AMERICAN CLINICAL LABORATORY ASSOCIATION

August 28, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Transitional Coverage for Emerging Technologies (CMS–3421–NC)

Dear Administrator Brooks-LaSure,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the proposed procedural notice entitled, "Medicare Program; Transitional Coverage for Emerging Technologies" (TCET).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

ACLA's comments are focused on the following issues:

- Inclusion of diagnostic laboratory test nominations for the TCET pathway.
- Sharing Evidence Previews with Medicare Administrative Contractors (MACs).
- Coverage of "similar devices."
- Coding and payment for emerging technologies.

ACLA appreciates that CMS values the input and feedback of specialty societies and patient advocacy organizations, encouraging the provision of feedback on the state of evidence for nominated devices, while indicating an intention to be flexible with review of such feedback, even after the close of an NCD public comment period.[2] ACLA values its collaborative relationship with CMS and hopes to have the opportunity to participate in the agency's process.

A. Inclusion of diagnostic laboratory test nominations for the TCET pathway

In the notice with comment period, CMS addresses the inclusion of diagnostic laboratory tests in the TCET program. CMS states:

> "In section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1), the definition of device includes diagnostic laboratory tests. Diagnostic laboratory tests are a highly specific area of coverage policy development, and CMS has historically delegated review of many of these tests to specialized MACs. We believe that the majority of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by the MAC through existing pathways."[3]

[1] 88 Fed. Reg. 41633 (Jun. 27, 2023).
[2] *Id.* at 41642.
[3] *Id.* at 41639.

ACLA is concerned that diagnostic laboratory tests that would otherwise meet the eligibility requirements for TCET will be excluded from the program arbitrarily. For the reasons described further below, ACLA urges CMS to treat all diagnostic laboratory tests as eligible for the TCET pathway on the same basis as other items and services if they otherwise meet the criteria of an "appropriate candidate" for the TCET pathway as set forth in section II.C. of the notice separate from this statement.

ACLA understands the term "diagnostic laboratory tests" to include both in vitro diagnostic (IVD) test kits that are distributed by device manufacturers and laboratory developed tests (LDTs) that are developed and offered by laboratories. ACLA's long-standing position is that LDTs do not qualify as "devices" as defined in the Food, Drug, and Cosmetic Act (FDCA) and, accordingly, FDA lacks statutory authority to require LDTs to be approved or cleared as medical devices. However, if the developer of an LDT voluntarily chooses to seek out and receives FDA clearance or approval for its test, it becomes subject to regulation as a medical device. Therefore, LDTs that receive voluntary FDA clearance or approval may be granted a Breakthrough Designation and could become eligible for the TCET pathway.

CMS proposes that the majority of coverage determinations for diagnostic laboratory tests granted Breakthrough Designation should continue to be determined by the MACs through existing pathways, and may not be eligible for the TCET pathway, based on two assertions: (1) diagnostic laboratory tests are a highly specific area of coverage policy development; (2) that CMS has historically delegated review of many of these tests to the MACs. Regarding the first assertion, while ACLA recognizes that there are many diagnostic laboratory tests covering a very broad array of diseases and conditions, there are also many non-diagnostic medical devices with other functions for which specific expertise may be needed for some coverage decisions. ACLA does not agree that singling out diagnostic laboratory tests for potential exclusion of eligibility in TCET is justified based on a potential for requiring specific expertise to review. The second assertion is true but is not sufficient to justify CMS's potential exclusion of diagnostic laboratory tests. While CMS notes its historical delegation of coverage review for many diagnostic laboratory tests to the MACs, CMS does have several longstanding and recent national coverage determinations (NCDs) specific to both routine and esoteric testing (*e.g.*, molecular diagnostics). Viewed separately and together, the justifications offered by CMS for its general exclusion of diagnostic laboratory tests from eligibility for the TCET coverage pathway do not adequately support exclusion from TCET eligibility and may discourage test developers from pursuing the TCET pathway, furthering delays in Medicare beneficiary access to innovative tests. With laboratory diagnostics comprising almost one-quarter of previously recognized Breakthrough devices that have received FDA clearance or approval, ACLA is concerned that this policy would limit program participation.

