Washington State Health Care Authority

March 21, 2025 Meeting Materials
Health Technology Clinical Committee

Continuous Glucose Monitoring (CGM)

Contents

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.

Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name: Pandora "Luke"

Middle initial: L

Last name: Wander (Januszewski)

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Employment (VA)		✔ Self	Family
B	Employment (Microsoft)		Self	✔ Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Not to my knowledge

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

2/14/25

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Health Technology Clinical Committee Application for Membership

Washington State Health Care Authority

1 Contact information

First name: Pandora "Luke"

Middle initial: L

Last name: Wander (Januszewski)

Address:

Phone number:

Best method, time to reach you: email, weekdays

Email:

Today's date: 2/13/25

2 Personal information (optional)

Gender:

- [ ] Male
- [x] Female
- [ ] X/non-binary[1]

Pronouns (select all that apply)

- [x] She/her
- [ ] He/him
- [ ] They/them
- [ ] Other (subj./obj.):

Race or Ethnicity

- [ ] American Indian or Alaska Native
- [ ] Asian or Pacific Islander American
- [ ] Black/ African American
- [ ] Latino, Hispanic, Spanish
- [x] White/ Caucasian
- [ ] Other:

3 Professional training

Education (list degrees): BFA, MD, MS

Health care practitioner licenses: MD-WA

Professional affiliations: American Diabetes Association, Society for General Internal Medicine, American College of Physicians (

Board certifications, formal training, or other designations: Internal Medicine, post-doctoral fellowship in cardiovascular epidemiology, post-doctoral fellowship in rep

Current position (title and employer): Associate Professor, University of Washington; Staff Physician, VA Puget Sound

Current practice type and years in practice: Hospital medicine physician, 11

Total years as an active practitioner: 14

Location of practice (city): Seattle, WA

1 *Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.*

4 Experience

Provide a brief explanation (up to 150 words each) addressing the following:

1) Why you would like to serve on the clinical committee;

I am very interested in the ways that groups incorporate scientific evidence to inform clinical practice. I'm excited to collaborate with others interested in this area.

2) The value of informing health policy decisions with scientific evidence, including any examples incorporating new evidence into your practice;

I feel very strongly that scientific evidence should inform health practice and try to follow the literature in diabetes and hospital medicine very closely. As a physician-scientist at an academic research center, I try to use my clinical teaching opportunities to help medical students, residents, and fellows become more comfortable reading and interpreting evidence. To that end, I have developed a mini-curriculum for clinical trainees focusing on these topics. Specifically, I teach about how to read scientific manuscripts, how to consider different "levels" of scientific evidence, and other related topics.

3) How your training and experience will inform your role on the committee

I have a masters degree in epidemiology and completed two post-doctoral fellowships in epidemiological methods. I have a grant-funded translational research program in type 2 diabetes. For the past four years, I have co-led the VA's National Long COVID Strategies & Best Practices group. In this role, I am leading a project in which we have commissioned evidence reviews from the VA's Evidence Synthesis Program. Following IOM standards, we developed an evidence-to-decision framework tailored for our scenario (which involves limited evidence, need for rapid decision-making, and VA-specific considerations) that we have used to develop some clinical guidance for Long COVID clinicians. We also developed "mad libs" style tools to help non-scientist clinicians on our panels think through the evidence presented.

4) Treating populations that may be underrepresented in clinical trials: women, children, elderly, or people with diverse ethnic and racial backgrounds, including recipients of Medicaid or other social safety net programs?

Equitable use of technology must be considered in every determination. Many groups have historically been excluded from clinical trials for a variety of reasons, which in some cases poses challenges in the development of guidance. For example, how do we know that treatments for chronic conditions such as heart failure are equally effective in older adults, who are often excluded from cardiac trials and have a higher burden of comorbidity, which may impact safety of, e.g., aggressive blood pressure or heart rate targets? When evidence is evaluated, consideration must be given to the populations that were studied and not studied, what these gaps mean, and how findings can be applied to inform recommendations equitably. Reviewers need to think carefully about when these gaps are--and when they are not--important factors to consider.

5 Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year? ✔ Yes ☐ No

Are you willing to commit to the responsibilities of a committee member, including:

- Attending meetings prepared for the topics of the day;
- Actively participating in discussions;
- Making decisions based on the evidence presented and the public interest1? ✔ Yes ☐ No

Could you, or any relative, benefit financially from the decisions made by the HTCC? ☐ Yes ✔ No

6 References

Provide three professional references:

1.
First name: Ed
Last name: Boyko
Relationship: Colleague
Title: Staff Physician, VA Puget Sound
Contact email:
Phone number:

2.
First name: Paul
Last name: Cornia
Relationship: Clinical supervisor
Title: Section head of hospital medicine, VA Puget Sour
Contact email:
Phone number:

3.
First name: Daniel
Last name: Enquobahrie
Relationship: Colleague
Title: Professor of Epidemology
Contact email:
Phone number:

For your application to be reviewed, please include:

✔ Completed application ✔ curriculum vitae ✔ **conflict of interest disclosure**

Download this form and send the completed version to **shtap@hca.wa.gov**

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

1 *Detailed in Washington Administrative Code (WAC) and committee bylaws*

Pandora Lucrezia "Luke" Wander (Januszewski), MD, MS
CURRICULUM VITAE

UNIVERSITY OF WASHINGTON **DATE OF CV: 1/4/2024**
SCHOOL OF MEDICINE/DOM

1. Personal Data: [redacted]

2. Education:

1997 Savannah College of Art & Design, BFA graphic design and computer animation, *magna cum laude*

2008 University of Washington School of Medicine, MD, *magna cum laude, Alpha Omega Alpha (elected in junior year)*

2014 University of Washington School of Public Health, MS epidemiology

3. Postgraduate Training:

2008–2011 *Internal Medicine residency,* University of Washington, Department of Medicine

2011–2013 *Cardiovascular Epidemiology fellowship,* University of Washington, Department of Epidemiology, Cardiovascular Epidemiology T32 HL007902-15 (PI: Siscovick)

2013–2014 *Perinatal Epidemiology fellowship,* University of Washington, Department of Epidemiology, Reproductive, Perinatal & Pediatric Epidemiology T32 HD052462-08 (PI: Reiber/Enquobahrie)

2013–2014 *Senior Fellow Trainee,* Department of Epidemiology, University of Washington

2021–2023 *Clinical Teaching Certificate program,* UW School of Medicine / Center for Learning and Innovation in Medical Education (CLIME), University of Washington, completed certificate requirements including six required synchronous and asynchronous sessions over 18 hours.

2023–2024 *Advanced Clinical Teaching Certificate program,* UW School of Medicine/CLIME, University of Washington, completed certificate requirements including six online sessions.

4. Faculty Positions Held:

2014–2017 *Acting Instructor,* Department of Medicine, University of Washington

2017–2023 *Assistant Professor,* Department of Medicine, University of Washington

2020–2023 *Assistant Professor (adjunct),* Department of Epidemiology, University of Washington

2023–present *Associate Professor,* Department of Medicine, University of Washington

2023–present *Associate Professor (adjunct),* Department of Epidemiology, University of Washington

2023–present *Associate Professor (adjunct),* Institute for Public Health Genetics, University of Washington

5. Hospital Positions Held:

2010–2014 Kindred Healthcare, *part-time night emergency physician*

2011–2014 The Everett Clinic (hospitalist group for Providence Regional Medical Center Everett), *part-time hospitalist*

2011–2014 VA Puget Sound Healthcare System, *fee-basis provider*

2014–present VA Puget Sound Healthcare System, *attending physician*

In this position, I serve as the inpatient medicine attending seven weeks per annum. I am responsible for overseeing patient management on the inpatient medicine service and teaching housestaff and medical students

6. Current (non-UW) employment: Not applicable

7. Honors:

2004–2006 UW School of Medicine Endowed Scholarship

2006–2008 UW School of Medicine George F. Odland Scholar

2007 Alpha Omega Alpha, elected in junior year, vice president of University of Washington chapter

2008 Seattle Internal Medicine Society's Medical Student of the Year Award

2011 Johns Hopkins General Internal Medicine Housestaff Research Becker Award, honorable mention

2017 UW Chair of Medicine Scholars Award

This award is given annually to meritorious University of Washington Department of Medicine trainees to foster their transition to the roles of physician-scientist and principal investigator. Each award offers $50,000 per year for two years in salary support to facilitate the transition to appointment as a junior faculty member.

2016–2020 National Institutes of Health Loan Repayment Program awardee

2019 Fellow, American College of Physicians

2020 *Annals of Internal Medicine,* top reviewer

8. Board Certification: Board certified in internal medicine, 2011–

9. Current License(s) to Practice: Washington, MD60183461, expires 8/31/2024

10. Diversity, equity, and inclusion activities:

1. Partnerships with community-based organizations

a. Seattle Fire Department paramedic student training program, *volunteer teacher* and *evaluator,* 2012–2021.

