Comments to the May 21, 2024 Meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)

Financial Disclosures

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- Advisory Boards:
  - NIH/NIDDK
  - Abbott Diabetes Care (<$10,000) Novo Nordisk (>$10,000), Dexcom (<$10,000), Insulet (<$10,000), Arecor Limited (<$10,000), Pendulum (<$10,000), Medical/Module (<$10,000), Mannkind (<$10,000), Cequr (<$10,000), Proventionbio (<$10,000), Eli Lilly (<$10,000), Medtronic Diabetes (<$10,000)
- Speaker Bureau:
  - Dexcom (>$10,000), Novo Nordisk (>$10,000), Eli Lilly (>$10,000), Cequr (<$10,000), Abbott (<$10,000)
- Institutional Research Support:
  - Abbott Diabetes Care, Novo Nordisk, Tandem, Insulet
- Stock Options:
  - Pendulum (not exercised)

General Commentary – Diabetes Technologies

- ADA guidelines[1] clearly state that real-time CGMs and insulin pump therapy should be available for all individuals with type 1 or insulin-requiring type 2 diabetes
- The clinical benefit of these technologies is not in dispute
  - Glucose control, as evidenced by current standard of care, improves outcomes
  - Glucose control is best-achieved (currently) through CGMs and insulin administration devices, notably insulin pumps
- The benefit of diabetes technologies is consistent across people with diabetes, regardless of type of diabetes and age[2]

[1] American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2024. Diabetes Care 1 January 2024; 47 (Supplement_1): S126–S144. https://doi.org/10.2337/dc24-S007

[2] See, e.g., Beck, R. W., Bergenstal, R. M., Riddlesworth, T. D., Kollman, C., Li, Z., Brown, A. S., & Close, K. L. (2019). Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. Diabetes care, 42(3), 400–405. https://doi.org/10.2337/dc18-1444, McGill, J.B., Hirsch, I.B., Parkin, C.G. et al. The Current and Future Role of Insulin Therapy in the Management of Type 2 Diabetes: A Narrative Review. Diabetes Ther (2024). https://doi.org/10.1007/s13300-024-01569-8, Aleppo, G., Hirsch, I.B., Parkin, C.G., McGill, J.B. et al. Coverage for Continuous Glucose Monitoring for Individuals with Type 2 Diabetes Treated with Nonintensive Therapies: An Evidence-Based Approach to Policymaking. Diabetes Technology & Therapeutics 2023 25:10, 741-751. https://doi.org/10.1089/dia.2023.0268

General Commentary – Diabetes Technologies

- The Diabetes Control and Complications Trial (DCCT)[1] conclusively demonstrated that good glucose control directly reduces the rates of several significant complications
  - This is the landmark diabetes study that serves as the foundation for clinical guidelines and evolution of new technologies
  - The duration of the main DCCT trial was 6.5 years
  - The primary consideration should be whether a device demonstrates the capacity to move patients to the target glucose range

[1] See, The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. Diabetes. 1996 Oct;45(10):1289-98. PMID: 8826962, The relationship of glycemic exposure (HbA1c) to the risk of development and progression of retinopathy in the diabetes control and complications trial. Diabetes. 1995 Aug;44(8):968-83. PMID: 7622004, Genuth S. Insights from the diabetes control and complications trial/epidemiology of diabetes interventions and complications study on the use of intensive glycemic treatment to reduce the risk of complications of type 1 diabetes. Endocr Pract. 2006 Jan-Feb;12 Suppl 1:34-41. doi: 10.4158/EP.12.S1.34. PMID: 16627378.

General Commentary – Clinical Trials

- Clinical trials for diabetes technologies are needed to demonstrate accuracy and utility of the diabetes device (e.g., CGM, insulin administration device)
  - Current device trials compare new technology to recently available technology
- Clinical benchmarks and study outcomes must be tailored to real-world considerations:
  - The control group may be using some diabetes technologies (CGM or current insulin pumps)
  - Accuracy and utility can be demonstrated in a clinical trial of 3 months duration
  - MCID, while an important metric, should consider the specific clinical trial design and population studied

Domains

- Across all domains, a three-month follow-up period for clinical trials is adequate and appropriate
  - This is the time frame that reflects changes in HbA1c, average blood glucose levels, TIR, and rates of hypoglycemia
  - This is also sufficient time to determine device safety
- There is no data that suggests longer follow-up periods are necessary for the Quality of Life and Health Outcomes domains

Endpoints

- Endpoints should be specific to:
  - Types of technologies being studied (e.g., CGM, insulin administration device, AID system)
  - Study population (e.g., T1D, insulin-requiring T2D, individuals experiencing hyper/hypoglycemic events)
  - Desired outcome(s) (e.g., addressing issues experienced by individuals with disabilities and diabetes)
- The primary consideration for endpoints should be:
  - Non-inferiority when current device is compared to recent technology (with respect to glycemic control endpoints, including hypoglycemia)
    - MCID for each “Surrogate Markers” metric is detailed in our written response
  - No worsening of quality of life (with respect to assessment tool scores)