CMS suggests that "the majority" of coverage determinations for diagnostic laboratory tests granted Breakthrough Designation would be deferred to the MACs without articulating clear criteria by which CMS would decide which tests would fall within the minority that could be eligible for the TCET pathway. Generally, CMS states that it anticipates accepting up to five TCET candidates annually and that it will "prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare."[4] While ACLA recognizes the resource constraints on the Agency in implementing the TCET program, we urge CMS to provide further details on the criteria the Agency will use to determine which devices

[4] *Id.* at 41644.

it would give priority in terms of TCET review, and more specifically, the criteria the Agency will use to determine which diagnostic laboratory tests will be eligible for the TCET pathway if it maintains its position to defer coverage determinations to the MACs for the majority of diagnostic laboratory tests.

CMS anticipates reviewing eight TCET candidates per year and proposes to limit the acceptance to only five candidates. ACLA recommends that CMS provide additional information on how the Agency will proceed once the first five candidates have been identified in any given year, since there may be other acceptable candidates later in a particular year.

B. CMS should not share an Evidence Preview with a MAC

ACLA strongly recommends that CMS not share an Evidence Preview with one or more MACs.[5] A MAC should conduct its own evidence review when considering coverage for an item or service, per the requirements for developing a local coverage determination outlined in the Medicare Program Integrity Manual, Chapter 13.[6] CMS indicates that an Evidence Preview will be conducted by a contractor using public resources, but some MACs are owned by parent companies that have non-Medicare business lines for which they may use an Evidence Preview without the technology developer's knowledge or consent. TCET communications should be for the express purpose of evaluating the technology within the confines of the TCET program. As an alternative, if CMS does share an Evidence Preview with a MAC, it should be required to get the technology developer's express consent prior to doing so.

C. Coverage of "similar devices"

CMS seeks comments on whether coverage of similar devices using CED would "establish a level playing field and avoid delays in access that would occur if a separate NCD were required to ensure coverage."[7] CMS has not defined what constitutes a "similar" device. ACLA recommends that CMS rely on historic coverage precedent such as that established in NCDs 210.3 (Colorectal Cancer Screening Tests) and 90.2 (Next Generation Sequencing (NGS)) that enable coverage of the category of tests rather than the coverage of a specific test that requires a reopening with each new technology. ACLA recommends that CMS define what constitutes a similar device so developers can understand their options in advance. For instance, it is possible that a second developer's device uses different technology, but the clinical application and performance of the tests are similar. This does not seem to be a 'similar device'. In addition, the Agency states that similar devices would be subject to the requirement to propose an Evidence Development Plan (EDP), which will require CMS's time and resources to review.[8] ACLA recommends that "similar devices" should not count towards the maximum five TCET candidates annually. We recommend that CMS provide additional guidance on the treatment of similar devices within the TCET program to enable industry to continue to have a productive dialogue related to bringing new technologies to market.[9]

D. Coding and payment

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[5] *Id.* at 41641.
[6] *See* 42 U.S.C. § 1395y(l)(5)(D); *see also* Medicare Program Integrity Manual (Pub. No. 100-08), Ch. 13, Sec. 13.5.3.
[7] 88 Fed. Reg. 41642.
[8] *Id.*
[9] *Id.* at 41644.

CMS notes that "CMS encourages manufacturers not to delay submitting nominations to facilitate alignment among CMS benefit category determination, and coverage, coding and payment considerations."[10] However, coding and payment processes related to the TCET program are not addressed in the notice with comment period. Coverage is an important step towards ensuring appropriate access to medical technologies for Medicare beneficiaries. Coding and payment also are essential aspects of access. As TCET candidates are truly innovative breakthrough technologies, it is unlikely that a Healthcare Common Procedure Coding System (HCPCS) code or Medicare payment rate already will be established at the time of FDA-approval/clearance and TCET candidate approval. We urge CMS to provide guidance on how the Agency will ensure that coding and payment are addressed quickly and efficiently to facilitate the claims process for TCET technologies. If a code for the technology does not already exist or the developer is not pursuing a code through other pathways, CMS should establish at least a temporary HCPCS code (or if possible, a permanent code) and associated payment rate(s) in consultation with the technology developer within three months of FDA approval/clearance.

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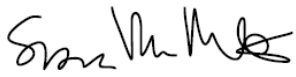
Thank you for your consideration of the ACLA's comments on this important program. Please contact ACLA's Senior Vice President of Policy & Strategy, Adam Borden, at aborden@acla.com, with any questions.

Sincerely,



Susan Van Meter
President
American Clinical Laboratory Association

[10] *Id.* at 41639.