In this role, I trained and evaluated paramedic students. This work contributes directly to the critical support Seattle and King County Medic One provide to under-resourced, marginalized, and URM populations in our communities.

2. Research in health disparities

a. **COVID-related health disparities.** Our published research in COVID-19 examines the contribution of health disparities to adverse outcomes after COVID-19 (e.g., PMID: 34083248).

b. **Health disparities in pregnancy.** We have evaluated the role of disparities related to race and ethnicity in the development of pregnancy complications (e.g., PMID: 34102936).

c. **Mitigation of health disparities in human subjects research.** Lastly, in my role as chair of the University of Washington's Human Subjects Committee A, I am collaborating with HSD leadership to revise researcher frameworks for inclusion of non-English speaking participants in research (see Section 15. Special Local Responsibilities)

3. **Mentoring underrepresented trainees or faculty**
    a. **URM mentorship.** I train diverse students including undergraduates, epidemiology PhD students, and medicine residents. I provide evidence-based guidance on strategies for URM students to leverage to get the most benefit out of their mentored relationships. In addition, I mentor trainees in the conduct of research related to DEI disparities (e.g., Stern K, Duncan SM, Gavin A, Littman A, Wander PL. **Cross-sectional Associations of Multiracial Identity with Self-Reported Asthma and Poor Health Among American Indian and Alaskan Native Adults.** PMID: 36205849)
    b. **Building Infrastructure Leading to Diversity (BUILD) Promoting Opportunities for Diversity in Education and Research (PODER) mentor training.** I completed the summer BUILD-PODER critical race theory-based summer mentor training program in 2024.

4. **Teaching related to diversity, equity, and inclusion**
    a. University of Washington Public Health Ethiopia: Summer Maternal and Child Health Study Abroad Program, *assistant course director,* 2020–2023

    In this role, I taught a Study Abroad course based in Ethiopia. Last year, >80% of students enrolled represent URM groups

    b. **DEI curriculum on the inpatient medicine service.** For learners of all backgrounds, I provide instruction on tools to identify and respond to micro-aggressions as a routine component of my teaching on the inpatient medicine service.

11. Professional Organizations:

American College of Physicians, 2010–; fellow, 2019–
American Diabetes Association, 2008–
Alpha Omega Alpha, 2007–
Society for General Internal Medicine, 2023–

12. Teaching Responsibilities:

2005 University of Washington School of Medicine, *student teaching assistant for biochemistry and anatomy*

2005–2008 University of Washington School of Medicine, *peer tutor*

2008 University of Washington School of Medicine ICM-1 course, *physical exam preceptor*

2010 Summer Medical Dental Education Program for Minority Undergraduates, *mentor*

2014–present VA Puget Sound Healthcare System, Seattle, *internal medicine ward attending*

2020–2023 University of Washington Study Abroad Program, *assistant course director*

In this role, I taught a public health study abroad course (Ethiopia) covering topics related to maternal and child health epidemiology

2020–present University of Washington Department of Epidemiology EPI 514, *research preceptor*

2023–present University of Washington General Internal Medicine Research Fellowship, *fellowship director*

University of Washington Course Lectures

Course Title	Course Number	Talk Title	Dates	Learners
Maternal and Child Health Seminar	EPI 592	Mentors: How to find them and how to work with them	November 2, 2020	Epidemiology graduate students

Maternal and Child Health Seminar	EPI 592	Ethical principles and practical concerns in IRB review	October 2017, 2019	Epidemiology graduate students
Fetal Origins of Adult Diseases: A Public Health Perspective	GEN ST 162	Fetal Origins of Cardiovascular and Metabolic Diseases	September 2017, 2018, 2019, 2020, 2021, 2022	Undergraduate students
Medical Student Keystone Course (Transition to Residency)	—	Quick Tips for Reviewing a Research Paper (parts I and II)	May 2020	Fourth-year medical students
College Edge: Fetal Origins	ARTSCI 162B	Fetal Origins of Cardiovascular and Metabolic Diseases	September 2024	Undergraduate students

Current and Recent Mentees

1. Michael Krug MD, 2015–2016
    a. Project title: **Changes in resident well-being measures over a decade of progressive duty-hour limitations**
    b. Scholarly product: Published in *Acad Med* (2017)
    c. Current position: Clinical Associate Professor of Medicine, University of Washington, and Associate Program Director UW Boise Internal Medicine Residency
2. Eileen Koh, MD, 2016–2017
    a. Project title: **C-peptidogenic index outperforms insulinogenic index in predicting incident diabetes** Scholarly product: Abstract presented at *American Diabetes Association 77th Scientific Sessions* (2017) Current position: Endocrinology fellow, University of California at San Francisco Medical Center
3. Talitha Moon, DO, 2019–2021
    a. Project title: **Novel lipid biomarkers and insulin resistance in Japanese Americans**
    b. Scholarly product: Masters thesis
    c. Current position: Military physician
4. Ruchi Tiwari, MPH, 2018–present
    a. Project title: **A Retrospective Cohort Study of Race and Ethnicity, Pre-pregnancy Weight, and Pregnancy Complications.**
    b. Scholarly product: Published in *J Matern Fetal Neonatal Med* (2021), masters thesis
    c. Current position: Epidemiology PhD student, University of Washington
5. Anh Tran, DO, 2019–present
    a. Project title: **Plasma Amino Acid Profile, a Biomarker for Visceral Adipose Tissue that can substitute for Waist Circumference in Japanese Americans**
    b. Scholarly product: Published in *Obes Res Clin Pract* (2021)
    c. Current position: Private practice endocrinology
6. Meghna Shah, MD, 2020–2022
    a. Project title: **Addiction Services for Veterans: Opportunities in Acute Care.**
    b. Scholarly product: Published in *Addiction Medicine*
    c. Current position: Clinical instructor/academic hospitalist, University of Washington/VA Puget Sound Health Care System
7. Mitchell Edwards, DO, 2020–2021
    a. Project title: **Trichobezoar without trichotillomania in an adult male—a case report**
    b. Scholarly product: Published in *J Gen Int Med 2022*
    c. Current position: Clinical assistant professor/academic hospitalist, University of Washington/VA Puget Sound Health Care System
8. Chen Wu, MD, 2020–2022
    a. Project title: **Estimated excess acute-care length of stay and extra cost of testing-based versus symptom-based isolation strategies among veterans hospitalized with coronavirus disease 2019 (COVID-19) discharging to a congregate setting.**
    b. Scholarly product: Published in *Infect Control Hosp Epidemiol*
    c. Current position: Clinical associate professor/academic hospitalist, University of Washington/VA Puget Sound Health Care System

9. Subbulaxmi Trikudanathan, MD, MRCP, MMSc, 2020–2022
    a. Project title: **Plasma miRNAs may be associated with waist circumference and insulin resistance among women with polycystic ovary syndrome – Pilot Study**
    b. Scholarly product: Published in *Mol Cell Endocrinol*
    c. Current position: Clinical associate professor, University of Washington
10. Ji Cheol Bae, MD, PhD, MS, 2020–present
    a. Project title: **Associations of plasma ceramides with insulin sensitivity, insulin secretion, and incident diabetes in Japanese Americans**
    b. Scholarly product: Manuscript under review
    c. Current position: Associate Professor for the Department of Internal Medicine, Samsung Changwon Hospital, Sungkyunkwan University School of Medicine in Changwon, South Korea; UW visiting scholar (Center for Korea Studies, Henry M. Jackson School of International Studies)
11. Katie Stern, MD, 2020–2022
    a. Project title: **Cross-sectional Associations of Multiracial Identity with Self-Reported Asthma and Poor Health Among American Indian and Alaskan Native Adults**
    b. Scholarly product: Published at *Journal of Racial and Ethnic Disparities*
    c. Current position: Surgery resident, University of San Francisco East Bay
12. Jacob Armitage, BS, 2021–2023
    a. Project title: **Testing a polygenic risk score for interactions with statin use on risk of incident diabetes**
    b. Scholarly product: Masters thesis*
    c. Current position: Epidemiology masters student, University of Washington
13. Makena Chandra, BS, 2023–2024
    a. Project title: **Determining the relationship between branched chain amino acids and measures of insulin sensitivity and secretion**
    b. Scholarly product: Masters thesis*
    c. Current position: Public Health Genetics masters student, University of Washington

    * indicates committee chair

13. Editorial Responsibilities:

Editorial board member, *Diabetes Care,* 2022–

At-large reviewer for:

Academic Medicine
Annals of Internal Medicine.
Recognized as a top reviewer at Annals of Internal Medicine, 2020.
BMC Cardiovascular Disorders
Clinical Epigenetics
Diabetes
Diabetes Care
Recognized in Editor's Note: A Special Thanks to the Reviewers of *Diabetes Care*, *April 2021.*
Diabetologia
Heart
Journal of Cellular & Molecular Medicine
Journal of Clinical Endocrinology & Metabolism
Journal of Diabetes and Its Complications
Diabetes & Metabolism
And many others

14. Special National Responsibilities:

2018 Southern California Clinical and Translational Science Institute pilot grant program, *reviewer*

2020 NIH National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) Kidney, Nutrition, Obesity and Diabetes (KNOD) study section, *selected to serve as an early career reviewer,* Feb. 6–7, 2020, San Diego, CA

2020 International Diabetes Federation Atlas 10th Edition, *committee member*

The International Diabetes Federation (IDF) is recognized as the authoritative source on evidence on the global burden of diabetes. As an IDF Atlas committee member, I collaborated with an international working group of diabetes researchers to develop the new IDF chapter on Type 1 Diabetes in Adults.

