Washington State Health Care Authority

Final Key Questions

Continuous Glucose Monitoring – Update

Background

People with diabetes need to manage their condition to help prevent or delay diabetes-related comorbidities such as stroke, kidney disease, and blindness.[1] A key part of managing diabetes is monitoring levels of blood glucose (also called blood sugar levels) to guide changes to diet, exercise, or medication.[1] There are several ways people with diabetes can measure blood glucose levels:

- Self-monitoring, using capillary (finger-stick) devices[2]
- Continuous glucose monitoring (CGM) devices[3]
  - Real-time CGM (rtCGM) devices measure and continuously display glucose levels.
  - Intermittently scanned CGM (isCGM or flash) devices, with and without alarms, continuously measure glucose levels but require scanning and storage of glucose values.
- Professional CGM devices placed on the person with diabetes in the clinic and worn for 7 to 14 days (this type of CGM is excluded from this update)

As of March 2024, these CGM devices were available in the US[4]:

- Dexcom G6
- Dexcom G7
- Stelo by Dexcom
- Freestyle Libre 14-day system
- Freestyle Libre 2
- Freestyle Libre 2 Plus
- Freestyle Libre 3
- Guardian 3
- Guardian 4
- Eversense E3

Devices vary by the age of the population for which it has FDA approval, the need for calibration, the type of CGM (rtCGM or isCGM), wear time, warm-up time, alarm or not, data display, design, and ability to integrate with an automated insulin delivery (AID) system.[4]

Topic Background

A health technology assessment (an update) on CGM[5] was published in December 2017 by the Health Care Authority and the coverage determination was adopted in March 2018 based on that report.[6] In 2024, the director of the Washington State Health Care Authority selected CGM for an update[7] because of new evidence that could change the 2018 coverage determination.[6] The director also highlighted medium concerns around the safety of CGM, and high concerns about efficacy and cost.[7]

Policy Context

In 2018, the Health Technology Clinical Committee made the following coverage determination[6]:

- Continuous glucose monitoring is a covered benefit with conditions. This determination does not pertain to closed loop or artificial pancreas systems.

The specified conditions were[6]:

- Continuous glucose monitoring is covered for children and adolescents less than 19 years old, adults with type 1 diabetes, and adults with type 2 diabetes who are:
  - Unable to achieve target HbA1C (hemoglobin A1c) despite adherence to an appropriate glycemic management plan (intensive insulin therapy; testing blood glucose 4 or more times per day), or
  - Suffering from 1 or more severe (blood glucose < 50 mg/dl or symptomatic) episodes of hypoglycemia despite adherence to an appropriate glycemic management plan (intensive insulin therapy, testing blood glucose 4 or more times per day), or
  - Unable to recognize, or communicate about, symptoms of hypoglycemia

- Continuous glucose monitoring is covered for pregnant women with[6]:
  - Type 1 diabetes, or
  - Type 2 diabetes and on insulin prior to pregnancy, or
  - Type 2 diabetes and blood glucose does not remain well controlled (HbA1C above target or experiencing episodes of hyperglycemia or hypoglycemia) on diet or oral medications during pregnancy and require insulin, or
  - Gestational diabetes whose blood glucose is not well controlled (HbA1C above target or experiencing episodes of hyperglycemia or hypoglycemia) during pregnancy and require insulin

The objective of the health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of CGM in adults and children with diabetes. This evidence review will help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use of CGM in adults and children with diabetes. The scope for the 2025 rereview will focus on the effectiveness and safety of CGM for populations in whom CGM is not currently covered (Table 1).

Key Questions

KQ1. What is the comparative effectiveness of continuous glucose monitoring in adults and children with type 2 diabetes versus other forms of monitoring (e.g., self-monitoring blood glucose or routine clinical monitoring)?

a. Adults with type 2 diabetes and using:
   i. Non-intensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication
   iii. No insulin and no oral hypoglycemic medication

b. Children with type 2 diabetes
   i. Non-intensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication
   iii. No insulin and no oral hypoglycemic medication

c. Pregnant people with type 2 diabetes who are not using insulin

d. Pregnant people with gestational diabetes who are not using insulin

KQ2. What is the device-related safety of continuous glucose monitoring in adults and children with type 2 diabetes?

