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Canadian Agency For Drugs And Technologies In Health (CADTH)
865 Carling Ave.
Ottawa, ON K1S 5S8

Re: Diabetes Canada Feedback on CADTH's Implementation Advice for the Freestyle Libre Flash Glucose Monitoring System (Abbott Diabetes Care Ltd.)

Thank you for the opportunity to provide feedback on *CADTH's Implementation Advice for the Freestyle Libre Flash Glucose Monitoring System (Abbott Diabetes Care Ltd.)*. Diabetes Canada and its expert reviewers have provided comments on this draft document, for your consideration.

People living with diabetes should have timely and equitable access to the medications, devices, and supplies that best suits their clinical needs and personal context based on best evidence, including the flash glucose monitoring system (FGMS). Access to the right medications, devices, supplies, and services with appropriate education and support, helps people living with diabetes achieve optimal health outcomes.

FGMS has the potential to improve blood sugar control and quality of life for people living with diabetes, resulting in physical, social, and emotional benefits.[1] It can help people living with diabetes identify when their blood sugar is trending down, which allows for appropriate, timely action to be taken to avoid hypoglycemia.[1] It can also provide early indication of hyperglycemia over the course of the day and prompt adjustments to medications, activity, and food intake to help achieve blood sugar targets. This in turn can reduce the risk of long-term complications, including heart attack, stroke, kidney failure, blindness, and amputation.[1] Unfortunately, while FGMS is included in many private and employment health insurance plans, public coverage is inconsistent across Canada. The cost of FGMS is a barrier to access for many Canadians living with type 1 diabetes and Canadians living with type 2 diabetes requiring insulin. Canadians living in provinces and territories with no coverage, limited coverage, or not meeting eligibility criteria for their provincial/territorial plan must pay up to ~$2,500 per annum in out-of-pocket costs for flash glucose monitoring.[2,3] Restricted access means a lost opportunity for some people living with diabetes to enhance their health outcomes, diabetes-specific quality of life, and disease management satisfaction.

We would like to take this opportunity to reiterate considerations we raised in our previous correspondence related to the synthesis of the two available HTA reports, as well as considerations related specifically to the implementation advice.

1. ***Scope of Included Literature:*** The implementation advice report is based on two health technology assessment (HTA) reports, which synthesize the evidence on the effectiveness of FGMS up to 2018. In 2018, flash glucose monitoring was still a relatively new technology; however, in the last two years (2018-2020), a series of new studies and recommendations have emerged. Therefore, it is recommended that the evidence that was produced in the last two years be assessed and incorporated into the implementation advice report. Further, Chapter 9, Monitoring Glycemic Control, of the *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* is currently under review; as such it may be valuable to wait to review the Canadian clinical consensus on the totality of evidence with respect to FGMS before finalizing the technology review and making recommendations. It is understood that this implementation advice report was produced in response to the jurisdictions' request to summarize the existing reports. However, from the perspective of patients and health-care providers, it would be more relevant to have implementation recommendations based on the most up-to-date evidence rather than a summary of older reports.

2. ***Economic Perspective and Evidence:*** In the implementation advice report, INESS/CSEMI noted that "the provincial funding recommendations for FGMS are based on the condition that the economic burden of FGMS lessened, otherwise it was recommended that this device be funded in exceptional circumstances." This statement is based on the adoption of a provincial public payer perspective, which accounts for provincial government-borne health and social care expenditures; but fails to consider other expenditures borne to patients, including personal health and social care expenditures, expenditures covered by private insurers, and personal wages and circumstances. For patients, this perspective fails to capture all the direct and indirect health-care expenditures borne from diabetes and its management.

   Diabetes Canada acknowledges that provincial/territorial governments have finite resources, but a more comprehensive analysis including patient costs should be considered. Individuals living with diabetes deserve to have timely and affordable access to the glucose monitoring method that suits their clinical needs, based on consultation with their health-care provider team. Publicly funding FGMS, expands glucose monitoring options for those who may not have been able to access this type of system otherwise. Further, given the current landscape with COVID-19 and the shift to virtual care, FGMS allow more complete information to be collected and easily shared virtually with all parties involved.