2021 American Diabetes Association Precision Medicine in Diabetes—prognostics, *working group member*

2022 VA Integrated Project Team for Long COVID, *Data & Metrics team co-lead/Best Practices team co-lead/Evidence-Based Medicine Consultant to the VA Evidence Synthesis Program*

This is a national team established by the Deputy Under Secretary for Health to organize, support, and report on the development and diffusion of long COVID clinical and research guidance and access.

2022– International Diabetes Federation Congress, *abstract reviewer*

2022– NIH National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) *ad hoc reviewer*

2023– Diabetes Prevention Program Outcomes Study Steering Committee member

2023– Diabetes Prevention Program Outcomes Study Outcomes Assessment Committee member

2023– Diabetes Prevention Program Outcomes Study Diabetes and Cardiometabolic Interest Group co-chair

2024– VA Long COVID Practice Based Research Network Advisory Board member

14a. Special Regional Responsibilities:

2018–present Institute of Translational Health Sciences, ad hoc *pilot grant reviewer*

2020–present VA Puget Sound Health Care System Epidemiologic Research & Information Center (ERIC), *affiliate investigator*

2021–present VA Puget Sound Health Care System Institutional Review Board 2, *committee member and co-chair*

In this role, I chair the IRB of record for VA Puget Sound as well as the Boise (Idaho) VA and the Mann-Grandstaff (Spokane) VA

2021 Western Region Islet Study Group Meeting, *session chair*

2024–present VA Puget Sound Health Care System Research & Development Committee, *committee member and co-chair*

15. Special Local Responsibilities:

2007–2008 University of Washington medical student admission committee, *Advisory Committee member* 2006–present University of Washington Institutional Review Board HSD Committee A, *committee member*

2014–present University of Washington Cardiovascular Health Research Unit, *affiliate investigator*

2014–present University of Washington Diabetes Research Center, *affiliate investigator*

2016–present University of Washington Institutional Review Board Human Subjects Division (HSD) Committee A, *committee chair*

In this role I manage conflicts of interest and demonstrate an ethical commitment to our profession as physicians. In addition to the routine responsibilities of this position, I have actively sought out collaborations with HSD leadership in the development of several innovative projects:

1. *Created researcher guidance for return of individual results for study participants. These are now in regular use throughout the university: https://www.washington.edu/research/policies/guidance-return-of-individual-results/, 2018*
2. *Developed HSD guidance for early-career PIs running high-risk clinical trials. These are now in regular use by HSD staff, 2019*
3. *Revising researcher-facing consent materials, 2020—*
4. *Revising researcher framework for inclusion of non-English speaking participants in research, 2021–*
5. *Developed HSD guidance for suicide risk mitigation, 2024*

2017–present University of Washington Medicine Residency Research Program, *proposal review committee member*

2017–present University of Washington Department of Epidemiology, Maternal & Child Health Center of Excellence, *affiliate faculty member*

2018, 2020 Institute of Translational Health Sciences, ad hoc *pilot grant reviewer*

2020–present VA Puget Sound Metabolism Research Group, *core investigator*

2020–present VA Puget Sound Health Care System Epidemiologic Research & Information Center (ERIC), *affiliate investigator*

2020–present University of Washington Nutrition Obesity Research Center (NORC), *affiliate investigator*

Recognized as in the inaugural investigator in the NORC Affiliate Investigator Spotlight Series, 9/2021 (https://uwnorc.org/uw-norc-affiliate-investigator-spotlight-dr-luke-wander/)

2022–present University of Washington Institute for Public Health Genetics, *affiliate faculty member*

2022–present University of Washington Nutrition Obesity Research Center (NORC), *assistant director for enrichment*

In this role I develop and host sessions that bring national and international scientists to the NORC to facilitate interdisciplinary exchange and foster new research collaborations.

2023–present University of Washington Division of General Internal Medicine Clinical Investigator Fellowship, *fellowship director*

2024–present VA Puget Sound R&D Seed Grant Program, *grant reviewer*

16. Research Funding (current and pending):

Current:

R01 DK132355 (Wander/Zraika) 4/1/22–3/31/26 1.2 CM
NIH NIDDK $1.9 million
Circulating miRNAs and prediction of beta-cell treatment response: The Restoring Insulin Secretion Study

The goal of this project is to identify miRNAs that are related to preservation or improvement in beta-cell function in prediabetes or early type 2 diabetes in youth and adults.

U19AG078558 (PI: Luchsinger) 9/22–8/27 0.6 CM
NIH NIA $2,264,916
Alzheimer's Disease and Alzheimer's Disease Related Dementias in Prediabetes and Type 2 Diabetes: The Diabetes Prevention Program Outcomes Study AD/ADRD Project
The goal of this project is to address the National Alzheimers Project Act goal to "prevent, halt, or reverse AD" in the high-risk group of persons with pre-diabetes and type 2 diabetes, who represent over half of the population aged 60 years and older in the US.
Role: Co-investigator

Past funding:

No number (Wander) 6/1/22–9/30/23 0.0 CM
VAPSHCS R&D $35,000
Long-term impacts of SARS-CoV-2 on diabetes outcomes
The goals of this project are to: 1) determine whether diabetes that occurs after SARS-CoV-2 infection is a permanent state, 2) determine whether individuals with new diabetes after recent SARS-CoV-2 infection are more likely than individuals with new diabetes without recent SARS-CoV-2 to require insulin, and 3) demonstrate the feasibility of using the VA EHR to identify long-term impacts of SARS-CoV-2 on clinically relevant diabetes outcomes.
Role: Principal investigator

No number (Wander) 07/01/20–06/30/22 3.0 CM
UW Diabetes Research Center $100,000/2 years
Identifying miRNA-mediated mechanisms driving the protective effects of metformin on beta-cell function
The goal of this project is to determine whether islet cell miRNAs mediate the effect of metformin on the β-cell, using next-generation miRNA sequencing followed by functional experiments with miRNA inhibitors or mimics in primary mouse islets with replication of key outcomes in isolated human β-cells.
Role: Principal investigator

R03DK122100 Wander (PI) 07/01/19–06/30/22
NIH NIDDK $116,625
Circulating miRNA Signatures of Beta-Cell Response to Metformin or Insulin in Youth with Dysglycemia
The goal of this project is to identify circulating miRNAs that are related to insulin resistance and beta-cell failure despite pharmacotherapy in youth with prediabetes or early type 2 diabetes.
Role: Principal investigator

K08DK103945 Wander (PI) 09/15/15–07/31/22
NIH DHHS $137,132
Circulating microRNAs and hyperglycemia
The goal of this project is to identify circulating epigenetic biomarkers that precede development of diabetes to better understand its pathogenesis, improve early detection, and facilitate new interventions aimed at diabetes prevention.
Role: Principal investigator

COVID19-8990-19 Boyko (PI) 05/01/20–03/31/21
VA Clinical Sciences R&D $111,179
The contribution of diabetes to adverse outcomes among veterans with COVID-19
The goal of this project is to determine the independent association of diabetes with adverse outcomes from COVID-19 and to evaluate whether these estimated effects are mediated by common cardiovascular comorbidities of diabetes.
Role: Co-investigator

T32 HD052462-08 Reiber, Gayle (PI) 04/01/13-06/30/14
Reproductive, pediatric, and perinatal epidemiology training grant
The goal of this project was to provide support for education and training of pre- and post-doctoral fellows in methods relevant to perinatal epidemiology.
Role: Senior research fellow

T32 HL007902-15 Siscovick, David (PI) 07/01/11-04/01/13
Cardiovascular epidemiology training grant
The goal of this project was to provide support for education and training of pre- and post-doctoral fellows in methods relevant to cardiovascular disease epidemiology.
Role: Post-doctoral research fellow

Pending funding:

