

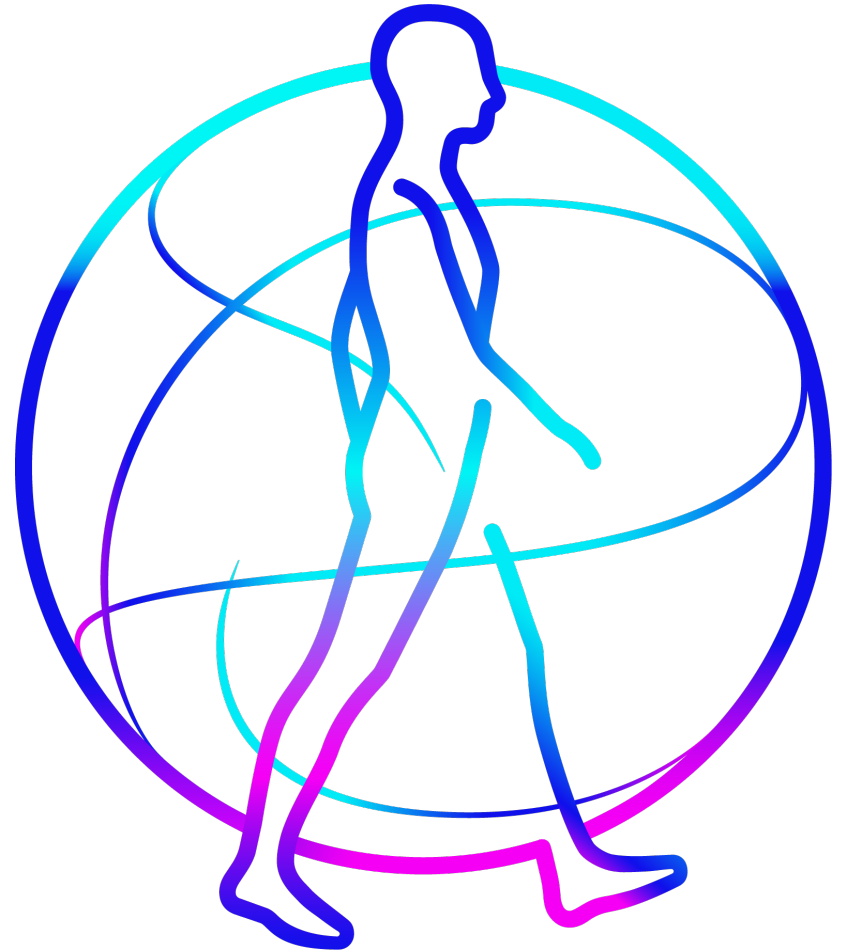


Engineering the extraordinary

Medicare Evidence Development and Coverage Advisory Committee on Coverage with Evidence Development Criteria

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Disclosures

- Lindsay Bockstedt is an employee of Medtronic, Inc. and shareholder of its parent company Medtronic plc (>\$10,000)
- Medtronic products are reimbursed directly and indirectly by Medicare and Medicaid programs and may be impacted by decisions related to the content of this meeting

Medtronic Experience with Coverage with Evidence Development (CED)

- Medtronic has a long history of working with CMS to generate meaningful evidence under CED with diverse approaches to evidence generation
 1. Implantable Cardiac Defibrillators for Primary Prevention: 2005-2018
 2. Transcatheter Aortic Valve Replacement: 2012 - ongoing
 3. Leadless Pacemakers: 2017 - ongoing
- Medtronic commends CMS on flexibility, engagement, and recent innovative approaches to CED
- CMS previously acknowledged the goal of striking a balance between broad patient access and additional evidence generation. We support this goal.
 - Micra CED study, and subsequent CED studies for leadless pacemakers, rely primarily on Medicare claims data to enroll patients, observe patient outcomes, and conduct comparative analyses
 - Exemplifies efficient and rigorous real-world evidence generation¹

1. El-Chami, M, Bockstedt, L., Longacre, C, et al. Comparison of Two-Year Outcomes Among Patients Implanted with a Leadless versus Transvenous Single-Chamber Ventricular Pacemaker in the Micra CED Study. European Heart Journal 2021 00, 1-9.; Piccini JP, El-Chami M, Wherry K, Crossley G, Kowal R, Stromberg K, Hinnenthal J, Bockstedt L. Contemporaneous Comparison of Outcomes Among Patients Implanted with a Leadless versus Transvenous Single-Chamber Ventricular Pacemaker. JAMA Cardiology 2021, 6(10):1187-1195; Wherry, K., Stromberg, K., Hinnenthal, J., Wallenfels, L., El-Chami, M., Bockstedt, L. Using Medicare Claims to Identify Acute Clinical Events Following Implantation of Leadless Pacemakers. Pragmatic and Observational Research 2020, 11: 19-26

Principles to Improve Coverage with Evidence Development (CED)

1. Ensure flexibility in study designs, data sources, methods and outcomes for CMS-approved CED studies
 - Flexibility ensures the studies are designed to address specific evidence gaps identified by CMS in the NCD
 - Continue strong engagement with manufacturers in evaluating evidence and developing fit-for-purpose CED study designs
 - Build upon recent CED studies that are examples of enabling patient access while simultaneously generating evidence and minimizing burden to providers on data collection
2. Ability for CMS to extend coverage for a technology/service to indicated Medicare beneficiaries beyond the enrolled CED study population
 - CMS should evaluate CED study populations to ensure it is representative of the demographic and clinical complexity of the Medicare population and that the study outcomes address evidence gaps identified by CMS in the NCD
 - Establishes a sustainable framework for CMS to continue considering innovative and efficient approaches to CED study designs
 - Balances goals of robust and efficient evidence generation with broad patient access to new technologies
3. Establish predetermined stopping rules for CED studies
 - Engage with manufacturers and other stakeholders to establish appropriate duration of CED studies upon study approval
 - Consider totality of evidence upon CED study sunseting