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04/22/2024

Medicare Evidence Development and Coverage Advisory Committee
Coverage and Analysis Group (CAG)
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Attention: CMS-3458-N
Submitted via MedCACpresentations@cms.hhs.gov

RE: Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee-May 21, 2024

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ABOUT JDRF

JDRF is the leading global organization funding type 1 diabetes research. Our mission is to accelerate life-changing breakthroughs to cure, prevent, and treat type 1 diabetes and its complications, and we collaborate with a wide spectrum of partners to achieve this mission. Founded in 1970 by parents of children with type 1 diabetes, JDRF has invested over $2.5 billion in research since its inception and employs doctorate-level scientists to manage our research portfolio. JDRF is proud of our history and ongoing efforts funding groundbreaking research advancing care for people with type 1 diabetes, including multiple studies focused on the impact of continuous glucose monitors in older Americans.[1]

ABOUT TYPE 1 DIABETES

Type 1 diabetes (T1D) is an autoimmune disease that strikes children and adults suddenly. Until cures are broadly available, T1D is fatal in the absence of insulin replacement therapy and blood glucose monitoring. Treatment with insulin is lifesaving but requires people with T1D to walk a tightrope between disease and treatment related adverse events. Too much insulin can result in seizures, coma, or death from hypoglycemia, or low glucose levels. Too little insulin over time leads to devastating kidney, heart, nerve, and eye damage from hyperglycemia, or high glucose levels. Given the nature of T1D, people are often left to make these adjustments on their own with guidance from their physician. To better support

[1] Pratley, R. E., Kanapka, L. G., Rickels, M. R., Ahmann, A., Aleppo, G., Beck, R., Bhargava, A., Bode, B. W., Carlson, A., Chaytor, N. S., Fox, D. S., Goland, R., Hirsch, I. B., Kruger, D., Kudva, Y. C., Levy, C., McGill, J. B., Peters, A., Philipson, L., Philis-Tsimikas, A., … Wireless Innovation for Seniors With Diabetes Mellitus (WISDM) Study Group (2020). Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*, *323*(23), 2397–2406. https://doi.org/10.1001/jama.2020.6928

the management of their T1D, patients and their caregivers use FDA approved devices on a daily basis and in many cases around the clock, relying on them to help maintain glucose control to avoid both short and long-term complications.

Despite advances and rates of adoption in technologies to continuously deliver insulin and monitor blood glucose levels, recent data from the T1D Exchange Clinic Network show that the majority of people in the US are not achieving the American Diabetes Association (ADA) recommended Hemoglobin A1c (HbA1c) targets with particularly high levels in adolescents and young adults.[2] The average patient spends 7 hours a day hyperglycemic and over 90 minutes hypoglycemic.[3] Where improvement in average A1c is observed, it is uneven across racial and sociodemographic categories.[4] People with diabetes urgently need continued access to therapies designed to treat and assist in the management of this difficult disease and prevent its life-threatening complications

There is Clear and Compelling Evidence for Use of Diabetes Devices in Older Adults with T1D

The use of diabetes devices is now the standard of care for everyone living with T1D. These guidelines are developed to inform clinical practice based on published evidence. The development and rapid advancement of diabetes devices, particularly continuous glucose monitors (CGMs) and closed-loop systems (CLS) has directly improved the health and well-being of people with T1D. Until the recent approval of the first T1D disease modifying therapy, Tzield, these innovative technologies marked the most significant advancement in care for the T1D community since the discovery of insulin 100 years ago.

On behalf of the T1D community, JDRF continues to play a leadership role in the advancement and adoption of insulin pumps and CGMs. JDRF also played a critical role in accelerating the development and commercialization of CLS by defining a roadmap for increasingly sophisticated systems that would, with each generation, further improve outcomes and reduce burden for people with T1D. Now, twenty years removed from JDRF's first funded CLS prototype grant, there are multiple CLS available on the market with a growing rate of adoption by the T1D community.[5]