R01 DK142781 Wander/Zraika (PI) 4/2025–3/2030
NIH NIDDK $2.4 million
Genetic variation in statin-associated diabetes
This project aims to elucidate the mechanisms by which genetic variations contribute to statin-associated β-cell failure and T2D.
Role: Principal investigator

17. Bibliography:

# first author	# senior author	# total
21	4	40

a. Manuscripts in Refereed Journals with authors listed in the order they appear in the original publication. Include manuscripts in press (i.e., accepted for publication):

1. Chun LS, Samii A, Hutter CM, Griffith A, Roberts JW, Leis BC, Mosley AD, **Wander PL,** Edwards KL, Payami H, Zabetian CP. **DBH -1021C-->T does not modify risk or age at onset in Parkinson's disease.** *Ann Neurol.* 2007 Jul; 62(1): 99-101. PMCID: PMC2823266 [original research]
2. **Wander PL,** Boyko EJ, Leonetti DL, McNeely MJ, Kahn SE, Fujimoto WY. **Greater hand-grip strength predicts a lower risk of developing type 2 diabetes over 10 years in leaner Japanese Americans.** *Diabetes Res Clin Pract.* 2011 May; 92(2): 261-4. PMCID: PMC3910507 [original research]
3. **Wander PL,** Boyko EJ, Leonetti DL, McNeely MJ, Kahn SE, Fujimoto WY. **Change in visceral adiposity independently predicts a greater risk of developing type 2 diabetes over 10 years in Japanese Americans.** *Diabetes Care.* 2013 Feb; 36(2): 289-93. PMCID: PMC3554282 [original research]
   This paper was among the first to examine longitudinal associations of visceral fat area with incident diabetes and has been cited 100 times since 2013.
4. **Wander PL,** Hochner H, Sitlani CM, Enquobahrie DA, Lumley T, Lawrence GM, Burger A, Savitsky B, Manor O, Meiner V, Hesselson S, Kwok PY, Siscovick DS, Friedlander Y. **Maternal genetic variation accounts in part for the associations of maternal size during pregnancy with offspring cardiometabolic risk in adulthood.** *PLoS One.* 2014 Mar 26;9(3):e91835. PMCID: PMC3966761 [original research]
5. Lawrence GM, Shulman S, Friedlander Y, Sitlani CM, Burger A, Savitsky B, Granot-Hershkovitz E, Lumley T, Kwok PY, Hesselson S, Enquobahrie D, **Wander PL,** Manor O, Siscovick DS, Hochner H. **Associations of Maternal Pre-pregnancy Body Mass Index and Gestational Weight Gain with Offspring**

Longitudinal Change in BMI. *Obesity (Silver Spring).* 2014 Apr;22(4):1165-71. PMCID: PMC3968220 [original research]

6. **Wander PL,** Fahrenbruch CE, Rea TD. **The Dispatcher Assisted Resuscitation Trial: Indirect Benefits of Emergency Research.** *Resus.* 2014 Sept 9. PMID: 25195982 [original research]
7. **Wander PL,** Sitlani M, Badon SE, Siscovick DS, Williams MA, Enquobahrie DA. **Associations of Early and Late Gestational Weight Gain With Offspring Birth Size.** *Matern Child Health J.* 2015 Nov;19(11):2462-9. PMID: 26093689 [original research]
8. Badon SE, **Wander PL,** Qiu C, Miller RS, Williams MA, Enquobahrie DA. **Maternal Leisure Time Physical Activity and Infant Birth Size.** *Epidemiology.* 2016 Jan;27(1):74-81. PMID: 26427724 [original research]
9. **Wander PL,** Enquobahrie DA, Pritchard C, McKnight B, Rice K, Christiansen M, Lemaitre R, Sotoodehnia N. **Circulating miRNAs and cardiac arrest outcomes.** *Resus*. 2016 Sep;106:96-101. PMID:27423422. [original research]
10. Enquobahrie DA, Tedesse MG, Qiu C, **Wander PL,** Holzmann C, Williams MA. **Maternal pre-pregnancy body-mass index and circulating microRNAs in pregnancy.** *Obes Res Clin Pract.* 2016 Oct 24. PMID: 27789200 [original research]
11. Krug MF, Golob A, **Wander PL,** Wipf JE. **Changes in resident well-being measures over a decade of progressive duty-hour limitations.** *Acad Med.* 2017 Mar 28. PMID: 28353505 [original research]
12. **Wander PL,** Boyko EJ, Hevner K, Parikh VJ, Tadesse MG, Sorensen TK, Williams MA, Enquobahrie DA. **Circulating early- and mid-pregnancy microRNAs and risk of gestational diabetes.** *Diabetes Res Clin Pract.* 2017 Jul 25;132:1-9. PMID: 28783527 [original research]

    This paper was one of the first longitudinal studies of circulating miRNAs and gestational diabetes risk and has been cited 68 times since 2017.

13. **Wander PL,** Hayashi T, Sato KK, Uehara S, Hikita Y, Leonetti DL, Kahn SE, Fujimoto WY, Boyko EJ. **Design and validation of a novel visceral adiposity estimation tool and comparison to existing adiposity surrogates.** *J Diabetes Complications.* 2018 Nov;32(11):1062-1067. doi: 10.1016/j.jdiacomp.2018.09.004. Epub 2018 Sep 11. PubMed PMID: 30236542; PubMed Central PMCID: PMC6174110 [original research]
14. Ley SH, Chavarro, JE, Li M, Bao W, Hinkle, SN, **Wander PL,** Rich-Edwards J, Olsen S, Damm P, Grunnet LG, Mills J, Hu FB, Zhang C. **Lifetime duration of lactation and incident type 2 diabetes risk and glucose metabolic biomarkers in high-risk women.** *Diabetes Care.* 2020 Feb 10. pii: dc192237. doi: 10.2337/dc19-2237. PMID:32041900 [original research]
15. **Wander PL,** Enquobahrie DA, Bammler T, MacDonald J, Kahn SE, Leonetti D, Fujimoto W, Boyko EJ. **Circulating microRNAs and incident type 2 diabetes in Japanese Americans.** *Nature Sci Rep.* 2020 Apr 16;10(1):6509. doi: 10.1038/s41598-020-63606-3. PMID: 32300167 [original research]
16. Orlov M, **Wander PL,** Morrell E, Mikacenic C, Wurfel M. **A case for targeting Th17 cells in SARS-CoV-2 infections.** *J Immunol.* 2020 Aug 15. PMID: 32651218 [narrative review]
17. Wu C, Tulloch-Palomino L, Demars S, Glass S, **Wander PL. Estimated excess acute-care length of stay and extra cost of testing-based versus symptom-based isolation strategies among veterans hospitalized with coronavirus disease 2019 (COVID-19) discharging to a congregate setting.** *Infect Control Hosp Epidemiol.* 2020 Oct 26. PMID: 3310237 [original research]
18. Tiwari R, Enquobahrie DE, **Wander PL,** Souter V. **A Retrospective Cohort Study of Race and Ethnicity, Pre-pregnancy Weight, and Pregnancy Complications.** *J Matern Fetal Neonatal Med.* 2021 Jun 8:1-8. PMID: 34102936. [original research]
19. **Wander PL,** Boyko EJ. **Long-term fasting glycemic variability and microvascular complications in type 2 diabetes.** *J Clin Endocrinol Metab.* 2021 Jun 16. PMID: 33720352 [invited commentary]
20. **Wander PL,** Lowy E, Beste LB, Tulloch-Palomino L, Korpak A, Peterson A, Young B, Boyko EJ. **Risk factors for adverse outcomes among 35,879 Veterans with and without diabetes after diagnosis with COVID-19.** *BMJ Open Diabetes Res Care.* 2021 Jun. PMID: 34083248. [original research]

    This paper was among the first national studies of adverse outcomes from SARS-CoV-2 infection among adults with diabetes.

