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Coverage for Real-Time Continuous Glucose Monitoring Systems

This document provides the answers to questions received during the informational webinar held on April 14, 2022, for representatives from the ADP-registered Diabetes Education Programs.

In this document:

- ADP refers to the Assistive Devices Program;
- rtCGM refers to a real-time Continuous Glucose Monitor;
- DEP refers to a Diabetes Education Program; and
- rtCGM PAM refers to the Real-Time Continuous Glucose Monitoring Systems Policy and Administration Manual.

If you have additional questions not covered in this document, please sent your questions to adp@ontario.ca

1. Eligibility Criteria to Receive ADP Coverage for Real-Time Continuous Glucose Monitoring Systems

Q1.1 Can you help the DEPs understand the medical eligibility criteria for a real-time continuous glucose monitoring system – specifically criterion 2 (a) within section 310.01 of the rtCGM PAM?

A1.1 Your patient with type 1 diabetes will be eligible for ADP coverage for a Real Time Continuous Glucose Monitoring System if they meet the Medical Eligibility Criteria set out in section 310.01 of the rtCGM PAM and are otherwise eligible for ADP.

In order to satisfy criterion 2 (a) of section 310.01 of the rtCGM PAM, your patient, due to their developmental stage or a previously diagnosed cognitive or physical impairment, must be unable to:

- recognize or communicate symptoms of hypoglycemia; or
- independently perform fingerstick glucose testing.

For Real-Time Continuous Glucose Monitoring Systems, ADP provides funding based on functional disability and does not impose an age criterion. It is the role of the prescriber from the ADP-registered DEP to determine if their patient's developmental stage, cognitive impairment or physical impairment meets this criterion.

Q1.2 Would severe attention deficit hyperactivity disorder fall into cognitive impairment?

A1.2 It would be the role of the prescriber and the health care team from the DEP to assess if their patient is unable to recognize or communicate symptoms of hypoglycemia/independently perform fingerstick glucose testing due to attention deficit hyperactivity disorder.

Q1.3 Will the ADP cover sensors for children under 2 years, since using a real-time continuous glucose monitoring system is off label for this age group?

A1.3 It is the role of the prescriber and the health care team from the ADP-registered DEP to determine if any patient with type 1 diabetes:

- meets the Medical Eligibility Criteria for ADP coverage for a Real-Time Continuous Glucose Monitoring System; and
- is an appropriate candidate for using a Real-Time Continuous Glucose Monitoring System.

As per the rtCGM PAM, a Real-Time Continuous Glucose Monitoring System includes the Supplies. The Supplies are the sensors and transmitters that are used with a Real-Time Continuous Glucose Monitor. Therefore, to be eligible for ADP coverage for the sensors, the Applicant would have to satisfy the Medical Eligibility Criteria for Real-Time Continuous Glucose Monitoring System.

Please note, although the rtCGM PAM does not specify a minimum age of eligibility within the Medical Eligibility Criteria, criterion 3 of the Medical Eligibility Criteria in section 310.01 requires the Applicant to demonstrate experience with and commitment to managing blood sugar control and an ability to use Real-Time Continuous Glucose Monitoring safely and effectively.

Prescribers and health care teams from the ADP-registered DEP should be informed of Health Canada's approval of devices and any conditions Health Canada has imposed when issuing a licence for the device.

Q1.4 Why were the medical eligibility criteria created with such strict limitations for who is eligible?

A1.4 The specific Medical Eligibility Criteria were developed based on the recommendation of Ontario Health (formerly Health Quality Ontario).

In 2018, after completing a Health Technology Assessment (HTA), Health Quality Ontario (HQO) recommended publicly funding real-time continuous glucose monitoring for individuals with type 1 diabetes who are willing to use real-time continuous glucose monitoring for the vast majority of the time and who meet one or more of the following criteria.

- Severe hypoglycemia without an obvious precipitant, despite optimized use of insulin therapy and conventional blood glucose monitoring.
- Inability to recognize, or communicate about, symptoms of hypoglycemia.

Q1.5 Will the ADP look into expanding the eligibility criteria in the future so that more people may benefit from real-time continuous glucose monitoring?

A1.5 Any future expansion of the ADP’s medical eligibility criteria would be subject to the government’s decision making and would take into consideration:

- any further HTAs completed by Ontario Health; and
- availability of funding.

2. ADP Coverage for Current Users of Real-Time Continuous Glucose Monitoring

Q2.1 Can you explain the process whereby people with type 1 diabetes who are currently using a rtCGM may receive coverage through the ADP?

