal represents a significant departure from national best practices and from the Legislature's own prior intent.

We recognize that the state faces real fiscal and administrative challenges and are committed to working collaboratively with the Legislature, state agencies, providers, and patient advocates to address implementation issues in a way that preserves patient access. However, the proposed Executive Budget changes would roll back an important advancement in health equity and should not be included in the one-house or final budgets.

For these reasons, I respectfully urge the Legislature to preserve Medicaid coverage for biomarker testing and to ensure that New Yorkers do not lose access to these critical, evidence-based diagnostic tools based solely on insurance status.

Thank you for your consideration and for your continued leadership on behalf of patients across New York State. I look forward to continued engagement as the budget process moves forward.

Respectfully submitted,

Alec Lewis

Regional Manager of Government Affairs

Natera Genetics

Economic Evaluation White Paper

Budget Impact Analysis of Biomarker Testing in the State of New York

Introduction

The use of biomarker testing in health care has significant clinical and economic implications for the healthcare system[1]. Biomarker testing has allowed for new approaches to diagnosis and treatment. It can assist decision-making by optimizing treatment for the right patients who will be responsive to the corresponding therapy, while providing guidance on excluding patients deemed unlikely to respond. Therefore, in addition to the direct effects of treatment, it has the potential to reduce adverse drug reactions and overtreatment, and hence may improve the health and quality of life of patients. Additionally, it can potentially limit the expenditure on ineffective therapies and create more sustainable and cost-effective health care systems[2], Figure 1.

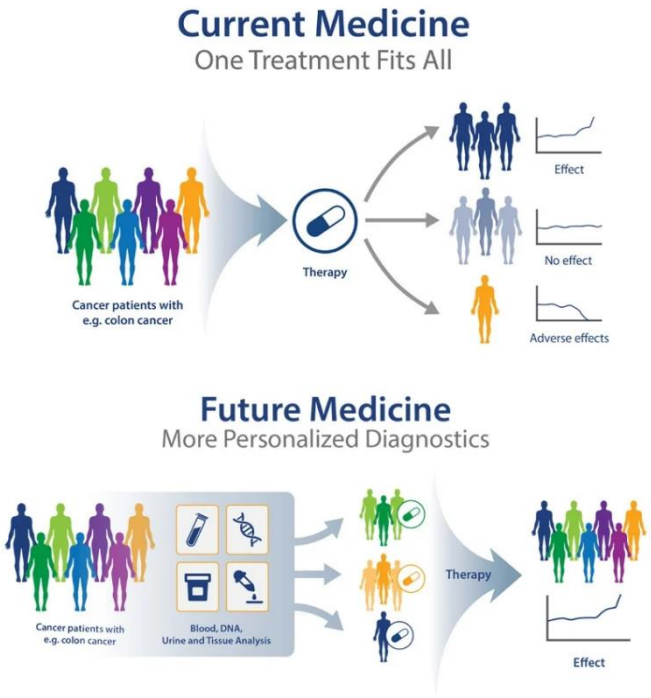

Figure 1. Biomarker testing offers the benefits of tailored treatments leading to effective care, fewer side effects, and potential cost savings in healthcare.

Although the advent of personalized medicine using biomarker testing holds the promise of improved outcomes and cost-effective healthcare delivery, it has made slower-than-expected progress[3]. Several factors contribute to this phenomenon, but paramount amongst them are the disparities in healthcare access to testing and inconsistent reimbursement policies[3]. Reimbursement policies that do not adequately cover biomarker testing intensify disparities in healthcare access. This means that only those who can afford to pay out-of-pocket or have Medicare coverage (coverage of novel biomarkers are relatively robust for Medicare plans but sparse for non-Medicare plans[4]) will have access to these advanced

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[1] D Avó Luís AB, Seo MK. Has the development of cancer biomarkers to guide treatment improved health outcomes? Eur J Health Econ. 2021 Jul;22(5):789-810. doi: 10.1007/s10198-021-01290-4.

[2] Oosterhoff M, van der Maas ME, Steuten LM. A systematic review of health economic evaluations of diagnostic biomarkers. *Appl. Health Econ. Health Policy.* 2016;14(1):51–65. doi: 10.1007/s40258-015-0198-x.