KQ3. What is the differential efficacy or safety by patient and clinical factors, such as:
a. Age
b. Gender
c. Race and ethnicity
d. Presence of comorbidities (e.g., hypertension)
e. Severity of disease (e.g., baseline HbA1c, number of self-tests per day)
f. Level of adherence to CGM use
g. Type of CGM (i.e., rtCGM vs. isCGM)
h. Duration of CGM monitoring
i. Timing of initiation of CGM monitoring relative to baseline level of control measured by A1C (i.e., A1C level indicating well-controlled vs. uncontrolled disease at initiation)

KQ4. What are the costs and cost-effectiveness of continuous glucose monitoring in adults and children with type 2 diabetes?
a. Adults with type 2 diabetes and using
   i. Non-intensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication
   iii. No insulin and no oral hypoglycemic medication
b. Children with type 2 diabetes
   i. Non-intensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication
   iii. No insulin and no oral hypoglycemic medication
c. Pregnant people with type 2 diabetes who are not using insulin
d. Pregnant people with gestational diabetes who are not using insulin

Detailed Inclusion and Exclusion Criteria

Table 1. Detailed Inclusion and Exclusion Criteria

Study Component	Inclusion	Exclusion
Populations	• Adults with T2D who are not on intensive insulin treatment • Children with T2D who are not on intensive insulin treatment • Pregnant people with T2D who are not using insulin • Pregnant people with gestational diabetes who are not using insulin	• Populations other than those listed
Interventions	• FDA-approved CGM devices (rtCGM and isCGM) • FDA-approved combination devices integrating CGM with insulin pump or infusion (including sensor-augmented insulin pumps) if the effect of the CGM component can be isolated	• Interventions other than those listed • Professional CGM

Study Component	Inclusion	Exclusion
Comparators	• Self-monitoring using conventional blood glucose meters • Attention control • Blinded or sham CGM • Routine lab monitoring • Usual care	• Comparators other than those stated • No comparator • Comparisons of different models of the same device

Outcomes	• Primary intermediate outcomes
	  ○ Achieving target HbA1C level
	  ○ Maintaining target HbA1C level
	  ○ Change in HbA1c
	  ○ Acute episodes of hypoglycemia requiring intervention
	• Secondary intermediate outcomes
	  ○ Quality of life (validated instruments only)
	  ○ Mortality
	  ○ Perinatal mortality
	  ○ Severe perinatal morbidity
	• Safety related to the device itself
	• Economic outcomes
	  ○ Cost-effectiveness
	  ○ Health care resource utilization and costs
		• Outcomes other than those listed
		• Economic outcomes from studies performed in non-US countries
		• Economic outcomes from studies performed in the US that were published more than 5 years ago

Timing	• When used for routine monitoring of glucose control in type 2 diabetes	• Other uses (e.g., monitoring hyperglycemia during hospitalization for coronary care)
Setting	• Any outpatient or inpatient clinical setting in countries categorized as *very high* on the UN Human Development Index	• Emergency settings • Nonclinical settings (e.g., studies in healthy volunteers) • Countries categorized other than *very high* on the UN Human Development Index

Study Design and Sample Size	• KQ1
	  ○ RCTs with no sample size limitation
	• KQ2
	  ○ RCTs with no sample size limitation
	  ○ FDA documentation on device-related safety concerns
	• KQ3
	  ○ RCTs with no sample size limitation
	• KQ4
	  ○ RCTs with no sample size limitation
	  ○ Formal economic studies with no sample size limitation
		• Studies other that those listed by KQ
		• Studies that do not report outcomes of interest
		• Noncomparative association or correlation studies
		• Proof-of-principle studies (e.g., device modification)

Study Duration	• 12 weeks or longer	• Fewer than 12 weeks
Publication	• Published, peer-reviewed, English-language articles	• Abstracts, conference proceedings, posters, editorials, letters

Abbreviations. CGM: continuous glucose monitoring; isCGM: intermittently scanned CGM; KQ: key question; RCT: randomized controlled trial; rtCGM: real-time CGM; T2D: type 2 diabetes; UN: United Nations.

References

1. National Institute of Diabetes and Digestive and Kidney Diseases. Managing diabetes. 2023; https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes. Accessed August 17, 2024.
2. American Diabetes Association Professional Practice C. 6. Glycemic goals and hypoglycemia: Standards of Care in diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S111-S125. doi: 10.2337/dc24-S006.
3. American Diabetes Association Professional Practice C. 7. Diabetes technology: Standards of Care in diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S126-S144. doi: 10.2337/dc24-S007.
4. The diaTribe Foundation. Continuous glucose monitors. 2024; https://diatribe.org/diabetes-technology/continuous-glucose-monitors. Accessed August 14, 2024.
5. Skelly AC, Brodt ED, Junge M, Winter C, Ferguson A. Continuous glucose monitoring – update. Final evidence report. 2017; https://www.hca.wa.gov/assets/program/continuous-glucose-monitoring-final-rpt-20171221.pdf. Accessed August 17, 2024.
6. Washington State Health Care Authority. Health Technology Clinical Committee findings and decision topic: continuous glucose monitoring - re-review. 2018; https://www.hca.wa.gov/assets/program/cgm-final-findings-decision-20180318.pdf. Accessed August 17, 2024.
7. Birch SE. Health Technology Assessment topic selection, 2024. 2024; https://www.hca.wa.gov/assets/program/Director-final-topic-selection-2024.pdf. Accessed August 17, 2024.