Impact of Mandate

Precision medicine shows promise as a key driver for optimal health and is essential in shaping the future of health care. In order to increase patient access to biomarker tests, policymakers are considering mandated coverage. Many are concerned such mandates may lead to coverage of unvalidated tests, harm patients and unnecessarily increase costs to patients and states.

• Mandate affects 20-30% of reference medical policy library (genetics:16%; pathology/lab:4%)

• These mandates state "biomarker testing must be covered for…diagnosis, treatment, appropriate management, or ongoing monitoring…when the test is supported by…evidence, including, but not limited to:

– Labeled indications for an FDA-approved or -cleared test; or

– Indicated tests for an FDA approved drug; or

– Centers for Medicare Services ("CMS") National Coverage Determinations; or

– Medicare Administrative Contractor ("MAC") Local Coverage Determinations; or

– Nationally recognized clinical practice guidelines and consensus statements." (NCOIL)

Concerns on Biomarker Mandate

1. Definition of biomarker testing in the NCOIL model

• The definition in the bill is too broad: includes nearly all laboratory tests.

• If the goal is to help cancer and/or alzheimer's patients, consider limiting to cancer and/or alzheimer's biomarker tests, such as what was done in Louisiana.

2. Unproven tests can be harmful.

• Biomarker tests can save lives if the right test is performed.

– If testing is not accurate, patients receive the wrong drugs that have no chance of helping, while depriving patients of drugs that could help them.

• Testing leads to a "cascade" of follow up actions which can do harm. Patient harms from unproven, inaccurate tests include pain and inconvenience from unnecessary biopsies, over diagnosis leading to unnecessary surgeries and other treatments, which in turn have additional potential harms.

– As an example, Arizona legislated coverage for biomarker tests using Theranos, which used a finger prick of blood to conduct hundreds of tests. Theranos was an unproven and fraudulent test. Patient results showed diseases that were not real, resulting in: unnecessary medical appointments, unneeded medication, invasive diagnostic tests, workup for cancer diagnosis when no cancer was present.

3. Mandate is unnecessary: Health Plans routinely cover useful tests.

• Health plans cover biomarker tests that have scientific evidence of clinical benefit.

• Timely updating is routine.

• When new evidence demonstrates the benefit of a test, health plans approve coverage.

4. Biomarker mandates are costly to states

• Mandated testing and follow-up leads to untenable health care costs for states.

• Arizona mandate for Theranos resulted in a $4.65 million consumer-fraud settlement.

Maryland conducted fiscal analysis for annual costs to Medicaid.
– 1% of enrollees receiving one test at $1700: $27 million
– Using estimates of 25% uptake of biomarker testing: $429.6 million
– 10% of pediatric enrollees tested in the emergency department: $30.6 million
– Cost savings accrued by earlier treatment: no reliable estimates

Ohio's Legislative Budget Office (LBO) estimate impact for cancer biomarkers.
– State Plans: $756,000 per year (current spend: $133,000 per year)
– School districts $2.8 million per year
– Other local governments: $2.2 million per year
– Costs will increase for Medicaid. No estimates provided.

Blue Cross VT Position

1. We are committed to ensuring Vermonters receive the safe and effective care they need.
• Health plans should retain flexibility when establishing evidence-based policies for coverage, allowing for coverage of biomarker tests after review of reliable scientific evidence and demonstration of clinical benefit.
• When new, high-quality evidence is published demonstrating the clinical benefit of biomarker tests, health plans approve coverage policies accordingly.
• Timely updating coverage policies is a routine part of plans' medical coverage policy process.

2. Biomarker tests can save lives if the right test is performed; however, unproven tests can lead to a "cascade" of events which can result in patient harm.
• If testing is not accurate, patients could receive the wrong diagnosis and treatment.
• Unproven, inaccurate tests can result in pain and inconvenience from unnecessary biopsies, over diagnosis leading to unnecessary surgeries, and other treatments, which, in turn, produce additional potential physical and mental harm.

3. Mandated coverage for biomarker testing would lead to increased costs for states and patients.
• The costs of unvalidated biomarker testing mandates include the test as well as the costs of the full cascade of follow-up care and its impact on patient health and well-being.
• Coverage mandates also increase costs for patients, health plans and state Medicaid programs by removing incentives for labs and test manufacturers to negotiate reasonable pricing with health plans.