The CMS published documents highlight in several places that there are limited trials and studies specific to older populations enrolled in Medicare. We reject any implication that the number of studies is in any way an indication of lack of evidence. While there are unique considerations for use of diabetes devices in older adults, we do not believe there is a fundamental difference in the physiology of older adults that warrants separate and unique data relative to younger adults (as is the case between usage of devices in a pediatric vs adult population). As shown in the data cited in CMS's materials, the benefits of diabetes devices remain constant across adult age groups. To complement this body of evidence and provide data on how treatment targets impact older people most likely to be enrolled in Medicare, it is also critical to incorporate existing research on the effects of diabetes technology in older adults. For example, one JDRF-supported study demonstrated that the use of CGMs in older adults resulted in statistically

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[2] State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-2018. Foster et al. Diabetes Technol Ther 2019;21(2):66-72. *Diabetes Technol Ther*. 2019;21(4):230. doi:10.1089/dia.2018.0384.correx

[3] The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, N Engl J Med 2008; 359:1464-1476. DOI: 10.1056/NEJMoa0805017.

[4] Ebekozien, O., Mungmode, A., Sanchez, J., Rompicherla, S., Berggren, C. C., Weinstock, R. S., Jacobsen, L. M., Davis, G., McKee, A. M., Aktürk, H. K., Maahs, D. M., & Kamboj, M. K. (2023). Longitudinal Trends in Glycemic Outcomes and Technology Use for Over 48,000 People with Type 1 Diabetes (2016–2022) from the T1D Exchange Quality Improvement Collaborative. *Diabetes Technology & Therapeutics*, *25*(11), 765–773. https://doi.org/10.1089/dia.2023.0320

[5] Munshi, M., Slyne, C., Davis, D., Michals, A., Sifre, K., Dewar, R., Atakov-Castillo, A., & Toschi, E. (2022). Use of Technology in Older Adults with Type 1 Diabetes: Clinical Characteristics and Glycemic Metrics. Diabetes technology & therapeutics, 24(1), 1–9. https://doi.org/10.1089/dia.2021.0246

significant reduction in hypoglycemia, relative to standard blood glucose monitoring.[6] Studies with broad populations showing impact across all age categories combined with studies specific to older adults with T1D provide a body of evidence that is of such a size and nature as to warrant confidence in the findings.

JDRF has funded or supported many of the studies and consensus statements cited in the Clinical Endpoints Review report and we are pleased to see such a thorough review of the compelling data showing the positive health impact that insulin pumps, CGMs, and CLS have on people with T1D. We believe that the endpoints identified by CMS for review are all relevant and important to everyone living with T1D. The Clinical Endpoints Review accurately indicates that FDA views A1c and Level 2 hypoglycemia as "clinically meaningful endpoints" for the development of drugs targeting glycemic control. However, it is clear that in the context of clinical care for diabetes, additional outcomes like time in range (TIR) and level 1 hypoglycemia are clinically important with robust evidence. A growing body of evidence continues to link TIR to clinical outcomes, including the development of retinopathy and microalbuminuria.[7] Further, a JDRF-funded 2020 patient preference study on T1D glycemic outcomes showed adults with T1D view avoiding one to five level 1 hypoglycemia events per week to be five times as important than being 0.5% above their target HbA1c.[8] As such, any consideration of endpoints should include both TIR metrics and level 1 hypoglycemia, in addition to A1c and level 2 hypoglycemia.

As highlighted in the Clinical Endpoints Review, minimal clinically important differences (MCID) are an important metric that warrants consideration. We caution against any attempt by CMS to establish MCID requirements or use MCIDs as criteria that could restrict or conflict with current standards of care. As ADA standards of care outline, impact on A1c is often the surrogate endpoint most frequently referenced but A1c may become of less value in an older population.[9] For example, reducing hypoglycemic events in older adults also reduces the risk of harms from falls that occur during hypoglycemia. In order to accommodate a multitude of situations, surrogate markers are crucial to show positive health impact on those aspects that are not only important clinically, but also important to the person with diabetes. We believe this important allowance and nuance is reflected in the lack of a standardized definition for MCIDs, as meaningful impact varies from person to person. As such, the lack of clear definition at present appropriately allows care to focus on the unique patient needs in any given moment.

