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Medtronic Comments to the Medicare Evidence Development and Coverage Advisory Committee on Coverage with Evidence Development Criteria

Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. Our devices and therapies address over 70 chronic conditions and diseases, and our product development process is firmly rooted in evidence-based medicine. We have a strong history of working with CMS to generate meaningful evidence under Coverage with Evidence Development (CED) for important technologies such as Implantable Cardioverter Defibrillators, Transcatheter Aortic Valve Repair, and Leadless Pacemakers. Through these CED programs we have experienced different approaches to conducting CED studies and that experience informs our comments on the CED requirements.

Specific to the MEDCAC review, Medtronic appreciates CMS's efforts, and that of the Agency for Healthcare Research and Quality (AHRQ), in updating the requirements for clinical studies submitted for CMS coverage under CED. CED is an important program, and we appreciate CMS's focus on maintaining a CED program that is rooted in efficient and methodologically rigorous criteria.

As CMS undertakes this update, Medtronic recommends that CMS focus on the following broad principles for CED requirements:

- **Ensure Flexibility in Study Designs, Data Sources, Methods, and Outcomes, Supporting CED.** In an effort to minimize burden in the generation of robust evidence, CMS should remain flexible in determining the most appropriate study design, data, outcomes, and analysis methods necessary to evaluate the effectiveness of individual technologies in the Medicare population (i.e., whether a comparative arm is necessary, types of data sources used and/or collected). Manufacturers, as developers of devices, are uniquely positioned to play a constructive role in ensuring that research will generate meaningful evidence. CMS should continue work with

manufacturers on fit-for-purpose study designs and clinical endpoints that will address specific evidence gaps necessary for CMS to make a coverage determination.

- **CMS Should Have the Flexibility to Extend Coverage for a Technology/Service to Indicated Medicare Beneficiaries Beyond the Enrolled CED Study Population.** Under the existing CED requirements, a technology/service is considered non-covered outside of CMS-approved CED study. Therefore, in order for a new technology/service to obtain broad patient access, every indicated Medicare beneficiary must be enrolled in the CED study to ensure coverage. This requirement can result in inefficient CED study designs, such as large national registries with costly and burdensome data collection for providers, in effort to advance patient access to the new technology/service. In recent CMS-approved CED studies, such as the leadless pacemaker CED study, the study sponsors were successful in designing efficient studies allowing them to strike a balance between broad patient access and robust evidence generation by using their Medicare administrative claims data. While the claims data-based studies represent an efficient study design and innovation in CED, Medtronic believes that in order to achieve efficiency within CED more broadly CMS should have the flexibility to extend coverage to the new technology/service for FDA-approved indications outside of a CMS-approved CED study in those instances when the study population reflects the demographic and clinical complexity of the Medicare patient population. There are a variety of innovative study designs, data sources, and methodological approaches (beyond the recent claims data-based studies) that could yield robust generalizable results on the impact that the new technology/service has on the Medicare patient population while simultaneously achieving broad patient access (i.e., not enrolling a census population).

  Extending coverage to an item/service beyond the specific population enrolled in the CED study as well as ensuring CMS has broad flexibility in CED study designs, data, methods, and outcomes it considers establishes a sustainable framework for CMS to consider innovative approaches to evidence development while also ensuring robust, yet efficient generation of meaningful evidence in the Medicare population.

- **Establish Predetermined Stopping Rules for CED Studies**. As part of efforts to develop efficient and fit-for-purpose study designs, CMS should work with manufacturers to establish predetermined stopping rules that dictate when evidence generated through CED is sufficient to inform an NCD.

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