Market Access
Updates & Hot Topics

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Agenda

- State Legislation for Biomarker Testing
- Transitional Coverage for Emerging Technologies (TCET)
- Protecting Access to Medicare Act (PAMA) & Saving Access to Laboratory Services Act (SALSA)
- Price Transparency Initiatives
- Q&A and RFI

Please note that the opinions expressed herein are my own.

State Legislation for Biomarker Testing

State legislation for biomarker testing: Overview

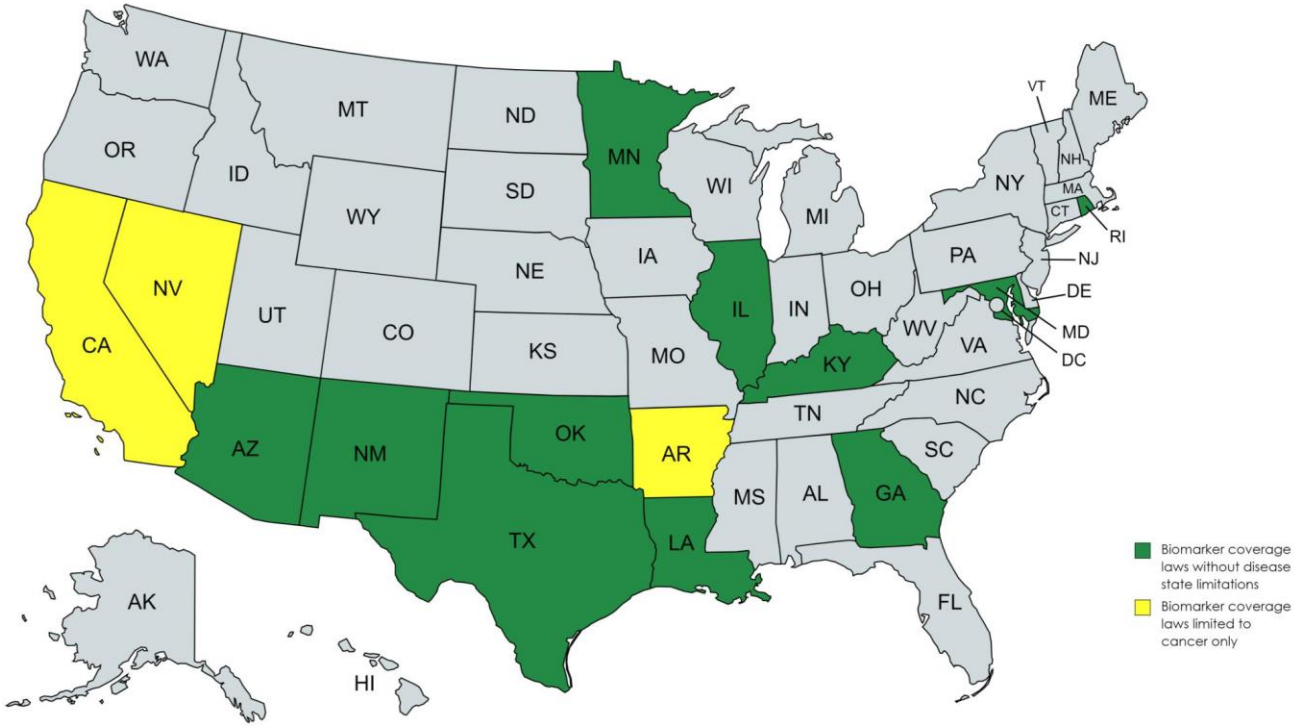
- Over the past few years, an increasing number of states have enacted laws mandating coverage of biomarker tests under certain circumstances

- Generally, these laws require health insurers in the state to cover biomarker testing for their enrollees when the testing meets certain evidentiary criteria
  - Usually apply to private payers but some apply to Medicaid
  - Some subject to utilization management review

- 11 states have enacted biomarker coverage laws that apply to all biomarker testing for all diseases
  - 3 states limit biomarker testing to cancer-related indications
  - Some states have enacted more focused laws (e.g., apply only to screening for hereditary cancer syndromes, whole genome sequencing, etc.)

