By: _____ __.B. No.

A BILL TO BE ENTITLED

AN ACT

relating to health benefit plan coverage for certain biomarker testing.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle E, Title 8, Insurance Code, is amended by adding Chapter 1372 to read as follows:

CHAPTER 1372. COVERAGE FOR BIOMARKER TESTING

Sec. 1372.001. DEFINITIONS. In this chapter:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. The term includes:

(A) gene mutations; and

(B) protein expression.

(2) "Biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes:

(A) single-analyte tests;

(B) multiplex panel tests; and

(C) whole genome sequencing.

Sec. 1372.002. APPLICABILITY OF CHAPTER. (a) This chapter applies only to a health benefit plan that provides benefits for medical or

Commented [1]: TAHP recommends removing the definitions in Subsection 3 and 4 based on the decision to remove language in section 1372.003 and instead reference existing Texas law. These definitions will not be necessary if the later language is removed. See later comment.

Deleted: (3) "Consensus statements" means statements that:

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Deleted: (A) address specific clinical circumstances based on the best available evidence for the purpose of optimizing clinical care outcomes; and

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Deleted: (4) "Nationally recognized clinical practice guidelines" means evidence-based clinical practice guidelines that:

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Deleted: (B) include recommendations intended to optimize patient care; and

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Deleted: (C) are developed by an independent organization or medical professional society that uses a transparent methodology and reporting structure and is subject to a conflict of interest policy.

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surgical expenses incurred as a result of a health condition, accident, or sickness, including an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage or similar coverage document that is offered by:

(1) an insurance company;

(2) a group hospital service corporation operating under Chapter 842;

(3) a health maintenance organization operating under Chapter 843;

(4) an approved nonprofit health corporation that holds a certificate of authority under Chapter 844;

(5) a multiple employer welfare arrangement that holds a certificate of authority under Chapter 846;

(6) a stipulated premium company operating under Chapter 884;

(7) a fraternal benefit society operating under Chapter 885;

(8) a Lloyd ’s plan operating under Chapter 941; or

(9) an exchange operating under Chapter 942.

(b) Notwithstanding any other law, this chapter applies to:

(1) a small employer health benefit plan subject to Chapter 1501, including coverage provided through a health group cooperative under Subchapter B of that chapter;

(2) a standard health benefit plan issued under Chapter 1507;

(3) a basic coverage plan under Chapter 1551;

(4) a basic plan under Chapter 1575;

(5) a primary care coverage plan under Chapter 1579;

(6) a plan providing basic coverage under Chapter 1601;

(7) health benefits provided by or through a church benefits board under Subchapter I, Chapter 22, Business Organizations Code;

(8) the state Medicaid program, including the Medicaid managed care program operated under Chapter 533, Government Code;

(9) the child health plan program under Chapter 62, Health and Safety Code;

(10) a regional or local health care program operated under Section 75.104, Health and Safety Code;

(11) a self-funded health benefit plan sponsored by a professional employer organization under Chapter 91, Labor Code;

(12) county employee group health benefits provided under Chapter 157, Local Government Code; and

(13) health and accident coverage provided by a risk pool created under Chapter 172, Local Government Code.

Sec. 1372.003. COVERAGE REQUIRED. (a) A health benefit plan must provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of various types of cancer.

(b) The coverage provided under this Section may be subject to evidence based, scientifically valid, outcome focused utilization review subject to Insurance Code §4201.153. The screening criteria

Commented [2]: TAHP is neutral about including Medicaid. Like the private market, there is no problem that needs to be solved for this coverage. Medicaid already covers biomarker testing when it is medically necessary and has a clinical utility. Similar to our other comments about prior authorization, the model act exempts the prior authorization timelines if the state already has existing timelines. Likewise, Medicaid already has specific timelines and processes for prior authorizations and appeals. Texas already has the shortest timelines for both in the country. Additionally, Texas should not create an entirely new and separate process that will add unnecessary administrative burden for the coverage of one type of test. This is not done for any other type of coverage mandate. Because Medicaid only covers items that are medically necessary, adding Medicaid to the bill is another reason to remove the very broad definitions in Sections 132.001 subsections 3 and 4 that could result in unnecessary biomarker testing and instead use utilization review criteria that is based on Texas law. This is how all other benefits are covered in the Medicaid program. This mandate should not be treated any differently.

