Point of Care TESTING ASSOCIATION

August 21, 2023

VIA Electronic Submission to regulations.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3421–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Transitional Coverage for Emerging Technologies (TCET) (CMS-3421-NC)

Dear Ms. Brooks-LaSure:

On behalf of the Point of Care Testing Association (POCTA), we would like to thank the administration for providing notice and inviting comments on TCET. We are writing to request certain improvements to the TCET pathway.

POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the point of care (POC) benefits patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients in a variety of care settings, from clinics to pharmacies to community centers to non-hospital facilities (e.g., assisted living). POCTA works to develop reimbursement policies that can improve health outcomes by supporting access to POC testing. POCTA is comprised of Abbott Rapid Dx, Abbott Point of Care, Beckman Coulter, Becton, Dickinson and Company (BD), Cepheid, Qiagen, Roche Diagnostics, and Siemens Healthineers.

In general, POCTA supports the agency's efforts to develop a transparent, predictable, collaborative, and expedited national coverage pathway for innovative medical devices. However, POCTA recommends that CMS make the following revisions to TCET:

In Vitro Diagnostics (IVDs) should be eligible for inclusion in TCET. The notice states "In section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), the definition of device includes diagnostic laboratory tests. Diagnostic lab 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."

Coverage policy development is highly specialized regardless of the intervention or disease condition. POCTA agrees that certain diagnostic tests – i.e., nucleic-acid (DNA or RNA)-based tests performed by (typically high-complexity) clinical laboratories in twenty-eight (28) states – are eligible for review by the Palmetto GBA Molecular Diagnostic Services (MolDX) Program. However, the MolDX Program's specialized expertise is not available to non-molecular tests nor clinical laboratories in the twenty-two (22) states physically located outside of the MolDX jurisdiction. Even for those labs/tests that do fall within MolDX's jurisdiction, FDA-approved breakthrough devices will only be eligible for coverage if a "foundational" LCD identifies the test as a coverable service and the performing lab then submits a detailed Technical Assessment, which may delay coverage for several months (if not years) following FDA approval. And finally, even if the MolDX program determines that an assay is promising but evidence does not yet support "full" Medicare coverage, MolDX does not have authority to leverage "coverage with evidence development" while laboratories generate additional performance data. Therefore, the MolDX Program is complementary to – but not a replacement for – TCET.

Furthermore, diagnostic devices have just as much potential to improve Medicare beneficiary health outcomes as therapeutic devices. For example:

- Several studies have found that HbA_{1c} testing at POC has the potential to improve diabetes management by changing physician and patient behavior alike.[1,2] A randomized controlled trial of type 1 and insulin treated type 2 diabetic patients found that patients who utilized POC HbA_{1c} testing had significantly decreased levels at 6 and 12 months compared to those who did not receive POC testing.[3] A prospective controlled trial found that POC HbA_{1c} testing in patients with type 2 diabetes increased both the frequency of intensification of therapy while also lowering A_{1c} levels compared to those were tested at routine visits.[4]
- A meta-analysis found evidence that dipstick tests are especially useful in excluding the presence of infection for urinary tract infections if the results of both

[1] UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352(9131):837-853.

[2] Cagliero E, Levina EV, Nathan DM. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. *Diabetes Care*. 1999;22(11):1785-1789. doi:10.2337/diacare.22.11.1785

[3] Cagliero E, Levina EV, Nathan DM. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. *Diabetes Care*. 1999;22(11):1785-1789. doi:10.2337/diacare.22.11.1785

[4] Miller CD, Barnes CS, Phillips LS, et al. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. *Diabetes Care*. 2003;26(4):1158-1163. doi:10.2337/diacare.26.4.1158

nitrites and leukocyte-esterase are negative, thus reducing unnecessary prescribing of antibiotics.[5]

- A retrospective study found that implementation of POC testing polymerase chain reaction (PCR) tests as standard of care in outpatients with acute pharyngitis symptoms reduced the volume of inappropriate antibiotic prescriptions by 44.1% for patients with a negative POC PCR test result.[6]

We further recommend that CMS refrain from limiting TCET eligibility to only those devices who receive "breakthrough" designation. While leveraging the "breakthrough" process is one way to identify impactful devices, any number of considerations may impact a manufacturer's willingness to apply for – and FDA's willingness to grant – breakthrough designation to a particular device. For those devices that do not have "breakthrough" designation, CMS should establish alternative criteria that it will consider when deciding whether a device is appropriate for inclusion in the program. (A potential analogue for this positioning is the New Technology Add-on Payment (NTAP) program, which establishes pathways to recognition for both breakthrough and non-breakthrough devices.)

Considering the above, we respectfully request that CMS create a "level playing field" for diagnostic testing services – including those without "breakthrough" designation – and evaluate such services without a presumption against inclusion.

Refine "prioritization" criteria to include additional considerations. When selecting the "up to 5" TCET candidates each year, CMS intends to prioritize "innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare." While the number of individuals potentially impacted is certainly one relevant consideration, CMS should publish an updated list that includes additional factors it will consider when making prioritization decisions, including:

- What is the magnitude of the benefit(s) to patients?
- How likely (and how quickly) will patients see such benefits?
- What unmet need(s) does the device address?
- Does the device expand access to underserved populations?
- Does the device support critical public health goals (e.g., reduced transmission of infectious disease, improved antimicrobial stewardship)?

[5] Devillé WL, Yzermans JC, van Duijn NP, Bezemer PD, van der Windt DA, Bouter LM. The urine dipstick test useful to rule out infections. A meta-analysis of the accuracy. BMC Urol. 2004 Jun 2; 4:4. doi: 10.1186/1471-2490-4-4. PMID: 15175113; PMCID: PMC434513.