Source: Triage Cancer, Foley Hoag

State legislation for biomarker testing: Geograhical differences



Source: Foley Hoag

State legislation for biomarker testing: Themes

- Mandates coverage “for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment decisions” for “biomarker testing” when the test has “clinical utility” supported by “medical and scientific evidence”

- “Biomarker” = “a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention.”
  - “Includes, but is not limited to, gene mutations or protein expression”

- “Clinical utility” = “the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision”

State legislation for biomarker testing: Themes

- What constitutes sufficient evidence?
  - Labeled indications for FDA-approved or cleared tests
  - Indicated tests for FDA-approved drugs or warnings on FDA-approved drug labels
  - CMS NCD
  - MAC LCD (except in Illinois)
  - Nationally recognized clinical practice guidelines and consensus statements

Source: Foley Hoag

State legislation for biomarker testing: Comments

- Definitions are broad, vague, and/or incorrect (e.g., biomarker, clinical utility, nationally recognized clinical practice guidelines, and consensus statements)

- Conflates validity (“safe and effective”) with utility (“medically necessary”) and ignores inconsistencies among (and “political influence” on) NCDs, LCDs, guidelines, and consensus statements, not to mention the significant variability in the rigor of their underlying evidence reviews

- Seems to mandate coverage of any test for any purpose with limited (and highly variable) evidence for its validity and utility

- Yet another example of leveraging real healthcare disparities to advance coverage for “innovations” of unproven benefit through legislation, not evidence, with uncertain and potentially significant budgetary implications

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Transitional Coverage for Emerging Technologies (TCET)

TCET:
A Brief History of Time

- January 14, 2021: Medicare Coverage of Innovative Technologies (MCIT) rule published (initiated under the Trump administration) with an effective date of March 15, 2021 (delayed to December 15, 2021)
- September 15, 2021: CMS published proposed rule to repeal MCIT
- November 12, 2021: CMS officially “cancels” MCIT
- June 27, 2023: CMS publishes TCET
- August 28, 2023: Public comment period for TCET ends

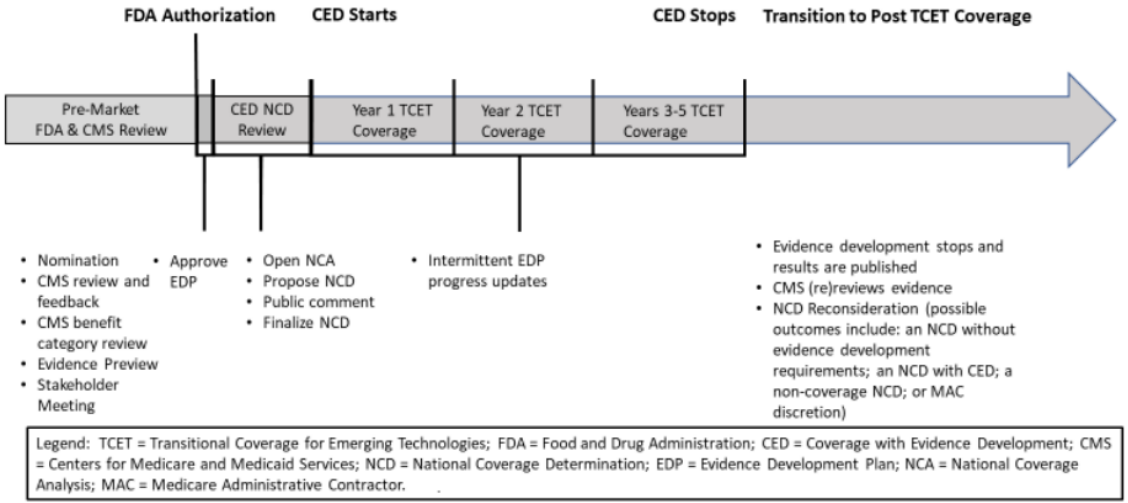
Source: CMS.gov

TCET:
Proposed Pathway/Timeline

Phase 1:
Premarket
(≤ 12 months)

Phase 2:
Coverage under TCET
(≥ 3-5 years)

Phase 3:
Post-TCET
Coverage or Non-coverage



Source: govinfo.gov

MCIT vs TCET

	MCIT	TCET
Eligibility	All FDA-authorized, breakthrough devices, including ones authorized within 2 years of the final rule	5 FDA-authorized breakthrough devices per year, excluding diagnostic tests
Initiation	Email CMS with intent	Submission of a complete nomination, review by CMS, CMS-FDA meeting, (potentially) a benefit category review, optional meeting with CMS/FDA/AHRQ, submission of formal NCD request
Evidence Generation	None required beyond that for FDA authorization (but encouraged)	Agreed upon evidence development plan (EDP) Public comment on TCET NCD Updated evidence review after transitional coverage

Source: National Law Review

MCIT vs TCET

	MCIT	TCET
Transitional Coverage	4 years from FDA authorization (or manufacturer request)	≥ 3-5 years from FDA authorization (based on EDP) effective within 6 months of authorization
Post-transitional coverage outcomes	1. Coverage NCD 2. Non-coverage NCD 3. MAC discretion (LCD or claim-by-claim adjudication)	1. Coverage NCD 2. Non-coverage NCD 3. NCD with CED 4. MAC discretion (LCD or claim-by-claim adjudication)