21. **Wander PL,** Christophi C, Araneta MRG, Boyko EJ, Enquobahrie DA, Dabelea D, Goldberg RB, Kahn SE, Kim C, Pi-Sunyer X, Knowler WC. **Adiposity, related biomarkers, and type 2 diabetes after gestational diabetes: The Diabetes Prevention Program.** *Obesity.* 2022 Jan 3. PMID: 34796678 [original research]
22. **Wander PL,** Lowy E, Beste LB, Tulloch-Palomino L, Korpak A, Peterson A, Kahn SE, Boyko EJ. **Prior glucose-lowering medication use and 30-day outcomes among 64,892 Veterans with diabetes and COVID-19.** *Diabetes Care.* 2021 Dec. PMID: 34615690 [original research]
    To our knowledge, this is the largest-U.S. based study of risk factors for adverse short-term outcomes after COVID-19 among individuals with diabetes.
23. Edwards, M, Kaz A, **Wander PL. Trichobezoar without trichotillomania in an adult male—a case report.** *J Gen Intern Med.* 2022 Jan 3. PMID: 34981351 [case report]
24. Tran A, **Wander PL,** Thomas MK, Leonetti D, Kahn SE, Fujimoto WY, Boyko EJ. **Plasma Amino Acid Profile, a Biomarker for Visceral Adipose Tissue that can substitute for Waist Circumference in Japanese Americans.** *Obes Res Clin Pract.* 2021 Nov–Dec. PMID: 34782257 [original research]
25. **Wander PL,** Lowy E, Beste LA, Tulloch-Palomino L, Korpak A, Peterson AC, Kahn SE, Boyko EJ. **The incidence of diabetes among 2,777,768 Veterans with and without recent SARS-CoV-2 infection.** *Diabetes Care.* 2022 Jan. PMID: 35085391 [original research]
    This was the first large national longitudinal cohort study to examine the association of SARS-CoV-2 infection with incident diabetes in adults.
26. Harding JL, **Wander PL,** Zhang X, Li X, Karurang S, Chen H, Sun H, Xie Y, Oram RA, Magliano DJ, Zhou Z, Jenkins AJ, Ma RCW. **The Global Incidence of Adult-Onset Type 1 Diabetes: A Systematic Review.** *Diabetes Care.* 2022 Mar. PMID: 35349653 [systematic review]
27. **Wander PL,** Lowy E, Beste LB, Tulloch-Palomino L, Korpak A, Peterson A, Kahn SE, Danaei G, Boyko EJ. **Associations of statin use at diagnosis with 30-day adverse outcomes among 4,801,406 Veterans with and without SARS-CoV-2.** *BMJ Open.* 2022 Mar. PMID: 35304400 [original research]
28. **Wander PL,** Hinkle SN, Enquobahrie DA, Wu J, Ley SH, Grunnet LG, Chavarro J, Li M, Bjerregaard AA, Liu A, Damm P, Sherman S, Rawal S, Zhu Y, Chen L, Mills J, Hu FB, Vaag A, Olsen SF, Zhang C. **Associations of lactation duration with cardiometabolic biomarkers and outcomes among Danish women with history of gestational diabetes.** *Nutrients.* 2022 Feb. PMID: 35277008 [original research]
29. Rangu R, **Wander PL,** Barrow B, Zraika S. **Going viral in the islet: Mediators of SARS-CoV-2 entry beyond ACE2.** *Accepted at* Journal of Molecular Endocrinology *4/22* [narrative review]
30. Shah M, Starks H, **Wander PL,** Saxon AJ. **Addiction Services for Veterans: Opportunities in Acute Care.** *J Addict Med.* 2022 Aug. PMID: 35914119 [original research]
31. **Wander PL,** Enquobahrie DE, Bammler TK, MacDonald JW, Srinouanprachanh S, Kaleru T, Khakpour D, Trikudanathan S. **Plasma miRNAs may be associated with waist circumference and insulin resistance among women with polycystic ovary syndrome – Pilot Study.** *Mol Cell Endocrinol.* 2022 Aug. PMID: 35843386 [original research]
32. Admon AJ, **Wander PL,** Iwashyna TJ, Ioannou GN, Boyko EJ, Hynes DM, Bowling B, Bohnert ASB, O'Hare AM, Smith VA, Pura J, Hebert PL, Wong ES, Niederhausen M, Maciejewski MJ. **Consensus Elements for Observational Research on COVID-19-related long-term outcomes.** *Accepted to* Medical Care *5/5/22* [original research]
33. Rangu R, **Wander PL,** Zraika S. **Does diabetes risk after SARS-CoV-2 infection depend on the viral variant?** *Diabetes Res Clin Pract.* 2022 Aug 28. PMID: 36038088 [commentary]
34. Gregory GA, Robinson TIG, Linklater SE, Wang F, Colagiuri S, de Beaufort C, Donaghue KC, International Diabetes Federation Diabetes Atlas Type 1 Diabetes in Adults Special Interest Group, Magliano DJ, Maniam J, Orchard TJ, Rai P, Ogle GD. **Global incidence, prevalence, and mortality of type 1 diabetes in 2021 with projection to 2040: A modelling study.** *Lancet Diabetes and Endocrinol.* 2022 Oct. PMID: 36113507 [Member of IDF DAT1DASIG, original research]
35. Stern K, Duncan SM, Gavin A, Littman A, **Wander PL. Cross-sectional Associations of Multiracial Identity with Self-Reported Asthma and Poor Health Among American Indian and Alaskan Native Adults.** *Journal of Racial and Ethnic Disparities.* 2022 Oct. PMID: 36205849 [original research]

36. **Wander PL**, Lowy E, Korpak A, Beste LA, Kahn SE, Boyko EJ. **SARS-CoV-2 infection is associated with higher odds of insulin treatment but not with hemoglobin A1c at 120 days in U.S. Veterans with new-onset diabetes.** *Diabetes Epidemiology and Management.* 2023 May PMID: pending [original research]
37. Bae JC*, **Wander PL***, Lemaitre RN, Fretts AM, Sitlani CM Bui HH, Thomas MK, Leonetti D, Fujimoto WY, Boyko EJ, Utzschneider KM. Associations of plasma sphingolipids with measures of insulin sensitivity, β-cell function, and incident diabetes in Japanese Americans. *Nutrition, Metabolism & Cardiovascular Diseases.* 2023 Nov. PMID: pending [original research]
38. **Wander PL,** Baraff A, Fox A, Cho K, Maripuri M, Honerlaw JP, Ho YL, Dey AT, O'Hare AM, Bohnert ASB, Boyko EJ, Maciejewski ML, Viglianti E, Iwashyna TJ, Hynes DM, Osborne TF, Ioannou GN. **Rates, risk factors, clinical settings and symptoms related to documentation of the ICD-10 code U09.9 for long COVID in the national Veterans Affairs healthcare system.** *JAMA Network Open.* 2023 Dec. PMID: pending [original research]
39. **Wander PL,** Enquobahrie DA, Boyko EJ, Bammler T, Macdonald J, Srinouanprachanh S, other authors TBD, Kahn SE. **The association of circulating miRNAs with treatment response in pediatric TODAY participants.** *Accepted at* Diabetes Care [original research]
40. Harding J. Pfaff E, Boyko EJ, **Wander PL. Addressing Common Sources of Bias in Studies of New-Onset Type 2 Diabetes Following COVID That Use Electronic Health Record Data.** *Accepted at* Diabetes Epidemiology & Management [invited review]

* denotes shared first-authorship

b. Book chapters:

1. Ma RCW, Harding JL, **Wander PL**, Zhang X, Li X, Karurang S, Chen H, Sun H, Xie Y, Oram RA, Magliano DJ, Zhou Z, Jenkins AJ. **Type 1 Diabetes in Adults.** *International Diabetes Federation Atlas 10th Edition* 2021

c. Published books, videos, software, etc.:

1. Lavietes S, Roush J, Moore C, **Wander PL**. *Savannah College of Art & Design Interactive Admissions Catalog.* 1996; Macromedia-Director–based CD-ROM software for undergraduate recruitment

d. Other publications (e.g., in non-refereed journals and letters to the editor).

1. **Wander PL**, Lavietes S. **Creating an interactive catalog for an art college.** *Proceedings of SIGGRAPH 96,* Annual Conference Series. 1996 Oct
2. **Wander PL**, Best J. **Key Clinical Question: What is the most cost-effective evaluation for a first syncopal episode?** *The Hospitalist.* 2010 Jul [narrative review]
3. **Wander PL,** Orlov M, Merel SE, Enquobahrie DA. **Risk factors for severe COVID-19 illness in health care workers: Too many unknowns.** *Infect Control Hosp Epidemiol.* 2020 Apr 27:1-2. PMID: 32336303 [letter]

e. Manuscripts submitted, listed separately with date of submission:

1. Wheeler S, Beste LA, Overland M, **Wander PL. Interventions by primary care clinicians to improve vaccine acceptance in adults: A systematic review.** *Submitted to* Vaccines *7/24*
2. **Wander PL,** Lowy E, Korpak A, Beste L, Kahn SE, Boyko EJ. **SARS-CoV-2 infection is associated with higher chance of diabetes remission among Veterans with incident diabetes using definitions derived from the electronic health record.** *Under review at* PLoS One [original research]
3. Avramovic S, Enquobahrie DA, Schwartz MD, Korpak A, Boyko EJ, Wander PL. **Age at T2D detection is inversely associated with glycemic control in a national inception cohort of U.S. Veterans with diabetes**. *Under review at* Diabetes Research & Clinical Practice [original research]
4. Schlak A, Seidel I, Awan O, Neal J, Janssen K, Warner D, Lee K, Park A, Adly M, Brill E, Atkins D, Jones B*, Wander PL* (co-senior authors). **Creating a Rapid Consensus Approach to Track Long COVID Symptoms Across the Veterans Health Administration.** *Under review at* JGIM [original research]

f. Abstracts:

1. Wander PL, Raskind MA, Zabetian CP, Warren DJ, Kumata J, Peskind ER. **Prazosin improves nightmares and sleep disturbance and does not worsen daytime symptoms in posttraumatic stress disorder.** *J Investig Med.* 2006 Jan;54(1):S167. Presented at the *Western Student and Medical Research Forum;* June 2006, Carmel, CA.
2. Wander PL, Boyko EJ, Leonetti DL, McNeely MJ, Kahn SE, Fujimoto WY. **Greater hand-grip strength predicts a lower risk of developing type 2 diabetes over 10 years in leaner Japanese Americans.** Presented at the *American Diabetes Association 70th Scientific Sessions*; June 2010, Orlando, FL.
3. Wander PL, Boyko EJ, Leonetti DL, McNeely MJ, Kahn SE, Fujimoto WY. **Change in visceral adiposity independently predicts a greater risk of developing type 2 diabetes over 10 years in Japanese Americans.** Presented at the *American Diabetes Association 71th Scientific Sessions*; June 2011, San Diego, CA.
4. Wander PL, Hochner H, Sitlani CM, Enquobahrie DA, Lumley T, Lawrence GM, Burger A, Savitsky B, Manor O, Meiner V, Hesselson S, Kwok PY, Siscovick DS, Friedlander Y. **Maternal genetic variation accounts in part for the associations of maternal size during pregnancy with offspring cardiometabolic risk in adulthood.** Presented at the *American Heart Association Epi/NPAM annual meeting*; March 2012, San Diego, CA.
5. Lawrence GM, Shulman S, Hochner H, Sitlani C, Burger A, Savitsky B, Granot-Hershkovitz E, Lumley T, Enquobahrie DA, Wander PL, Manor O, Siscovick DS, Friedlander Y. **Associations of Maternal Pre-pregnancy Body Mass Index and Gestational Weight Gain with Offspring Longitudinal Change in BMI.** Presented at the *American Heart Association Epi/NPAM annual meeting*; March 2012, San Diego, CA.
6. Wander PL, Fahrenbruch CE, Rea TD. **The Dispatcher Assisted Resuscitation Trial: Indirect Benefits of Emergency Research.** Presented at the *American Heart Association Epi/NPAM annual meeting*; March 2013, New Orleans, LA.
7. Krug MF, Davidson HL, Wander PL, Wipf JE. **The Effects of a Decade of Progressive Duty Hour Limitations at a Multi-hospital Internal Medicine Residency Program.** Presented at the *Society for General Internal Medicine Norwest Regional Meeting*; March 2013, Portland, OR.
8. Wander PL, Sitlani M, Badon SE, Siscovick DS, Williams MA, Enquobahrie DA. **Associations of Early and Late Gestational Weight Gain With Offspring Birth Size.** Presented at the *Society for Pediatric and Perinatal Epidemiologic Research Annual Meeting;* June 2014, Seattle, WA.
9. Paquette AG, Wander PL, Sangar V, Sorensen TK, Williams M, Price N, Enquobahrie DA. **Pre-Pregnancy Obesity and Metabolomic and Transcriptomic Networks in Early-Mid Pregnancy.** Presented at the *Society for Reproductive Investigation* annual meeting; March 2017, Orlando, FL.
10. Koh E, Wander PL, Utzschneider KM, Kahn SE, Leonetti D, Fujimoto WY. Boyko EJ. **Oral Glucose Stimulated C-Peptide Concentrations Predict Incident Type 2 Diabetes over 10 Years in Japanese Americans.** Presented at *American Diabetes Association 77th Scientific Sessions;* June 2017, San Diego, CA.
11. Wander PL, Boyko EJ, Enquobahrie DA. **Circulating miR-155 and miR-21-3p may mediate associations of maternal pre-pregnancy BMI with subsequent gestational diabetes mellitus is mothers of male but not female offspring.** Presented at NIDDK workshop: *Body Composition Measurements from Birth through 5 Years: Challenges, Gaps, and Existing & Emerging Technologies;* May 2019, Bethesda, MD.
12. Tran A, Wander PL, Thomas MK, Leonetti DL, Kahn SE, Fujimoto WY, Boyko EJ. **Plasma Amino Acid Profile as a Predictive Biomarker for Visceral Adiposity in Japanese Americans.** Presented at *American Diabetes Association 81st Scientific Session;* June 2021, online only.
13. Avramovic S, Schwartz MD, Enquobahrie DA, Boyko EJ, **Wander PL. Early-Onset Type 2 Diabetes Is Associated With Higher A1c and Glycemic Variability in a Cohort of Veterans Followed Prospectively.** Presented at *American Diabetes Association 82st Scientific Session;* June 2022, New Orleans, LA.
14. **Wander PL.** Enquobahrie DA, Bammler TK, MacDonald JW, Srinouanprachanh S, Kaleru T, Khakpour D, Trikudanathan S. **Plasma miRNAs may be associated with waist circumference and insulin resistance among women with polycystic ovary syndrome—Pilot Study.** Presented at *American Diabetes Association 82st Scientific Session;* June 2022, New Orleans, LA.
15. Zraika S, Barrow BM, Enquobahrie DA, Bammler TK, MacDonald JW, Srinouanprachanh S, Chan KCG, Boyko EJ, Kahn SE, **Wander PL. Direct β-cell effects of miR-6727-3p, an miRNA related to improved β-**

cell function in humans. Presented at *American Diabetes Association 83st Scientific Session;* June 2023, San Diego, CA.

16. Huang L, VA Cooperative Study #2028, Sugimoto J, Lee JS, Shah JA, **Wander PL. Associations of SARS-CoV-2 Infection with Incident Diabetes Among U.S. Veterans in a Longitudinal Observational Cohort.** Presented at *American Diabetes Association 84st Scientific Session;* June 2024, Orlando, FL.

18. Selected Presentations

a. National/international

1. Wander PL. **Associations of Diabetes and Adverse COVID-19 Outcomes in Veterans.** *VA Office of Research and Development Field-based Meeting on the Impact of COVID-19 in Veterans with Diabetes,* May 14, 2021, online only. [invited talk]
2. Wander PL. **Bidirectional associations of COVID-19 and diabetes.** *NIH National Institute of Child Health and Development Division of Intramural Population Health Research Seminar,* Oct. 28, 2021, online only. [invited talk]
3. Wander PL. **Diabetes and COVID-19.** *International Diabetes Federation Podcast: D-Talk,* April 22, 2022, online only. [podcast]
4. Wander PL. **Understanding the link between COVID and diabetes.** *VA COVID-19 Observational Research Collaboratory meeting,* June 13, 2023, online only. [invited talk]
5. Wander PL. **VA Cooperative Study #2028: Incident Diabetes After SARS-CoV-2.** *CSP2028 Executive Committee meeting,* September 12, 2023, online only. [invited talk]
6. Awan O, Neal J, Seidel I, Trinh H, Wander PL. **VHA Whole Health System Approach to Long COVID Operations and Clinical Care.** *Office of the Assistant Secretary for Health Long COVID Clinical Workgroup meeting.* May 2, 2024, online only. [invited talk]
7. Wander PL. **VA Cooperative Study #2028: Updates on Incident Diabetes After SARS-CoV-2.** *CSP2028 Scientific Retreat 2024.* July 9, 2024, Seattle, WA [invited talk]
8. Neal J, Seidel I, Wander PL, Awan O. **Long COVID.** *VA Extension for Community Healthcare Outcomes (VA-ECHO) Emerging Issues in Healthcare.* September 4, 2024, online only. [invited talk]
9. Neal J, Seidel I, Wander PL. **VA Nervous System Guide for Long COVID.** *CDC/University of New Mexico Long COVID and Fatiguing Illness Recovery Program ECHO.* December 12, 2024, online only. [invited talk]
10. Neal J, Seidel I, Wander PL, Awan O. **Long COVID Field Advisory Board Strategies and Best Practices.** *VHA National Specialty Care Program Office National Program Executive Directors Office Hours for Hot Topics/Urgent/Emergent Issues.* January 4, 2025, online only. [invited talk]

b. Regional:

1. Wander PL. **Circulating miRNAs as mediators or markers of beta-cell treatment response in youth.** *University of Washington Diabetes Research Center Diabetes and Metabolism Seminar Series: Islet Biology Workshop,* Dec. 10, 2020, online only. [invited talk]
2. Wander PL. **Bidirectional associations of COVID-19 and diabetes in Veterans.** *VA Boise Medical Center Grand Rounds,* Oct. 14, 2021, online only. [invited talk]
3. Wander PL. **Do miRNAs mediate the protective effects of metformin in the beta cell?** *University of Washington Nutrition Obesity Research Center-Diabetes Research Center Research Retreat,* Nov. 18, 2021 [invited talk]
4. Wander PL. **Expert Panel: Career Paths in Medicine and Scholarship.** *American College of Physicians Washington Chapter Spring Scientific Scholarship Day,* May 27, 2022, online only.
5. Wander PL. **Expert Panel: Career Paths in Medicine and Scholarship.** *American College of Physicians Washington Chapter Spring Scientific Scholarship Day,* May 27, 2023, online only.

