COLLEGE of AMERICAN PATHOLOGISTS

November 7, 2022

To Whom It May Concern:

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 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. Therefore, as the MEDCAC meets to evaluate the CED criteria and related issues, we urge the Centers for Medicare & Medicaid Services (CMS) to improve the current process by using CED selectively to provide evidence-based coverage, establishing specific and transparent timelines, and generally increasing transparency, flexibility, and stakeholder input to incentivize innovation and afford timely access to services for patients.

As you know, Medicare generally does not cover experimental or investigational items and services as reasonable and necessary under section 1862(a)(1)(A) of the Act (and regulations at 42 CFR 411.15(o)). However, CED allows Medicare to provide conditional coverage for new technology and services while CMS collects additional evidence on the efficacy of the technology or service. Medicare has employed the concept of CED for years, but it “has been nearly 8 years since the criteria for CED were last evaluated and codified.” As CMS notes, in that time, technologies have become more complex and “there has been growing appreciation and commitment to transparency in decision-making” as well as to make certain that the populations studied are representative of the diversity in the Medicare beneficiary population. Further, while the CED program “can provide support for items and services that are likely to benefit the Medicare population,” the CAP is concerned that – as currently employed – the CED process takes too long to result in a coverage or non-coverage decision that would provide reasonable access to new technologies, and only offers treatment to a limited population of patients who have access to trials and registries.

To improve the current process, the CAP believes 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 use by providers. For example, the CAP expressed concern to CMS regarding CED around CAR-T therapy and Next Generation Sequencing as we felt the requirements were not practical and the policies not flexible, which could limit patient access to the best treatments. Instead, CED should support evidence development for certain innovative services and items where the evidence may not yet be complete or sufficiently persuasive without further data, information, or study. CED should apply only after a formal review of clinical literature and a decision to cover an item or service in the context of an approved clinical

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study or to assess the appropriateness of the item or service. The rationale for further study or collection of additional data/information should be well supported by available clinical literature and not duplicate existing knowledge. Additional data/information collection or study shall be methodologically appropriate and conducted in accordance with the applicable standards of scientific integrity. Further, CED should not be relied on as a response to requests for coverage of certain items and services by interested parties, especially where provision of those items/services are more limited/proprietary.

Improving the predictability of the CED process through set start and end dates and/or a specific and transparent timeline would address additional issues. Notably, a recent study identified the "wide range of program duration for the 4 programs with retired data collection requirements (4 to 12 years) and the long duration of CED programs resulting in NCD revocation (10 and 13 years)."[1] Another article, discussing the CMS decision to cover FDA approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, noted the need for a "timeframe for CED completion and for a decision on whether coverage should be modified or withdrawn, based on the results, and mechanisms to ensure that results are published in the peer-reviewed literature."[2] The CAP believes that for any technology or service provided coverage through CED, an endpoint should be established for when the process is complete.

Additionally, CMS has noted that CED occurs within the existing coverage determination process, which is transparent and open to public comment. We agree that the CED process should be conducted transparently and afford the opportunity for stakeholder input and engagement. This should include open, public, and on the record meetings with minutes posted for public inspection, and the CAP would stress that CED should apply clear evidentiary criteria made available and communicated to stakeholders with sufficient advance notice. This will facilitate the effective information exchange CED requires and also bolster accountability. Indeed, a recent study stressed that the CED design process should be collaborative with input from relevant stakeholders (including patient groups, professional societies, regulators, and others) and "identify a priori how data collection mechanisms will be funded, executed, and maintained, with contingencies for reconsideration as needed."[3] Transparency and stakeholder involvement should also be increased around the analysis of collected data generated in a trial or collected through a registry to avoid ambiguous conclusions.

Finally, CMS principles governing the application of CED include that CED will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices; CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials; and CED will be consistent with federal laws, regulations, and patient protection. The CAP believes these points are critical to the CED paradigm and coverage process.

[1] https://www.ajmc.com/view/coverage-with-evidence-development-where-are-we-now-
[2] https://www.healthaffairs.org/do/10.1377/forefront.20220124.479741/
[3] https://www.ajmc.com/view/coverage-with-evidence-development-where-are-we-now-

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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 contact Elizabeth Fassbender, CAP Assistant Director, Economic and Regulatory Affairs at efassbe@cap.org if you have any questions on these comments.

Sincerely,

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