[3] Garrison LP, Towse A. Personalized medicine: pricing and reimbursement policies as a potential barrier to development and adoption, economics of. In: Culyer AJ, editor. Encyclopedia of Health Economics. Amsterdam: Elsevier; 2014. pp. 484–490.

[4] Brant A, Weinstein IC, Lewicki P, Zhu A, Johnson JP, Sze C, Shoag JE. Insurer coverage of prostate cancer biomarkers. Urol Oncol. 2023 Jul;41(7):324.e9-324.e12. doi: 10.1016/j.urolonc.2023.04.020.

diagnostic tools, exacerbating health inequalities. Moreover, although many commercial self-insured/large-group employers provide some coverage, policy criteria vary since there are currently no consistent minimum coverage requirements for biomarker testing[5]. A patient survey completed in 2020 indicated that 29% of patients did not have testing done due to lack of insurance coverage or because they could not afford the out-of-pocket costs[6]. Lack of access to biomarker testing and coverage barriers are issues for many patients but appear to have a greater impact among racial and ethnic minorities and socioeconomically disadvantaged patients[7]. Consequently, many patients are denied the benefits of these critical diagnostic tools. Furthermore, barriers to testing access can exacerbate health inequities, leading to sub-optimal treatment plans and outcomes among populations already struggling with healthcare disparities.

As noted, biomarker testing can ensure that patients receive therapies from which they are most likely to benefit while avoiding treatments that are unlikely to be effective or could cause harm[8]. In this way, biomarker testing can potentially limit costs to the healthcare system, insurers, and employers. A 2012 study of metastatic colorectal cancer revealed that using an identified biomarker to direct treatment decisions can ensure that only those patients who may benefit from a treatment receive it, while avoiding unnecessary costs and harm to those unlikely to benefit. This study found that it is possible to increase expected overall survival while saving approximately $7,500 per patient when compared to using non-biomarker-directed treatment[9]. While no comprehensive data source includes all biomarker testing or economic analysis of such tests, an interactive budget impact model was created linking multiple, best available published sources to postulate the monetary impact of mandatory cancer biomarker coverage for a hypothetical cohort in the state of Florida.

Methods and Results

A budget impact analysis evaluates the financial implications of implementing comprehensive biomarker testing in oncology populations covered under New York health plans, consistent with the requirements of New York's biomarker testing law. The model assesses costs and offsets associated with biomarker-informed treatment selection relative to a scenario in which testing is underutilized or inconsistently applied, despite statutory coverage requirements.

The model is structured to reflect real-world cancer care delivery and incorporates established estimates of cancer prevalence, treatment utilization, and phase-of-care costs, including initial treatment, continuing care, and end-of-life management. These cost inputs are aligned with published national cancer expenditure data and applied conservatively to a New York payer population to avoid overstating economic benefit.

While biomarker testing introduces an incremental upfront diagnostic cost, the model demonstrates that these costs are more than offset by downstream savings driven by improved clinical decision-making. Biomarker-informed care enables clinicians to more accurately match patients to therapies with a higher likelihood of response and to avoid ineffective or low-value treatments. As a result, the model shows meaningful reductions in avoidable drug spend, treatment-related adverse event management, and costs associated with early disease progression.

A key driver of savings in the model is the avoidance of ineffective systemic therapies. Cancer drug expenditures represent the largest and fastest-growing component of oncology spend. By identifying patients unlikely to benefit from certain therapies, biomarker testing reduces unnecessary exposure to high-cost treatments that do not improve outcomes. This effect is particularly pronounced in later lines of therapy, where costs escalate rapidly and clinical benefit is often marginal in the absence of predictive biomarkers.

In addition, the model captures cost offsets related to reduced complications and downstream utilization. Patients who receive biomarker-guided therapy are less likely to experience severe toxicities associated with ineffective treatment, lowering the need for supportive care, emergency department visits, and hospitalizations. Over time, improved treatment selection also contributes to delayed disease progression for biomarker-appropriate patients, which defers the substantial costs associated with metastatic or end-stage cancer care.