c. Local

1. Wander PL. **Considerations for preparing your first career development award application.** University of Washington Reproductive, Perinatal & Pediatric Epidemiology Seminar, Jan. 8, 2014. [invited talk]
2. Wander PL. **Demystifying the Institutional Review Board (for Epidemiologists).** University of Washington Epidemiology Seminar Series, April 7, 2020, online only. [invited talk]

3. Wander PL. **Epi Methods: Observational Studies of Fluoroquinolones and Aortic Dissection.** *VA Puget Sound Hospital Medicine Journal Club,* Jan. 28, 2021, online only.
4. Wander PL. **Circulating miRNAs as mediators or markers of beta-cell treatment response in youth.** *University of Washington Pediatric Endocrinology Research Conference,* Oct. 9, 2020, online only. [invited talk]
5. Wander PL. **Associations of Diabetes and Adverse COVID-19 Outcomes in Veterans.** *VA Puget Sound Weight Matters Research Forum,* May 10, 2021, online only. [invited talk]
6. Wander PL. **Bidirectional associations of COVID-19 and diabetes in VA Veterans.** *VA Puget Sound Hospital Medicine Works in Progress,* Jan 6, 2022, online only.
7. Wander PL. **Works in Progress: Circulating miRNAs in beta-cell treatment.** *VA Puget Sound Chief of Medicine Rounds,* Feb. 16, 2022, online only.
8. Wander PL. **Why consider sex in diabetes and obesity research? Examples in the context of pregnancy.** *UW Nutrition Obesity Research Center Symposium,* Dec. 8, 2022.
9. Wander PL. **Understanding the link between COVID and diabetes: Caveats from the epi literature.** *South Lake Union "Basic-Clinical Mixer,"* April 25, 2023.

Washington State Health Care Authority

Agency medical director comments

Continuous Glucose Monitor: Re-review

Christopher Chen, MD, MBA
Medical Director, Medicaid
WA Health Care Authority

March 21, 2025

Continuous Glucose Monitor: Device

- Blood glucose monitoring is an important component of treating diabetes to provide regular feedback about glycemic variability or incidents of hypoglycemia
- The predominant method of measuring blood glucose is using self-monitored blood glucose systems to measure glucose in a fingerstick blood sample
- Continuous glucose monitors estimate blood glucose levels every few minutes and can provide more detailed data about trends in BG levels
- Information is typically collected by a sensor, either placed on the skin (replaced every 7-14 days) or implanted (replaced every 180 days)

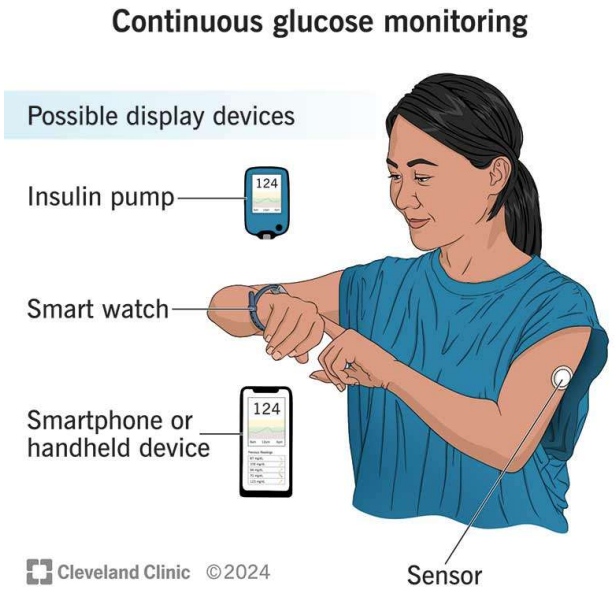

Photo credit: Cleveland Clinic

Continuous Glucose Monitor Background: FDA Approval

Table 1. CGM Devices Available in the US[27,28]

Device	Manufacturer	Fingerstick Calibration	Approved Patient Age and Patient Population	Sensor Wear Duration	Alarms for Low and High Blood Sugar
rtCGM					
Eversense E3	Senseonics	2 per day minimum for first 21 days, then 1 per day	18+ years	180 days	Yes
Freestyle Libre 2	Abbott	Not required	4+ years and in pregnancy	14 days	Yes
Freestyle Libre 2 Plus	Abbott	Not required	2+ years and in pregnancy	15 days	Yes
Freestyle Libre 3	Abbott	Not required	4+ years and in pregnancy	14 days	Yes
Freestyle Libre 3 Plus	Abbott	Not required	2+ years and in pregnancy	15 days	Yes
Guardian 3	Medtronic	2 per day, minimum	3+ years	7 days	Yes
Guardian 4	Medtronic	Not required	7+ years	7 days	Yes
G6	Dexcom	Not required	2+ years	10 days	Yes
G7	Dexcom	Not required	2+ years and in pregnancy	10 days	Yes
isCGM					
Freestyle Libre 14-day System	Abbott	Not required	18+	14 days	No
Over-the-Counter CGM					

Previous HTCC decisions

- Continuous Glucose Monitoring was first reviewed by the HTA program in 2011
  - Covered with conditions: T1DM < 19 using insulin, with recurrent hypoglycemia or enrolled in clinical trial
- Continuous Glucose Monitoring was re-reviewed in 2018
  - Covered with conditions: children and adults with T1DM, adults with T2DM with intensive insulin therapy/poor control/recurrent hypoglycemia, and pregnant individuals on insulin
- In 2024, the HCA director selected CGMs for rereview based on published evidence that could change the original coverage determination

Scope of discussion today

In scope	Out of scope/not reviewed

• Population for whom CGM is not currently covered:
  • T2DM not on intensive insulin regimens
  • Pregnant individuals with T2DM or GM not on insulin
	• Population for whom CGM is currently covered, including:
	  • Type 1 DM
	  • Type 2 DM with intensive insulin regimen
	  • Pregnant individuals on insulin
	• Professional CGM

Agency medical director concerns - overall

Efficacy = High -> Medium

Safety = Medium -> Low

Cost = High

Evidence Report: Key Questions

- 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)?

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

- What are the **costs and cost-effectiveness** of continuous glucose monitoring in adults and children with type 2 diabetes?

AMDG Evidence Considerations

- Efficacy:
  - Adults with T2D not on intensive insulin regimen
    - Statistically significant reduction in HbA1c but not clinically meaningful difference from baseline (moderate CoE, 7 RCTs)
    - No difference in achieving target A1c, or quality of life
  - Children with T2D not on intensive insulin regimen
    - No RCTs identified
  - Pregnant individuals with DM not on insulin:
    - No RCTs identified for T2DM; for GDM, CGM not associated with significantly lower A1C
- Safety:
  - No serious adverse events in clinical trials; mostly site sensor insertion site-related issues of mild to moderate intensity
  - 5 open recalls of CGM systems; 4 categorized as Class 1, “may cause serious injury or death”, related to possibility of errors detecting hypoglycemia (no deaths have been reported)
- Cost:
  - 1 simulated cost effectiveness study

Cost: Agency Experience

- Apple Health (Medicaid)
  - Gestational diabetes: $12K
  - Type 1 Diabetes: $2.2M
  - Type 2 Diabetes: $1.9M
  - Total: $4.2M
- Uniform Medical Plan (UMP)
  - Across populations: ~$11.8M total; after rebate is $6.8M

Current Coverage: CGMs

- **Medicare** (2024) [1]:
  - Patient with DM, received training for the device, device is FDA approved
  - Treated with insulin, OR have a history of problematic hypoglycemia
  - Seen for diabetes management in 6 months preceding prescription
- **Aetna**[2]:
  - Initiation: Patient with DM, using intensive insulin regimen or insulin pump, and < 18/uncontrolled/hypoglycemia
  - Continuation: using intensive insulin regimen or pump, and improved glycemic control/decreased hypoglycemia, or being assessed every 6 months

1 Medicare LCD - Glucose Monitors (L33822)
2 Diabetes Tests, Programs and Supplies - Medical Clinical Policy Bulletins | Aetna

Washington State Health Care Authority

Agency Medical Director Group
Recommendation

CGM is a covered benefit for:

- Individuals with Type 1 diabetes OR
- Individuals with Type 2 diabetes who are using intensive insulin therapy, AND
  - Are unable to achieve target HbA1C despite adherence to an appropriate glycemic management plan, OR
  - Are suffering from recurrent severe episodes of hypoglycemia (blood glucose < 50 mg/dl or symptomatic), OR
  - Have hypoglycemia unawareness, OR
- Individuals who are pregnant who have:
  - Type 1 diabetes, OR
  - Type 2 diabetes or gestational diabetes, AND require insulin therapy

CGM is a noncovered benefit for:

- Individuals with Type 2 diabetes who:
  - Are not on insulin therapy AND
  - Are on non-intensive insulin regimens (except for pregnant individuals)

Washington State Health Care Authority

Questions?