- Timeline commitments in TCET are “squishy”
- CMS may outsource some of the technology assessment workload

Source: National Law Review

Congressional response:
Ensuring Patient Access to Critical Breakthrough Products Act of 2023

- First introduced on June 22, 2021 and re-introduced as H.R. 1961 on March 22, 2023

- Essentially codifies the original MCIT rule

- Potential headwinds:
  - Has Democratic cosponsors but may not want to oppose TCET (since proposed by Biden administration)
  - CBO has not yet provided budget estimates (expected to be significant)
  - No companion bill in Senate
  - Current situation in Congress (and the world)

Source: Congress.gov, Arnold & Porter

Protecting Access to Medicare Act (PAMA)
&
Saving Access to Laboratory Services Act (SALSA)

PAMA changed the CLFS to a market-based system

- Implemented in January 2018, the Protecting Access to Medicare Act (PAMA) attempts to make CLFS payment rates (more) market-based: Rates reflect the weighted median (by volume) of commercial payer rates

- PAMA data collection and reporting cycles are supposed to occur every 3 years but has been repeatedly delayed after 10% year-over-year cuts in 2018-2020

Private Payer Rates From	Reported	Set Payment Rate For
January - June 2016	January - May 2017	2018 - 2024
January - June 2019	January - March 2024	2025 - 2027

- In between these cycles, new codes are priced on the CLFS by crosswalk or gapfill

Source(s): Foley Hoag, ADVI

PAMA "Reform:"
Saving Access to Laboratory Services Act (SALSA)

- First introduced as H.R. 1835 and S. 1000 on March 28, 2023
- Moves the next data collection period to 2026 and the next data reporting period to 2027
- Changes data reporting to every 4 (versus 3) years
- Collects private payer rate data from a "statistically valid" sample of applicable laboratories rather than all applicable labs
    - Includes non-independent labs like hospital laboratories, hospital outreach laboratories, and physician office laboratories

Source: Congress.gov, Foley Hoag

PAMA "Reform:"
Saving Access to Laboratory Services Act (SALSA)

- Defines "widely available CDLT" as a CDLT with a payment rate under $1,000 for which Medicare makes payment to at least 100 labs
  - Likely excludes most molecular (and all sole source) tests

- Lowers the cap on year-to-year rate decreases and makes it permanent, while also capping rate increases

- Excludes Medicaid MCOs from reporting requirements

Source: Congress.gov, Foley Hoag

SALSA is “very unlikely to pass” . . . and implementation would take years

- Potential headwinds
  - Status quo saves money, whereas implementation will cost money
  - CBO has not yet provided budget estimates (expected to be significant)
  - Current situation in Congress (and the world)

- Implementation will take 4-5 years
  - CMS does not have statisticians to develop the sampling methodology
  - Must do rulemaking before implementation is even possible

Source: 2023 AdvaMed Diagnostic Summit

Price Transparency Initiatives

Price transparency initiatives: Lower Costs, More Transparency Act

- First introduced as H.R. 5378 on September 8, 2023 (no Senate companion?)
- Reviewed by House Committees on Energy and Commerce, Ways and Means, and Education and the Workforce
- Title I, section 102 of the bill addresses clinical diagnostic laboratory test (CDLT) price transparency

Source: Congress.gov, Foley Hoag

Lower Costs, More Transparency Act (H.R. 5378): CDLT price transparency requirements

- Requires applicable laboratories, effective January 1, 2026, to publish and annually update the following information regarding “specified clinical diagnostic laboratory test[s]”
  - Discounted cash price
  - De-identified minimum payer-specific negotiated charge
  - De-identified maximum payer-specific negotiated charge between laboratory and third-party payer

- Must include the price or rate for any ancillary item or services (e.g., specimen collection) normally furnished by laboratories as part of the specified clinical diagnostic laboratory test

Source: Foley Hoag

Lower Costs, More Transparency Act (H.R. 5378): CDLT price transparency requirements

- Transparency requirements only apply to applicable laboratories as defined in PAMA regulations, excluding all labs that do not receive Medicare payment

- Reporting requirements apply only to "specified clinical diagnostic laboratory tests" (defined as "clinical diagnostic laboratory test that is included on the list of shoppable services specified by [CMS] . . . other than such a test that is only available to be furnished by a single provider of services or supplier" (so sole source tests are excluded)

Source: Foley Hoag

Thank you.

Questions and comments are welcome.

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