From a health plan perspective, the budget impact analysis demonstrates that compliance with the New York biomarker testing law is economically sustainable and, in many scenarios, cost neutral or cost saving. When evaluated on a per-member per-month basis, the incremental cost of expanded biomarker testing is modest and is outweighed by reductions in total cancer care expenditures. Importantly, these savings accrue within the same budget periods in which diagnostic costs are incurred, mitigating concerns about long-term return on investment.

The findings of this model reinforce that biomarker testing should not be viewed as an added financial burden but rather as a utilization management and quality-of-care tool that aligns clinical appropriateness with fiscal responsibility. Denial or restriction of biomarker testing—contrary to New York law—does not control costs and instead perpetuates inefficient care pathways that increase overall oncology spend.

The interactive budget impact model was developed (Excel Based) to estimate the effect of mandating biomarker testing coverage on the incidence, prevalence and associated costs of cancer care in the state of New York (NY). National cancer-attributed medical care costs for the state of NY were derived from the “Medical Care Costs Associated with Cancer Survivorship in the

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[5] A white paper on the need for consistent terms for testing in precision medicine. Retrieved Jan 19, 2024, from https://media.cancercare.org/publications/original/409-Consistent_Testing_Terminology_Whitepaper_Final_070720.pdf

[6] Survivor Views: Biomarker Testing Survey Findings Summary. American Cancer Society Cancer Action Network (2020, September). Retrieved Jan 19, 2024, from https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf

[7] Bruno, D. S., Hess, L. M., Li, X., Su, E. W., Zhu, Y. E., & Patel, M. (2021). Racial disparities in biomarker testing and clinical trial enrollment in non-small cell lung cancer (NSCLC). Journal of Clinical Oncology, 39(15_suppl), 9005–9005. https://doi.org/10.1200/jco.2021.39.15_suppl.9005

[8] Committee on policy issues in the clinical development and use of biomarkers for molecularly targeted therapies: Keys to unlocking precision medicine. Retrieved October 21, 2022, from https://www.ncbi.nlm.nih.gov/books/NBK379341/

[9] Behl, A. S., Goddard, K. A., Flottemesch, T. J., Veenstra, D., Meenan, R. T., Lin, J. S., Maciosek, M. V. (2012). Cost-effectiveness analysis of screening for KRAS and BRAF mutations in metastatic colorectal cancer. JNCI: Journal of the National Cancer Institute, 104(23), 1785–1795. https://doi.org/10.1093/jnci/djs433

United States study, published in the journal Cancer Epidemiology, Biomarkers & Prevention[10, 11]. These cost estimates include physician, hospital and prescription drugs were divided into phases of care: initial (first year after diagnosis), end-of-life (year before cancer death) and continuing/surveillance (the time in between) phases. The estimated number of new incidences for selected cancers in NY were obtained from the American Cancer Society Cancer Statistics Center[12]. The prevalence of cancer rates (all sites) in NY was 493.0 per 100,000 population[13]. Therefore, the total estimated NY population with either a new cancer diagnosis (123,810) or existing cancer diagnosis (104,562) is 228,372 individuals. The estimated percent of the NY population with a cancer diagnosis in each phase of the treatment algorithm was determined using the Centers of Disease Control and Prevention's National Program of Cancer Registries database[13] and showed 54% in the initial phase, 26% in the continuous/surveillance phase and 20% in the end-of-life phase. The estimated weighted average annual medical costs per cancer survivor[10] (Annualized average cancer attributable costs, or the estimated costs for one year related to cancer) is $166,048.00.

The payor landscape analysis used to determine the proportion of the NY population with specific coverage by insurance type was derived from Policy Reporter[14]. The estimated total population with a cancer diagnosis that is ensured with a government health plan, commercial health plan and public employer plan was 119,895, 103,710 and 4,767, respectively.

Under the assumptions derived in the model we postulated 50% of cancer patients receiving access to biomarker testing as a result of the proposed legislation. At an estimated annual median cost per patient of $477 for biomarker testing[15], the total additional costs added to the overall cost of healthcare burden are $28,594,938 for government plans, $24,734,913 for commercial plans and $1,136,960 for public employer plans. The potential cost of healthcare savings estimated for the use of biomarker testing to incorporate changes in treatment decisions and those decisions producing a net health benefit resulted in a total annual cost of healthcare savings of approximately

$66,376,464 for the government plans, $57,416,318 for commercial plans and $2,639,188 for public employer plans.

