COLLEGE of AMERICAN PATHOLOGISTS

August 21, 2023

Coverage with Evidence Development Proposed Guidance Document, June 22,2023
Coverage and Analysis Group, Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS)
Mailstop: S3-02-01, 7500 Security Blvd.
Baltimore, MD 21244
Re: College of American Pathologists comments

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP has been active in working to improve both local and national coverage processes to ensure equal access to quality care for Medicare beneficiaries. Part of this work includes ensuring appropriate conditional coverage through an effective coverage with evidence development (CED) process. As the Centers for Medicare & Medicaid Services (CMS) notes in their updated guidance document, CED has been used to support evidence development for certain items and services that are likely to show benefit for the Medicare population. The CAP has previously urged CMS to improve the current process by using establishing specific and transparent timelines and endpoints, and generally increasing transparency, flexibility, and stakeholder input to incentivize innovation and afford timely access to services for patients.

The CAP supports CMS' proposed guidance on the factors it considers in making NCDs using the CED paradigm. Specifically, we agree with the additional details around milestones and study population, and we support any efforts that increase transparency and stakeholder input. Although the proposed guidance does not substantively alter the process for national coverage using the CED paradigm, it does reflect CMS' commitment to ensuring access to promising treatments for Medicare beneficiaries by providing a framework for more predictable and transparent evidence development, ensuring populations studied represent the diversity in the Medicare beneficiary population, and providing for the timely completion of the CED process. However, while not discussed in this guidance document, the CAP also maintains that CED must be selectively utilized and intended only to provide for evidence-based coverage that will accelerate and expand access to services and items for patients, rather than restrict their use by physicians and other providers.

Transparency

As CMS notes, CED occurs within the existing national coverage determination (NCD) process which is transparent and open to public comment. We agree with CMS that the CED process should be conducted transparently to facilitate effective information exchange and afford the opportunity for relevant stakeholder input and engagement, including patient groups, professional societies, regulators, and others. The CAP also agrees with CMS' proposal to publish its findings of data from clinical studies regardless

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

of whether a study is completed or generates favorable evidence, as a way to inform patients and providers about the benefits and risks of available health care options and to further promote transparency. Additionally, as a way of increasing transparency and availability of study results, we support any added flexibility around the publishing of results outside of peer-reviewed publications when peer-reviewed publication is not possible, while ensuring appropriate standards and safeguards. Finally, the proposed guidance specifies that the CED study be registered with ClinicalTrials.gov, which CMS hopes will help ensure that Medicare beneficiaries and their treating health care professionals have pertinent information about CED studies. And the guidance also specifies that the study be conducted by sponsors/investigators with the resources to complete it successfully. However, we remain concerned about the lack of transparency around the funding and maintenance of data collection and the CAP urges CMS to also make this information available to the public.

Study population

As is noted in the guidance document, CED has been a pathway whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. For these studies and data to be relevant, it is imperative that CMS improve the criteria around study population. The CAP believes addressing barriers to entry for underrepresented diverse populations in clinical trials will improve clinical research, patient safety, and ensure high-quality care in disease diagnosis and management. We applaud CMS for recognizing the importance of a study population that reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended users of the intervention and for requiring a plan for the retention and reporting of the populations in a clinical trial. A carefully and accurately defined study population will enhance the completed study's relevancy and help assure the overall validity of the study results.

Timeline for completing the CED process

The CAP agrees with CMS that an NCD that requires CED as a condition of coverage should not last indefinitely, and in fact, we continue to believe that for any technology or service provided coverage through CED, an endpoint should be established for when the process is complete. We are hopeful that the inclusion of a written plan that describes the schedule for completion of key study milestones, including results reporting, will help ensure timely completion of the CED process. However, any further standards that improve the predictability of the CED process through set start and end dates and/or a specific and transparent timeline and endpoint would address additional issues.

Additionally, during the premarket stage of the Transitional Coverage for Emerging Technologies (TCET) pathway, a study approved by CMS as part of an Evidence Development Plan (EDP) must have established start and end dates. However, for studies transitioning to post TCET coverage that require additional CED to generate sufficient evidence to support a national coverage determination, the proposed CED guidance does not define "sufficient evidence" or specify a time limitation or outcome criterion for generating such evidence. The CAP recommends CMS define "sufficient evidence" to meet the threshold for national coverage and specify a time limitation or outcome criterion to meet that threshold.

COLLEGE of AMERICAN PATHOLOGISTS

Transition to Medicare coverage determination

The proposed CED guidance suggests that when transitioning from a CED NCD to coverage without evidence development requirements, sponsors should build interim analyses into their study design and communicate these results to CMS. Although this may increase the burdens on the trial sponsor, the CAP believes that interim analyses have the potential to modify the conduct of a study by allowing for decisions and changes to be made in the population sample or study protocol during the evidence gathering stage, thus potentially saving time in operations and coverage decision-making processes. As we outlined in our comments in response to the TCET proposed procedural notice, the CAP supports expedited coverage that ensures Medicare beneficiaries have more timely and predictable access to new and innovative medical technologies.

Thank you for your willingness to consider our comments on the general requirements for clinical studies submitted for CMS coverage requiring CED. The CAP welcomes the opportunity to provide CMS with additional clinical or other information to assist CMS with its coverage policy decisions and we look forward to continuing our work to improve access to care for all patients. Please direct questions to Nonda Wilson at nwilson@cap.org or (202) 354-7116.

Sincerely,

College of American Pathologists

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100