DIABETES CANADA

Reimbursement of Intermittently-Scanned and Real-Time Continuous Glucose Monitoring Systems

A Policy Statement

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About Diabetes Canada: Diabetes Canada is a national health charity representing close to 11.5 million Canadians living with diabetes or prediabetes. Diabetes Canada leads the fight against diabetes by helping those affected live healthy lives, preventing the onset and consequences of the disease and discovering a cure. It has a heritage of excellence and leadership, and its founder, Dr. Charles Best, is credited alongside Dr. Frederick Banting with the discovery of insulin. Diabetes Canada is supported in its efforts by a community-based network of volunteers, employees, health-care professionals, researchers and partners. By providing education and services, advocating on behalf of people living with diabetes, supporting research and translating it into practical applications, Diabetes Canada is delivering on its mission. Diabetes Canada will continue to change the world for those affected by diabetes through healthier communities, exceptional care and high-impact research.

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Introduction

Glucose monitoring can play an important role in optimizing clinical outcomes, improving treatment satisfaction and enhancing quality of life for many people living with diabetes.

There are different glucose self-monitoring modalities, including:

1. **Capillary blood glucose** monitoring (CBG; previously referred to as "self-monitored blood glucose" or "SMBG")
2. **Intermittently-scanned continuous glucose monitoring** (isCGM; previously referred to as "flash glucose monitoring" or "FGM")
3. **Real-time continuous glucose monitoring** (rtCGM; previously referred to as "continuous glucose monitoring" or "CGM")

Glucose self-monitoring is necessary for all people with type 1 diabetes and in pregnancy (for those with type 1, type 2 and gestational diabetes), and is recommended for many people with type 2 diabetes. Selection of a glucose monitoring method and system is dependent on individual patient characteristics, obstacles to living well with diabetes and short- and long-term health-related goals. People living with diabetes are advised to speak with their health-care team to determine the type of device that best suits their needs.

Optimal management and best practices around CBG monitoring are described in a previously published Diabetes Canada briefing document.[1] Recommendations to public and private payers for yearly minimum coverage of CBG test strips are also detailed elsewhere.[2] This leaves a gap in the reimbursement recommendations for other types of glucose monitoring, namely isCGM and rtCGM. The purpose of this policy statement is, therefore, to:

1. Offer context to inform the creation of policies to support access to appropriate glucose monitoring devices and supplies for people living with diabetes.
2. Describe the considerations that are important in developing glucose monitoring reimbursement policies that will contribute to greater equity in our health-care system.

3. Provide evidence-informed recommendations for reimbursement of isCGM and rtCGM systems.

Background

Most people with diabetes derive benefit from glucose self-monitoring. Data generated from self-monitoring serve as a useful adjunct to other longer-term glycemic measures, like glycated hemoglobin (A1C).

Recently, there has been an increased interest and uptake in isCGM and rtCGM use for diabetes management. These newer monitoring technologies can:

- Support healthy behaviours and behaviour change and guide management strategies by providing data on the impact of things like food choices and exercise on glycemia.
- Inform treatment decisions, including medication choice and dose adjustment.
- Promote safety from acute complications, such as diabetic ketoacidosis and hypoglycemia, by allowing for identification of patterns and trajectories of glycemia, and protection from long-term complications of diabetes by providing overall averages of glycemia and proportion and timing of glycemia in or out of target range.
- Enhance virtual care by allowing health-care providers to access uploaded data about daily glycemic trends, average daytime and nighttime glycemia, time in range and the glycemic response to specific interventions.
- Empower people living with diabetes by providing knowledge of current and trending glycemia to inform self-management decisions.

In order to maximize the utility of different monitoring systems, health-care providers, people living with diabetes and their caregivers should receive training on the proper function of devices and their associated components, and on how to access, interpret and utilize glucose data, including any available trend data.

The *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* recommend the mode and frequency of monitoring be individualized to each person's unique circumstances and take into consideration various factors, such as type of diabetes, pharmacotherapy, awareness of hypoglycemia, and school and occupational requirements and risks. Recommendations for glucose monitoring in adults, adolescents and children, updated in 2021, are available online and include guidance for health-care providers on the specific populations who may benefit from isCGM and rtCGM.