A2.1 Current users may be eligible to receive ADP coverage for the sensors and transmitters used with their rtCGM if they meet all of the following:

- use a rtCGM covered by the ADP;
- are under the supervision or care of an ADP-registered DEP; and,
- a physician or nurse practitioner, registered with the ADP-registered DEP as a prescriber, confirms that prior to starting real time continuous glucose monitoring, they met the device-specific Medical Eligibility Criteria.

If your patient meets the criteria listed above, an application may be submitted on their behalf.

Instructions for the DEP:

- Complete the *Application for Funding Real-Time Continuous Glucose Monitoring System*.
- Indicate that your patient does not currently meet the Medical Eligibility Criteria (e.g. select “no” in the eligibility criteria boxes for 2a and/or 2b in section 2 of the application form, as applicable).

- Provide the manufacturer with the application and a supporting letter from the prescriber indicating which medical eligibility criteria (in section 2a or 2b of the application form) your patient met before they started using a rtCGM.

Please note, to receive ADP coverage, the prescriber must still confirm on the application form that their patient has type 1 diabetes and demonstrates experience with and commitment to managing blood sugar control and an ability to use a rtCGM safely and effectively.

Instructions for the Vendor:

- Submit the application electronically through the eSubmission process.
- Provide the ADP with the supporting documentation via email to adpvendors@ontario.ca.

Q2.2 How far back would they qualify for 2b?

A2.2 An Applicant with type 1 diabetes who is currently using a rtCGM, would satisfy 2(b) of the Medical Eligibility Criteria set out in section 310 of the rtCGM PAM (also set out in 2(b) of Section 2 of the Application Form), if the severe hypoglycemia that resulted in one of the following, occurred within the two (2) year period prior to when the individual started using a rtCGM:

- the suspension of their driving licence;
- a hospitalization or emergency room or EMS visit; or
- glucagon administration, unconsciousness, or seizure.

3. Renewing ADP Coverage for the Supplies

Q3.1 How will the ADP monitor if our patient wears their rtCGM a minimum of 70% of the time?

A3.1 To continue to receive ADP coverage for the sensors and transmitters used with their rtCGM, your patient must:

- submit a renewal form; and
- confirm that they meet the Renewal Eligibility Criteria set out in section 315 of the rtCGM PAM, including the requirement that they wear the monitor 70% of the time.

As a recipient of ADP coverage, your patient is subject to reviews by the ADP to monitor or verify the patient’s receipt of benefits/funding under the ADP. For real-time continuous Glucose monitoring system, this could include:

- reviewing the invoices submitted by the Vendor that confirms the number of sensor and transmitters provided to your patient; and

- follow-up verification letters to the ADP-registered DEP.
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4. ADP Process

Q4.1 Should the DEP send the renewal forms back to the ADP?

A4.1 Please refer to section 705 of the rtCGM PAM. The Vendor will provide the Renewal Form to the patient. Once your patient has completed and signed the Renewal Form, your patient should return the form to their Vendor, who will submit the renewal form electronically through the esubmission process.

Q4.2 Does the ADP accept applications scanned and submitted in a PDF format?

A4.2 As part of the ADP's electronic submission process (esubmission), the Program does not accept scanned and PDF applications.

Q4.3 If our patient is currently receiving social assistance through one of the Ontario Disability Support Program (ODSP), should they apply to ODSP or the ADP for coverage of their real-time continuous glucose monitoring system?

A4.3 Your patient should apply to the ADP. When completing the application, under the Confirmation of Benefits section, be sure to indicate the following:

- your patient is receiving social assistance; and
 - the specific funding program (Ontario Works, Ontario Disability Support Program or Assistance to Children with Severe Disabilities).
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5. Reviewing DEPs

Q5.1 Will the ADP audit DEPs to confirm our patient's eligibility?

A5.1 The ADP's Verification and Testing Unit routinely conducts reviews to ensure that ADP-registered vendors, prescribers of ADP-funded devices, and ADP-registered clinics adhere to ADP policies and procedures.

Please refer to section 410 of the Policies and Procedures Manual for the Assistive Devices Program. In order to participate in the ADP, a DEP must be registered as an ADP clinic, and is therefore subject to reviews.

As outlined in section 515 of the rtCGM PAM, an ADP registered DEP is required to maintain accurate record keeping. The ADP can ask to see their patient's clinical assessment to confirm that their patient met the medical eligibility criteria and/or as part of the ADP's review procedures.

As a recipient of ADP coverage, your patient is also subject to reviews by the ADP to ensure that they meet the eligibility and renewal criteria.

Q5.2 What is the role/responsibility of the ADP registered DEP if the prescriber has completed the ADP application indicating Hypo-unawareness as the criteria being met?

A5.2 The roles and responsibilities of the DEP are set out in section 115.02 of the rtCGM PAM. Among other things, it is the role of the prescriber and the health care team from the DEP to assess if their patient:

- meets the Medical Eligibility Criteria, including whether the patient is unable to recognize or communicate symptoms of hypoglycemia due to their patient's development stage, cognitive impairment, or physical impairment.