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[10] Mariotto AB, Enewold L, Zhao JX, Zeruto CA, Yabroff KR. Medical Care Costs Associated with Cancer Survivorship in the United States. Cancer Epidemiol Biomarkers Prev. 2020;29(7):1304-12.

[11] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. J Natl Cancer Inst. 2011;103(2):117-28.

[12]Estimated cases for cancer sites by state can be found in Supplemental Data at cancer.org/statistics or via the Cancer Statistics Center (cancerstatisticscenter.cancer.org).

[13]NAACCR, 2022. Data are collected by cancer registries participating in the National Cancer Institute's SEER program and the Centers for Disease Control and Prevention's National Program of Cancer Registries. Rates are per 100,000, age adjusted to the 2000 US standard population.

[14]Policy Reporter Website: About Us - Policy Reporter: Live Medical Policy Email Alerts; accessed Jan 2024.

[15]Hess LM, Michael D, Krein PM, Marquart T, Sireci AN. Costs of biomarker testing among patients with metastatic lung or thyroid cancer in the USA: a real-world commercial claims database study. J Med Econ. 2023 Jan-Dec;26(1):43-50.

Overall, the model demonstrates that adoption and adherence to the state's biomarker testing law supports both improved patient outcomes and responsible health care spending. By enabling precision oncology and reducing low-value treatment utilization, biomarker testing delivers measurable economic benefits to New York health plans while fulfilling statutory coverage obligations and advancing evidence-based cancer care.

Discussion

Biomarker testing in cancer plays a crucial role in guiding treatment decisions and personalized medicine. By identifying specific genetic or molecular markers in a patient's tumor, healthcare providers can determine the most appropriate treatment approach and potentially avoid ineffective or unnecessary therapies. This targeted approach can lead to improved patient outcomes and cost savings in several ways:

- **Avoiding ineffective treatments**: Biomarker testing can identify patients who are unlikely to respond to certain therapies, thereby avoiding the expense of administering ineffective treatments. This helps to prevent unnecessary drug expenditures and reduces the potential for adverse side effects.
- **Guiding treatment selection:** Biomarker testing can help healthcare providers identify targeted therapies or immunotherapies that are more likely to be effective for specific patients. This personalized approach can increase treatment efficacy and potentially reduce the need for more expensive and less targeted treatments.
- **Reducing trial-and-error approaches**: Biomarker testing can help avoid a trial-and-error approach to treatment selection, where patients are subjected to multiple treatment attempts before finding an effective therapy. By identifying biomarkers early on, healthcare providers can make more informed treatment decisions, reducing the time and costs associated with ineffective treatments.
- **Preventing disease progression and early relapse detection:** Early detection of biomarkers associated with cancer can facilitate earlier intervention and treatment, potentially preventing disease progression.

Timely treatment can lead to better patient outcomes and potentially reduce the need for more extensive and expensive interventions in advanced stages of cancer. The cost increment of introducing comprehensive biomarker testing into routine cancer care is insignificant in comparison to the ever-increasing costs of cancer therapies. A key benefit of biomarker testing comes from the potential to reduce drug costs through the more efficient deployment of available treatments. Biomarker testing can ensure that patients do not receive drugs from which they are unlikely to benefit. This can save money by reducing drug costs and protecting patients from exposure to ineffective treatments.

Conclusion

In conclusion, biomarker testing stands as a revolutionary advancement in healthcare, offering a multitude of benefits that promise to transform patient care. By enabling early detection and diagnosis of diseases, biomarker testing paves the way for timely and targeted interventions,

significantly improving patient outcomes. Its role in personalizing treatment plans ensures that patients receive the most effective therapies tailored to their specific conditions, thereby enhancing treatment efficacy and reducing the likelihood of adverse reactions. Furthermore, biomarker testing contributes to cost efficiency in healthcare systems by streamlining the diagnostic process, reducing unnecessary treatments, and minimizing hospital stays. The integration of biomarker testing into routine clinical practice heralds a new era of precision medicine, where treatments are not just effective but also optimally aligned with the unique needs of each patient, ultimately leading to a healthier society.