These recommendations are based largely on research focused on the glycemic improvements that can result from the use of different monitoring devices, as well as some other clinical and quality of life measures. Continuous glucose monitoring technologies (isCGM and rtCGM) have been shown to help people in many ways, including increasing their time in target glucose range and/or reducing hypoglycemia. The risks of hypoglycemia depend on multiple factors, including clinical, biological, personal, employment, education and social circumstances. The consequences of hypoglycemia can be life-threatening, so should always be a priority consideration in policy development related to reimbursement of isCGM and rtCGM systems. Additional variables that ought to be considered in policy decisions for the coverage of isCGM and rtCGM systems include:

- Clinical indications and desired outcomes.
- Treatment satisfaction.
- Individual circumstances.

Many important outcomes reported by people living with diabetes and their caregivers that are associated with glucose monitoring are often not fully captured in clinical trials and scientific reports. Through accounts of the lived experience of people with diabetes and feedback from caregivers and health-care providers, Diabetes Canada is aware of the many benefits of isCGM and rtCGM for glucose management, prevention of hypoglycemia and addressing anxiety related to potential hypoglycemia, as well as overall feelings of anxiety and diabetes distress.

The positive impact isCGM and rtCGM devices have on disease management and quality of life attest to their value. It is, therefore, extremely important for health-care providers to consider a wide range of outcomes when developing treatment goals with people living with diabetes, and for policy makers to also take into account a variety of outcomes when creating policies that influence people's ability to manage their disease and live optimally.

Recommendations

The totality of available evidence shows isCGM and rtCGM technology to be transformative for many people living with diabetes. Thus, access should be extended to all Canadians for whom these systems have been shown to provide positive benefit to their diabetes management.

Diabetes Canada proposes that payers reimburse isCGM and rtCGM systems (including devices and any necessary supplies) based on the considerations described in this policy statement and the evidence-informed recommendations outlined in Table 1. These recommendations:

- Are informed by the recommendations for device use described in Blood Glucose Monitoring in Adults and Children with Diabetes – Update 2021, which were developed from a review of relevant literature published between November 1, 2017 and October 28, 2020.
- Pertain to isCGM and rtCGM systems included in the literature that was examined during this review period.
- Apply to adults, adolescents and children living with diabetes.
- Are based on clinical indications to improve outcomes in people with diabetes and individual circumstances.
- Prioritize safety for people living with diabetes.
- Consider the frequency and magnitude of hypoglycemia-related risks for individuals using insulin.
- Are particularly attentive to people who are at high risk for hypoglycemia and for whom the consequences of hypoglycemia would be catastrophic.

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At a minimum, glucose monitoring policies should allow people with diabetes to access the monitoring methods described for their subgroup. An exceptions process should be in place that allows for glucose monitoring systems reimbursement outside of these recommendations on a case-by-case basis where individual circumstances warrant it.

Table 1: isCGM and rtCGM systems reimbursement recommendations

Diabetes Type and Treatment	**Glucose Monitoring Type**	
	isCGM	**rtCGM**
Type 1 **not** included in the exceptional populations described below	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ increase time in range ▪ reduce frequency of hypoglycemia ▪ reduce duration of hypoglycemia ▪ increase treatment satisfaction	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ reduce A1C ▪ increase time in range ▪ reduce duration of hypoglycemia ▪ reduce incidence of hypoglycemia ▪ improve quality of life ▪ increase treatment satisfaction in those using CSII (i.e. insulin pump)
Type 2 requiring insulin **not** included in the exceptional populations described below	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ reduce frequency of hypoglycemia ▪ reduce duration of hypoglycemia OR • under specific circumstances*	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ reduce A1C ▪ reduce duration of hypoglycemia OR • under specific circumstances*
Type 2 not requiring insulin	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication
Gestational diabetes not requiring insulin	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication

EXCEPTIONAL POPULATIONS		
Considerations	**Glucose Monitoring Type**	
	isCGM	**rtCGM**
Any form of diabetes[3] requiring insulin, with impaired hypoglycemia awareness or recent history of severe hypoglycemia	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ reduce incidence of hypoglycemia ▪ reduce severe hypoglycemia ▪ reduce time in hypoglycemia
Type 1 and pregnant	Not possible to make a recommendation due to lack of clinical evidence of benefit at the time of publication	FULLY REIMBURSE • when used to support one or more of the following goals of care: ▪ reduce risk of large for gestational age infants, neonatal hypoglycemia and NICU admissions greater than 24 hours ▪ increase time in range ▪ reduce time above range
Type 2 requiring insulin in pregnancy	FULLY REIMBURSE SHORT-TERM IN PREGNANCY • under specific circumstances** *Note: CBG monitoring may be required to dose insulin*	FULLY REIMBURSE SHORT-TERM IN PREGNANCY • under specific circumstances** *Note: CBG monitoring may be required to dose insulin*
Gestational diabetes requiring insulin	FULLY REIMBURSE SHORT-TERM IN PREGNANCY • under specific circumstances** *Note: CBG monitoring may be required to dose insulin*	FULLY REIMBURSE SHORT-TERM IN PREGNANCY • under specific circumstances** *Note: CBG monitoring may be required to dose insulin*

Abbreviations:
CSII, continuous subcutaneous insulin infusion; *NICU*, neonatal intensive care unit

*This includes:
- Those who, for various reasons, have not been able to achieve and maintain their individualized glycemic targets despite their best efforts and who are willing and able to use these devices at least 75% of the time.
- Those with a history of adverse outcomes who have achieved their treatment goals with the current use of isCGM or rtCGM.
- Children who are unable to recognize and/or communicate symptoms of hypoglycemia or hyperglycemia.
- Those with cognition (e.g. memory loss) or communication-related issues (e.g. language problems).

- Those in occupations and/or environments where episodes of hypoglycemia would present a risk to themselves or others (e.g. single parent, daycare provider, personal support worker, heavy equipment operator, commercial truck driver, etc.).
- Those who may require individual consideration due to their unique context (e.g. person residing in a correctional facility, individual with a physical disability or functional restriction that makes other forms of monitoring impossible, etc.).

**This includes:

- Those who are at high risk of adverse outcomes in pregnancy (e.g. preeclampsia) or adverse neonatal health outcomes (e.g. neonatal hypoglycemia).
- Those who, for various reasons, have not been able to achieve and maintain their individualized glycemic targets despite their best efforts and who are willing and able to use these devices at least 75% of the time.
- Those with a history of adverse outcomes who have achieved their treatment goals with the current use of isCGM or rtCGM.
- Those with cognition (e.g. memory loss) or communication-related issues (e.g. language problems).
- Those in occupations and/or environments where episodes of hypoglycemia would present a risk to themselves or others (e.g. single parent, daycare provider, personal support worker, heavy equipment operator, commercial truck driver, etc.).
- Those who may require individual consideration due to their unique context (e.g. person residing in a correctional facility, individual with a physical disability or functional restriction that makes other forms of monitoring impossible, etc.).

Many Canadians living with diabetes exclusively engage in CBG monitoring. CBG monitoring is not fully supported across the country, with coverage of test strips falling well below recommended amounts in many jurisdictions. Diabetes Canada continues to advocate for:

1. Reimbursement of test strips to meet Diabetes Canada's recommended yearly minimum amount.
2. Eligibility clauses allowing exceptions without limits to test strips coverage policies on a case-by-case basis where clinically indicated.
3. Elimination of co-pays and deductibles on test strips where they are barriers to access.
4. The education and support people with diabetes require to allow them to test with purpose and effectively self-manage their disease.[2]

Conclusion

Diabetes rates have risen significantly in Canada and worldwide over the past few decades and, increasingly, funding decisions related to health systems and services are being made in an environment of limited financial resources. Under all circumstances, patients must remain at the centre of health policy decisions. People with diabetes should be supported to achieve their full health potential, with

rightful consideration given to the cost of doing so. Improved access to glucose monitoring systems will reduce downstream diabetes-related costs by helping enhance health and quality of life for people with diabetes. Most importantly, expanding access to monitoring technologies will save lives. Thus, it is imperative that payers establish appropriate policies to support access.

References

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