JDRF Strongly Cautions Against Any Action to Restrict or Reduce Access to Current or Future Diabetes Technologies for People with T1D

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[6] Pratley, R. E., Kanapka, L. G., Rickels, M. R., Ahmann, A., Aleppo, G., Beck, R., Bhargava, A., Bode, B. W., Carlson, A., Chaytor, N. S., Fox, D. S., Goland, R., Hirsch, I. B., Kruger, D., Kudva, Y. C., Levy, C., McGill, J. B., Peters, A., Philipson, L., Philis-Tsimikas, A., … Wireless Innovation for Seniors With Diabetes Mellitus (WISDM) Study Group (2020). Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*, *323*(23), 2397–2406. https://doi.org/10.1001/jama.2020.6928

[7] 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[7] Marinac, M., Sutphin, J., Hutton, C., Klein, K., Sullivan, S., & Mansfield, C. (2020). Preferences for Outcomes Among Adults with Type 1 Diabetes and Caregivers of Children with Type 1 Diabetes. Patient preference and adherence, 14, 1719–1731. https://doi.org/10.2147/PPA.S262358

[8] Marinac, M., Sutphin, J., Hutton, C., Klein, K., Sullivan, S., & Mansfield, C. (2020). Preferences for Outcomes Among Adults with Type 1 Diabetes and Caregivers of Children with Type 1 Diabetes. *Patient preference and adherence*, *14*, 1719–1731. https://doi.org/10.2147/PPA.S262358

[9] Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R. W., Biester, T., Bosi, E., Buckingham, B. A., Cefalu, W. T., Close, K. L., Cobelli, C., Dassau, E., DeVries, J. H., Donaghue, K. C., Dovč, K., Doyle, F. J., Garg, S. K., Grunberger, G., Heller, S., . . . Phillip, M. (2019). Clinical targets for continuous glucose monitoring Data interpretation: Recommendations from the international consensus on Time in range. Diabetes Care, 42(8), 1593–1603. https://doi.org/10.2337/dci19-0028

[10] US Food and Drug Administration. (2023). Guidance for Industry and Food and Drug Administration Staff. In *Food and Drug Administration*. Retrieved April 18, 2024, from https://www.fda.gov/media/162413/download

[11] *LCD - Implantable Continuous Glucose Monitors (I-CGM) (L38617)*. (n.d.). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38617#:~:text=LCD%20revised%20in%20response%20to,insulin%20therapy%20meeting%20certain%20criteria

While encouraged by the thorough analysis of the compelling evidence regarding endpoints for assessing outcomes of diabetes devices for T1D, we strongly caution against any action by CMS that may restrict or reduce access to any currently available or future diabetes devices. Medicare coverage of new technologies historically lags behind the coverage offered by commercial health insurance. It is critically important that Medicare beneficiaries living with T1D gain access to innovative medical technology as soon as possible after it is authorized by FDA, especially when that technology has Breakthrough status from FDA, a designation directly linked to potential improved health outcomes.[10]

After years of research and direct advocacy, JDRF and the broader T1D community applauded CMS's final expansion of coverage for all approved CGMs in 2022. [11] While we appreciate that Medicare now covers CGMs, we remember with concern the near decade it took CMS to provide Medicare beneficiaries initial access to CGMs following FDA authorization.

Any future guidance from CMS regarding trial and study design should, to the extent reasonable and possible, be aligned with requirements of the FDA. This reduced duplication will allow for faster compliance, thus resulting in quicker long-term access for patients. We caution against any action that conditions Medicare coverage on unnecessarily complicated or lengthy additional studies as this would not only result in delayed access to FDA authorized devices but would dampen innovation at a time of rapid advancements in technology and care.

Everyone should have ready access to FDA authorized technologies that hold the potential to improve a person's clinical outcomes. The nature of one's insurance should not determine access to these life-changing or life-saving technologies. JDRF believes that any consideration for the appropriate use of a device should be at the discretion of the person with diabetes and their physician, whether they're 63 and commercially insured or 65 and covered by Medicare. We trust that as CMS continues its work, it will consider what people with T1D and the clinical community deem as valuable and important in the devices designed for their use.

We appreciate the opportunity to provide comments in advance of the scheduled meeting. We hope that any future work following this meeting will be done in a transparent manner consistent with CMS's commitment to the diabetes community. We stand ready to support CMS's efforts to ensure everyone has access to the devices and care they need. If you have any questions or wish to discuss any of our comments in greater detail, please contact Aaron Turner-Phifer at aturnerphifer@jdrf.org.