COLLEGE of AMERICAN PATHOLOGISTS

August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Atten: CMS-3421-NC
P.O. Box 8013
Baltimore, MD 21244-8103

Subject: Medicare Program; Transitional Coverage for Emerging Technologies

Dear Administrator Brooks-LaSure,

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed procedural notice CMS-3421-NC creating the "Transitional Coverage for Emerging Technologies (TCET)" pathway. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP applauds CMS' continuing commitment to ensuring Medicare beneficiaries have more timely and predictable access to new and innovative medical technologies. We strongly believe that the quality of care provided to Medicare beneficiaries depends on access to treatments appropriate to their needs and we support the creation of an expedited coverage pathway that leverages, rather than undermines or circumvents, the current Medicare processes. We recommend that CMS move to finalize the TCET pathway with the clarifications and refinements outlined below. Additionally, as the TCET pathway utilizes the existing coverage with evidence development (CED) national coverage determination (NCD) process, the CAP is providing separate comments to CMS related to CED improvements.

Inclusion of diagnostic tests in TCET pathway

The proposed TCET pathway is designed to expedite Medicare coverage for FDA-designated breakthrough devices. As CMS notes, 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. Further, under the 21st Century Cures Act, to qualify as "breakthrough" a device must demonstrate that it has a reasonable chance of providing more effective treatment than the standard of care for the treatment or diagnosis of life threatening or irreversibly debilitating human disease or condition. CMS acknowledges that diagnostic tests, as devices, would be eligible for the TCET pathway. However, CMS states that coverage determinations for diagnostic tests granted breakthrough designation ought nonetheless to continue to be determined by the Medicare Administrative Contractors (MACs) through the existing local coverage determination (LCD) pathway.

The CAP has previously argued that coverage decisions by CMS should not preclude MACs from determining coverage for new technologies at the local level as they become available. Indeed, we continue to believe that MACs should retain the flexibility to reasonably choose to cover new technologies not yet reviewed by the FDA, by applying a rigorous review process per national guidelines. However, the current LCD process does not offer a viable option for expedited coverage for promising tests that lack

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sufficient evidence, nor do MACs have the authority to develop such alternative coverage pathways. Instead, the local process – like an NCD – relies heavily on health outcomes data, particularly with regard to Medicare beneficiaries, to determine whether a device meets the "reasonable and necessary" criteria for coverage. Therefore, under the current LCD process, diagnostic tests that show promise but have gaps in evidence continue to lack coverage. Excluding diagnostic tests from the TCET pathway ignores the value and benefit that emerging diagnostic tests can have for Medicare beneficiaries.

Additionally, the CMS Program Integrity Manual, Chapter 13, Local Coverage Determinations, does not specify timelines for MACs to conduct and conclude coverage decisions for new local coverage requests. New requests require MACs to follow the LCD development process outlined in Chapter 13, of Pub. 100-08. In the absence of timelines in the LCD guidelines for MACs to review available evidence, solicit input from the public, and assess public comments, it can take a year or longer before learning if a request will receive coverage, substantially delaying the benefits that a new diagnostic test can bring to Medicare beneficiaries.

We understand that the new TCET pathway uses existing NCD and CED processes, and as mentioned above, the CAP is submitting separate comments in response to CMS' recently proposed CED guidance document. As we have commented before, the CAP is concerned that – as currently deployed – the CED process takes too long to result in a coverage or non-coverage decision that would ensure timely access to new technologies, and only offers treatment to a limited population of patients who have access to trials and registries.

**Given the key differences between the LCD process used by MACs, the existing NCD processes, and the TCET pathway, the CAP is concerned that excluding diagnostic tests from the TCET pathway would deny Medicare beneficiaries the important benefits that emerging diagnostic tests can have for patients, and the CAP strongly urges CMS to ensure that diagnostic tests can appropriately access the TCET pathway.** We therefore urge CMS to remove the language suggesting that coverage for diagnostic tests qualifying for breakthrough designation should continue to be determined by the MACs through existing pathways. The CAP further encourages CMS to evaluate future ways to broaden the TCET pathway to include innovative medical technologies beyond FDA-designated breakthrough devices and existing Medicare benefit categories.

<u>Transparency</u>
CMS states it anticipates receiving approximately eight TCET nominations per year but approving only five candidates from those nominations, citing CMS' resource constraints. Not only are we skeptical of the number of nominations CMS expects to receive, as we believe the number could be much larger, but CMS' proposal to only allow five devices per year into the TCET pathway fails to create an adequate coverage pathway for breakthrough devices. Further, CMS states it intends to prioritize innovative medical devices that, "as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare." Yet, CMS fails to describe the criteria upon which the agency intends to base its determination or to specify how it intends to balance the number of potential beneficiaries against the potential degree of benefit.

The CAP appreciates that the TCET pathway is designed to deliver "transparent, predictable, and expedited national coverage," but we are concerned about the unspecified criteria CMS may use to prioritize those innovative technologies the agency

believes have "the potential to benefit the greatest number of individuals with Medicare." As we have expressed before, the CAP has concern about coverage pathways that have the potential to arbitrarily decide which technologies receive a head start or other advantage in the traditional coverage process. **To increase transparency in this area, the CAP recommends that CMS make public its list of review requests, its methodology for determining which innovative technologies have the potential for greatest benefit to Medicare beneficiaries, and how the technologies are selected to participate in the TCET pathway. Further, we ask that CMS provide information on how frequently it will publicly update this information.**

Timelines and stakeholder involvement

The CAP has consistently called for increased transparency and stakeholder involvement in coverage processes, together with predictable timelines. While CMS is attempting to improve both predictability and transparency, there are gaps in the TCET pathway timeline. Specifically, in the premarket state, CMS acknowledges some timeframes may take longer, such as with the evidence preview and FDA market authorization. Given these gaps, it is unclear if the proposed timeline for the TCET pathway is realistic. We appreciate the estimated timelines provided thus far and ask CMS to continue efforts to create specific/predictable and transparent timelines.

Finally, the CAP appreciates that as the TCET pathway utilizes the current NCD process, the same opportunities for stakeholder engagement would also be available in TCET. We also support CMS' consideration of any information provided that is in the public domain while undertaking an NCD, including specialty society feedback posted publicly on websites.

Sharing evidence with MACs

The CAP supports an opt-in approach wherein a manufacturer would voluntarily notify CMS of its interest in pursuing the TCET pathway and have the option to withdraw from the process at any point in time. This approach allows manufacturers/test developers to pursue their own business judgment. However, CMS states that if a manufacturer withdraws from the TCET pathway during the premarket process it will not publicly post the evidence preview but will share it with MACs to aid them in their decision making. The CAP believes that CMS should make every effort to ensure the protection of a developer or manufacturer's proprietary information about a device that it has developed. **If a manufacturer withdraws from the process during the premarket stage, proprietary information should remain protected by CMS unless the developer or manufacturer of a device consents to releasing the information to MACs.**

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The CAP is pleased to have the opportunity to comment on these important issues and appreciates your consideration of these comments. Please direct questions to Nonda Wilson at nwilson@cap.org or (202) 354-7116.