[6] May L, Sickler J, Robbins EM, Tang S, Chugh K, Tran N. The Impact of Point-of-Care Polymerase Chain Reaction Testing on Prescribing Practices in Primary Care for Management of Strep A: A Retrospective Before-After Study. Open Forum Infect Dis. 2022 Mar 24;9(5):ofac147. doi: 10.1093/ofid/ofac147. PMID: 35531385; PMCID: PMC9070329.

We recognize that these factors may, to some extent, have been considered by the FDA when making the decision to grant "breakthrough" designation. However, focusing solely on those technologies that will benefit "the greatest number of individuals" will exclude technologies that may have a profound impact on smaller (including orphan) populations. Furthermore, insofar as CMS coverage decisions are made with different considerations in mind than FDA "breakthrough" designations, we recommend that CMS expressly retain the flexibility to consider additional factors.

Qualifications of contractor performing Evidence Preview (and substantive criteria for same). The notice contemplates the use of a third-party contractor to draft the initial Evidence Preview, and then again to revise the same after receiving feedback from the manufacturer. The notice does not, however, outline specific qualifications that CMS would use to select the contractor (e.g., qualifications, procedures to prevent conflicts of interest), nor does it provide a summary of the criteria that the contractors will use when making such assessments (beyond saying that it will be conducted using "standardized evidence grading, risk of bias assessment, and applicability assessment according to a protocol initially developed in collaboration with AHRQ)." We urge CMS to clarify its position on both points, so that manufacturers can make an informed decision on participation.

Limitations on use of the Evidence Preview document. In the event the manufacturer withdraws from the TCET pathway, CMS intends to share the underlying Evidence Preview with the local MACs to inform their decision-making. We note, however, that an Evidence Preview based on a review of a portion of the evidence that will eventually be available – and drafted with an eye towards identifying evidentiary gaps to be addressed in future studies – is prepared with a fundamentally different aim than a MAC LCD, which entails review of all available information at the time, including information that may not have been available at the Evidence Preview stage. Given the limitations of this document, we urge CMS to reconsider its plans to share the Evidence Preview with the local MACs. That being said, insofar as CMS intends to give MACs access to this document, CMS should instruct the MACs that if they decide to utilize the Evidence Preview to inform the development of an LCD, they must do so in a manner consistent with the Program Integrity Manual – i.e., the Evidence Preview can be a piece of evidence that informs the development of an LCD, but the LCD itself must be subject to the same notice and comment requirements as any other proposed LCD. Furthermore, CMS should instruct the MACs that they must consider any additional evidence generated between the Evidence Preview finalization and a MAC's consideration of a potential LCD.

Coordination of benefit category determination, coding, and payment reviews. CMS "aims to coordinate" benefit category, coding, and payment reviews as part of TCET. The notice does not, however, provide any meaningful information on how such coordination will occur – particularly as it relates to coding and payment reviews, respectively. With respect to benefit category determinations, CMS notes that they are working to "better align the coverage and BCD process" – but then acknowledges that

such reviews may not be completed within 3 months in some cases (e.g., for combination products, or products that span multiple benefit categories). We urge CMS to provide more granular information on how this process will work – and the timelines on which it will work – so manufacturers may evaluate whether to participate in the program.

Timelines to issuance of final NCD. The notice is not clear regarding the timing of the final NCD. In one place, CMS states that it intends to finalize an NCD within 6 months after market authorization, while in another, CMS explains that it intends to issue a proposed NCD and EDP within 6 months of opening the NCD. We understand that CMS would likely need ~90 days from the time of publishing a draft NCD to finalization (to account for the statutory 30-day comment period on the draft, and then consideration of those comments), but would encourage CMS to (a) consider what it can do to reasonably streamline the period between posting of the tracking sheet and the draft NCD, and (b) commit to more definitive timepoints when making going through the TCET/NCD process.

Furthermore, with respect to the NCD development and implementation process more generally, we offer the following recommendations:

- *Timeline for response to a formal NCD request.* In the TCET notice, CMS states that it will make a preliminary decision to provisionally accept or decline a nomination within 30 business days. POCTA strongly supports this timeline, as it will allow manufacturers to obtain feedback in a timely manner. In the accompanying "CMS National Coverage Analysis Evidence Review" document, however, CMS makes no similar commitment to respond to non-TCET NCD requests. In practice, formal acceptance does not occur on a predictable timeline, and may take many months (if not years). To enhance the transparency of the NCD process more generally, we urge CMS to commit to responding to non-TCET NCD requests on a more well-defined timeline, like what CMS proposes for TCET.
- *Timeline for publication of implementing transmittals.* Neither the TCET notice nor the NCA document more generally establish a timeline by which CMS will publish a transmittal implementing a new or revised NCD. In practice, the publication of these transmittals may be delayed several months after an NCD effective date, causing confusion for providers, beneficiaries, MACs, and Medicare Advantage plans while waiting for updated guidance. To facilitate timely beneficiary access to novel technologies and minimize burden on healthcare providers, we urge CMS to commit to publishing implementing transmittals in a timely fashion (e.g., within 90 days of an NCD).

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We thank you in advance for your consideration of these comments, and we value CMS's ongoing efforts to expedite coverage for novel medical devices. If you have any

questions about these recommendations, we would be pleased to meet virtually to discuss at your convenience. Please contact Mike Ryan at 202.756.8088, or via e-mail to mryan@mwe.com, if we can be helpful to CMS in any way.

Sincerely,

Mike Ryan
On behalf of the Point of Care Testing Association