Commented [3]: TAHP recommends adding “various types of cancer” since the intent behind this bill is to ensure patients have access to early cancer screening and optimal treatment.

Commented [4]: TAHP supports removing most of this section and instead referencing or adopting the current Texas laws and regulations for screening criteria, so this benefit mandate has appropriate guardrails and is consistent with how utilization review is handled in Texas already for all other coverage mandates. The proposed language in the model act is extremely vague and broad, so this type of mandate would prohibit us from doing any meaningful management of laboratory testing based on evidence-based standards. Additionally, this type of vague criteria does not exist for any other coverage in Texas. Adding new vague criteria would make this coverage mandate inconsistent with any other type of mandate. The consequence could result in coverage of tests that have very little proven clinical value.

The list in the proposed model act would require insurers to cover testing anytime it is approved by the FDA or recommended by "consensus statements" and "medical societies," which is extremely broad. As an example, Aduhelm is a drug that the FDA recently approved for Alzheimer's, but CMS won't even cover it for Medicare, given its lack of proven efficacy. This new language would ensure that the coverage is subject to evidence-based medical necessity criteria, protecting patients from the unnecessary test. A test may be scientifically valid, approved, and part of a practice guideline, but that does not mean that it is appropriate for a particular patient at a particular point in time in their disease process. ... [1]

must also recognize that if evidence-based medicine is not available for a particular health care service provided, the utilization review agent must utilize generally accepted standards of medical practice recognized in the medical community. This section does not require a health benefit plan to cover a biomarker test that predominantly does not address an acute issue for which the test is being ordered.

(c) A health benefit plan must provide coverage under Subsection (a) in a manner that limits disruptions in care, including limiting the number of biopsies and biospecimen samples.

SECTION 2. The change in law made by this Act applies only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2024.

SECTION 3. This Act takes effect September 1, 2023.

Commented [5]: Add a subsection to the language clarifying "this section does not require a health benefit plan to cover a biomarker test that predominantly does not address an acute issue for which the test is being ordered."

"Multiplex panel size" is unaddressed. TAHP is neutral on covering medically necessary tests in which the panel is full of results that are actually necessary. However, several testing companies have extremely broad panels, many of which aren't medically necessary. If there is no clarification around the necessity of the panel itself, a lab company could in theory establish a testing panel that has one medically necessary element, and 50 unnecessary elements. They would then of course charge for the 51-element panel test and argue the whole thing is medically ... [2]

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TAHP supports removing most of this section and instead referencing or adopting the current Texas laws and regulations for screening criteria, so this benefit mandate has appropriate guardrails and is consistent with how utilization review is handled in Texas already for all other coverage mandates. The proposed language in the model act is extremely vague and broad, so this type of mandate would prohibit us from doing any meaningful management of laboratory testing based on evidence-based standards. Additionally, this type of vague criteria does not exist for any other coverage in Texas. Adding new vague criteria would make this coverage mandate inconsistent with any other type of mandate. The consequence could result in coverage of tests that have very little proven clinical value.

The list in the proposed model act would require insurers to cover testing anytime it is approved by the FDA or recommended by "consensus statements" and "medical societies," which is extremely broad. As an example, Aduhelm is a drug that the FDA recently approved for Alzheimer's, but CMS won't even cover it for Medicare, given its lack of proven efficacy. This new language would ensure that the coverage is subject to evidence-based medical necessity criteria, protecting patients from the unnecessary test. A test may be scientifically valid, approved, and part of a practice guideline, but that does not mean that it is appropriate for a particular patient at a particular point in time in their disease process.

Governor Newsom vetoed the biomarker bill, because this broad language in the model act would lead to coverage for tests that “may not be evidence-based.”