As indicated in section 515 of the rtCGM Pam, DEPs are also responsible for maintaining accurate records, including patient files, for review purposes.

6. Ministry of Transportation and the Highway Traffic Act

Q6.1 Will ADP report the medical information contained within our patient's application form to the Ministry of Transportation?

A6.1 As outlined on the Application for Funding Real-Time Continuous Glucose Monitoring System (rtCGM) form, the Ministry of Health will only use and disclose an Applicant's personal health information in accordance with the *Personal Health Information Protection Act, 2004*, and the Ministry's "Statement of Information Practices" which is accessible at www.health.gov.on.ca.

For example, this may include disclosing personal health information if the Ministry of Health believes disclosure is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons or if disclosure is permitted or required by law.

In addition, as outlined on the application form, the Ministry of Health and the Workplace Safety and Insurance Board may collect, use and disclose personal information about an Applicant related to the Applicant's entitlement to health care benefits under the *Workplace Safety and Insurance Act (WSIA)*, for the purpose of assessing and verifying the Applicant's eligibility to receive benefits under the ADP and WSIA, and the WSIB may collect, use and disclose personal information about the Applicant for the purpose of administering and enforcing WSIA.

Under the Highway Traffic Act, it is the role of the physician, nurse practitioner or optometrist to report to the Registrar of Motor Vehicles if their patient has certain high risk medical conditions that might impair their ability to drive.

For more information on the Highway Traffic Act, you may go to the Ministry of Transportation's website.

7. Individuals with Insurance Coverage

Q7.1 Does the ADP have any information on whether insurance companies will now stop coverage of CGM?

A7.1 While the ADP does not have control over insurance companies and what they fund, the Program is working with insurance companies to better understand the impacts of ADP policies on coverage of medical devices.

Q7.2 Many insurance companies are telling our patients that they will no longer be eligible for insurance coverage - how do we handle these situations, will ADP provide a letter confirming they are not eligible for ADP coverage?

A7.2 As per ADP policy, the Program does not provide letters to the insurance companies.

ADP will work with the manufacturers to reiterate the Medical Eligibility Criteria for ADP coverage.

Q7.3 Will ADP offer "top up" for patients with insurance coverage or should patients submit for full coverage from ADP?

A7.3 If your patient's application is approved, as per section 600.01 and subject to section 600.02, under the ADP, the Vendor will provide your patient with a Real-Time Continuous Glucose Monitoring System at no cost to your patient.

As per section 600.02, the Vendor will provide your patient with the Supplies (i.e. sensors and transmitter), up to the maximum quantity allowed per 24-month renewal period.

The maximum quantities allowed per 24-month period are based on the rtCGM manufacturer's recommendation on when the sensor or transmitter must be replaced.

If your patient needs more sensors or transmitters than the maximum quantity allowed, your patient or their family is advised to contact their vendor.

8. Other Questions

Q8.1 How does funding for a real-time continuous glucose monitoring system overlap with existing ADP funding supports for insulin pumps?

A8.1 ADP coverage for a real-time continuous glucose monitoring system is **separate** from ADP coverage for an insulin pump and the related supplies.

The supplies used with a real-time continuous glucose monitoring system are not part of the \$2,400 used to purchase the supplies used with insulin pumps funded by ADP.

Your patients **do not** have to be using an insulin pump to get coverage for a real-time continuous glucose monitoring system.

As per section 200.02 of the rtCGM PAM, for ADP coverage of an insulin pump and the pump supplies, a patient must meet the medical eligibility criteria outlined in the Insulin Pump and Supplies Policy and Administration Manual, Part 3: Applicant Eligibility Criteria for Insulin Pump and Supplies, and a separate Application Form must be submitted for the patient (Application for Funding Insulin Pumps and Supplies).

Q8.2 **What is the expected % of people in Ontario with type 1 diabetes who will be eligible for ADP coverage?**

A8.2 The ADP has estimated that approximately 10% to 15% of people in Ontario with type 1 diabetes will be eligible for ADP coverage.

Q8.3 **What about patients who would benefit from a hybrid closed loop insulin delivery system?**

A8.3 ADP coverage for real-time continuous glucose monitoring systems is limited to Applicants who are eligible for the ADP and meet the specific Medical Eligibility Criteria. This includes any of your patients who may currently be using a hybrid closed loop insulin delivery system.

To receive coverage for a hybrid closed loop insulin delivery system your patient would need to meet the Medical Eligibility Criteria for the following:

- the insulin pump and the related supplies; and
- the Real-Time Continuous Glucose Monitoring System.