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3. ***Conclusion and Recommendations:*** While considering financial constraints and policy development, patients need to remain at the center of health policy decision-making. This entails meaningfully engaging patients early and frequently in the policy development process. The conclusions and recommendations provided in the implementation advice report are largely focused on cost-effectiveness and ways to mitigate the potentially high expenditure for FGMS by providing selective reimbursement for this technology, while placing a lesser emphasis on patient-centered outcomes. Therefore, while developing health policy recommendations, it is important to be inclusive of, and move beyond only cost-effectiveness, and to adopt a patient-centered approach that considers significant patient experiences that include a range of structural and psychosocial aspects that affect patients' lives, treatment, care, and environment. These include, but are not limited to, caregiver support, overall well-being (including mental health and distress), employment, socioeconomic status, education, etc.

   The benefits of FGMS for health-care providers and optimal health-care delivery should also be given appropriate consideration. Many clinicians have found this intervention to be very impactful for both themselves and their patients. The ability of this technology to be used in virtual care should not be undervalued.

4. ***Implementation Issue 1 – Population Expected to Benefit Most from Using Freestyle Libre FGMS:*** Implementation Issue 1 states that "among patients with insulin-treated diabetes, certain subgroups may be expected to benefit from using FGMS. The Panel then noted that "evidence was not available in the HTAs reviewed for all subgroups identified in the aforementioned paragraph; as such some of these statements are based on their expert opinion."

   We ask the Panel to consider that clinical trials may have underestimated the magnitude of benefit for FGMS. Clinical trials often exclude pediatric or pregnant participants, and those with severe hypoglycemia unawareness. Thus, the benefit of FGMS in terms of glucose control may be underestimated for the whole diabetes population.

   FGMS may be clinically appropriate in specific contexts for patients where the risk and consequences of hypoglycemia are unacceptable. For example, this may include people with a history of hypoglycemia and who live alone or are a primary caregiver of a young child, and those for whom hypoglycemia would be dangerous in the workplace (e.g., truck drivers, shift workers, pilots).

5. ***Implementation Issue 3 – Anticipated Improved Outcomes:*** Implementation issue 3 outlines the anticipated improved outcomes of using Freestyle Libre FGMS for the population(s) expected to benefit the most from using this technology. In this section, it appears that patient-centered

outcomes are listed as secondary to major clinical outcomes, such as improved time spent in target glycemic range in adults with type 1 diabetes, among others. From the patient perspective these outcomes are very important and should not be viewed as secondary outcomes. Patient-centered outcomes ensure alignment with patients preferences, needs, and values, and that these guide all clinical decisions.[4] Further, patient-centered outcomes are associated with improved clinical outcomes.[5]

The Panel is commended for stressing the importance of education for the use of FGMS. Education and training are essential to achieving the full benefits of the technology and encouraging patients to persist with use. Patients require training and support from health-care professionals to use the device and the information it provides. Within a program for reimbursement, there should be a strong component of training and education to support diabetes management practices to improve outcomes.

Diabetes Canada is an organization that produces world-renowned, evidence-based clinical practice guidelines and represents clinicians who practice evidence-based medicine. We believe that treatment standards and protocols should be based on currently available data. However, we note that the evolution of blood glucose monitoring technology is rapid, and it is difficult for guidelines, health technology assessments, and public policy to quickly incorporate this information to support the best possible outcomes. Therefore, it is essential that all stakeholders commit to participating in 'living' analyses and implementation that can incorporate evidence as it emerges.

We look forward to people with diabetes having access to the supports they need to manage their disease. Use of evidence-based and purposeful glucose monitoring will help people living with diabetes achieve their health potential. The selection of a particular glucose monitoring regimen, the most appropriate device/approach (flash glucose monitoring, continuous glucose monitoring, capillary glucose monitoring using test strips) and the response to testing depends on the individual and should be tailored to each patient's unique needs and situation.

Sincerely,

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