Instead, this mandate should be consistent with current Texas rules and regulations. Already in Insurance TAC: Each URA must utilize written screening criteria that are evidence-based, scientifically valid, outcome-focused, and that comply with the requirements in Insurance Code §4201.153. The screening criteria must also recognize that if evidence-based medicine is not av

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Add a subsection to the language clarifying “this section does not require a health benefit plan to cover a biomarker test that predominantly does not address an acute issue for which the test is being ordered.”

“Multiplex panel size” is unaddressed. TAHP is neutral on covering medically necessary tests in which the panel is full of results that are actually necessary. However, several testing companies have extremely broad panels, many of which aren’t medically necessary. If there is no clarification around the necessity of the panel itself, a lab company could in theory establish a testing panel that has one medically necessary element, and 50 unnecessary elements. They would then of course charge for the 51-element panel test and argue the whole thing is medically necessary.

Texas has a history of unnecessary testing as a result of coverage mandates. Under the COVID-19 testing mandate, labs were running extensive tests on samples that went beyond identifying COVID-19, then billing insurers for the full panel of tests.

This mandate could be interpreted to require coverage of any “biomarker” for any indication (not just cancer) that is recommended in any guideline from any medical professional society or “independent organization” or any consensus statement from any “independent multidisciplinary panel of experts” or recommended in any Medicare National Coverage Determination or any Medicare Local Coverage Determination or has FDA approval or even merely FDA clearance.

This is extremely vague and broad, such that this type of mandate might prohibit a plan from doing any meaningful management of laboratory testing. This mandate abandons any analysis of evidence (note that the mandate has no evidence standards); the consequence would be coverage of tests that have very little proven clinical value.

If the definitions stay this broad, carriers will necessarily end up putting prior auth requirements in place for any number of tests since the mandate otherwise requires us to cover an extremely broad set of unne

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TAHP supports eliminating the section on prior authorizations. No state has included this language. Additionally, the model act as drafted does not apply because subsection (c) exempts products that already have preauthorization timelines in place, meaning the language is essentially moot in Texas.
The private market, Medicaid, and ERS already have established prior authorization and appeals processes.

Texas already has the strictest preauthorization timelines in the country. We also have other patient protections, such as preauthorization exemptions ("goldcarding"), which make this language unnecessary. If passed without this language, the mandate would default to the existing preauthorization laws, as all other mandates do. Texas should not add a new prior authorization and appeals process that is different from the current process for the coverage of one type of test. This would force plans and Medicaid to create a cumbersome and administratively expensive process for just one type of test. Similar to all other coverage requirements, Texas should use the existing PA processes in state law. The existing time

frames in Texas are much shorter than any other state (the NCQA standard is 15 days), and have been in place for many years without need for modification. Texas has tight timeframes for medical necessity decisions for HMO and PPO plans as outlined in the Insurance Code and TDI rules. Requests for PA must be responded to (from receipt of request) not later than 3 calendar days after the request is received. For post-emergency stabilization the timeline is one hour and for concurrent hospitalization 24 hours. Adding new shortened timeframes will add to administrative costs and require additional staffing.

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TAHP recommends deleting this section. If passed without this language, the mandate would default to the existing appeals laws, as all other mandates do. Texas should not add an appeals process that is different from the current process for the coverage of one type of test. This would force private plans and Medicaid plans to create a separate cumbersome and administratively expensive process for just one type of test. Similar to all other coverage requirements, Texas should use the existing appeals processes in state law. There are already significant laws in the insurance code and in federal law that address appeals for denials of prior authorization.

Similar to the preauthorization timelines, Texas has some of the strictest appeals process requirements in the country, and law would default to those if passed without this language. It is unclear how "clear, readily accessible, and convenient" would be interpreted, but we have concerns that this would require issuers to use a completely separate appeals process for one specific procedure. It would be extremely burdensome to apply a unique appeals process to this minor procedure. It would also make the process confusing and complex for patients. It would set a bad precedent to start creating a separate process based on each sepearate coverage item. This section is unnecessary. The insurance code already takes care of this.

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