More Information:

shtap@hca.wa.gov

Washington State Health Care Authority

Continuous glucose monitoring

Order of scheduled presentations:

	Name
1	Nicole Ehrhardt, MD – University of Washington
2	Greg Norman, PhD – Senior Director of Health Econ & Outcomes Research, Dexcom
3	Qaashif Panjwani, PharmD – Medical Outcome Manager, Abbott
4	Nicole Treanor, RD – Franciscan Endocrine Associates – Tacoma
5	Kevin Wren – T1International and #insulin4all
6	Alyson Blum, PharmD – Providence Medical Group

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

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1 Applicant information

First name: NIcole

Middle initial:

Last name: Ehrhardt

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

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C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
A	Dexcom advisory board- march 2023		✓ Self	Family
A	Medtronic advisory board Feb 2025		✓ Self	Family
D	I received no payment the university received the		Self	Family
D	I received no payment the university received the		Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

CGM- submitted manuscript: The Cut Diabetes study
CGM- Castorio, Ehrhardt et al Continuous Glucose Monitoring for Gestational Diabetes Management Working Group. J Womens Health (Larchmt). 025 Jan;34(1):10-20. doi: 10.1089/jwh.2023.0864

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

I am part of a writing group for American Diabetes Association reviewing literature on CGM couple to behavior lifestyle modification

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

I do research and evaluate the use of CGM in GDM and also non-insulin-requiring patients living with DM.

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

UNIVERSITY of WASHINGTON

METABOLISM, ENDOCRINOLOGY & NUTRITION

Increasing Access to CGM in Type 2 Diabetes

Ni

Nicole Ehrhardt, MD

Arthi Thirumalai, MBBS MACP

Irl B. Hirsch, MD

With Support From:

Lorena Alarcon-Casas Wright, MD
Professor of Clinical Practice
Director UW Medicine LatinX Diabetes Clinic

Tiffany Nguyen, MD
Clinical Assistant Professor

Stephanie Kim, MD
Clinical Assistant Professor

Amy Eby, MD
Clinical Assistant Professor

Savitha Subramanian, MD
Professor of Medicine

Roini Wadhwani, ARNP
Sarah Loebner, PA-C, MPH

Subbulaxmi Trikudanathan, MD
Clinical Professor of Medicine

Mayumi Endo, MD
Clinical Assistant Professor

Kate Weaver, MD
Clinical Associate Professor

Anthony Desantis, MD
Clinical Professor of Medicine

University of Washington Diabetes Institute and Harborview Medical Center
Division of Metabolism, Endocrinology and Nutrition | UW Medicine

Endocrinologists and Health Care Professionals at UW strongly support increased CGM access and following ADA 2025 guidelines on CGM use

- **American Diabetes Association Professional Practice Committee:**

-7.15 Recommend real-time **CGM** (rtCGM) **A** or intermittently scanned CGM (isCGM) for diabetes management to youth **C** and adults **B** with diabetes **on any type of insulin therapy**. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.

-7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes **treated with glucose-lowering medications** other than insulin to achieve and maintain individualized glycemic goals **B (**1).

7. Diabetes Technology: Standards of Care in Diabetes—2025 | Diabetes Care | American Diabetes Association

Multiple guidelines recently expanded CGM recommendations to include **patients with all types of diabetes**

GUIDELINES	RECOMMENDATIONS
American Diabetes Association. **Diabetes Technology: Standards of Care in Diabetes (2025)[1,*]**	rtCGM should be offered to adults: • Early in the disease, **even at time of diagnosis (Level C)** • For diabetes management regardless of their **type of insulin therapy (Level A)** • With type 2 diabetes being **treated with glucose-lowering medications other than insulin (Level B)** • With type 1 diabetes and pregnancy to help achieve glycemic goals **(Level A)** • Who are **pregnant with any type of diabetes (Level E)**
AACE American Association of Clinical Endocrinology. **Consensus Statement: Comprehensive T2D Management Algorithm (2023)[2]**	CGM is a major advance for persons with **all forms of diabetes** based on clinical trials showing increased time in range, improved A1C, and decreased hypoglycemia **Optimal treatment for T2D** should take into **account the risk of hypoglycemia** • CGM including alarms or **alerts is recommended**, particularly for persons with hypoglycemia who would benefit from these warnings

CGM = continuous glucose monitoring; rtCGM = real-time CGM; T2D = type 2 diabetes.
*The American Diabetes Association (ADA) recommendations receive a rating of A, B, C, or E depending on the quality and strength of the evidence to support their recommendations. Evidence Level A has clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered. Evidence Level B has supportive evidence from well-conducted cohort studies. Evidence Level C has supportive evidence from poorly controlled or uncontrolled studies. Evidence Level E is from expert consensus or clinical experience.[3]
1 American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2025;48(Suppl 1):S146-S166. 2 Samson SL, et al. *Endocr Pract*. 2023;29(5):305-340. 3 American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2024;47(Suppl 1):S1-S4.

CGM is an important “tool” in the toolkit for Individualized Diabetes Patient Care

AGP Report

March 6, 2024 - March 19, 2024 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

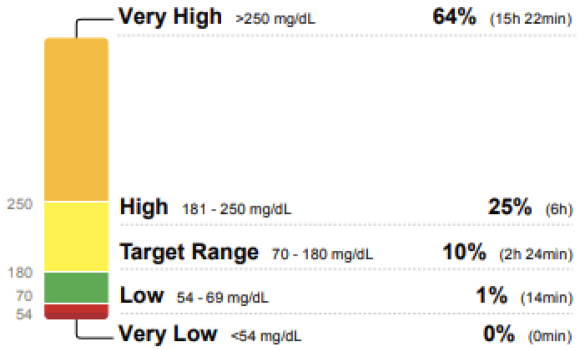
March 6, 2024 - March 19, 2024	**14 Days**
Time CGM Active:	**91%**

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	**266** mg/dL
Glucose Management Indicator (GMI)	**9.7%**
Glucose Variability	**24.9%**

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



Very High	>250 mg/dL	**64%**	(15h 22min)
High	181 - 250 mg/dL	**25%**	(6h)
Target Range	70 - 180 mg/dL	**10%**	(2h 24min)
Low	54 - 69 mg/dL	**1%**	(14min)
Very Low	<54 mg/dL	**0%**	(0min)

Baseline

AGP Report

May 9, 2024 - May 22, 2024 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

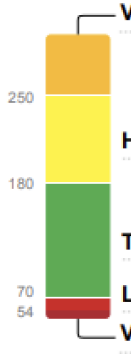
May 9, 2024 - May 22, 2024	**14 Days**
Time CGM Active:	**85%**

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	**192** mg/dL
Glucose Management Indicator (GMI)	**7.9%**
Glucose Variability	**33.2%**

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



Very High	>250 mg/dL	**22%**	(5h 17min)
High	181 - 250 mg/dL	**32%**	(7h 41min)
Target Range	70 - 180 mg/dL	**43%**	(10h 19min)
Low	54 - 69 mg/dL	**2%**	(29min)
Very Low	<54 mg/dL	**1%**	(14min)

2 months

- T2 DM since 2010
- 53 y/M
- On 2 injections daily of mixed insulin
- A1C had never been <9-11% since 2010
- Usually limited glucose meter data at visits
- No change to insulin dose made but CGM provided to patient for 6 months

AGP Report

November 28, 2024 - December 11, 2024 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

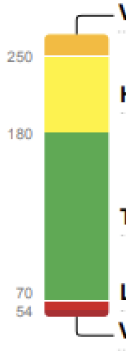
November 28, 2024 - December 11, 2024	**14 Days**
Time CGM Active:	**86%**

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	**163** mg/dL
Glucose Management Indicator (GMI)	**7.2%**
Glucose Variability	**31.0%**

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



Very High	>250 mg/dL	**6%**	(1h 26min)
High	181 - 250 mg/dL	**28%**	(6h 43min)
Target Range	70 - 180 mg/dL	**65%**	(15h 37min)
Low	54 - 69 mg/dL	**1%**	(14min)
Very Low	<54 mg/dL	**0%**	(0min)

6 months

CGM is an important “tool” in the toolkit for Individualized DM Patient Care

Visit	Date	Weight (kg)	Height (cm)	Fasting glucose	A1c	Calc BMI
Screening	1/26/2024	90.58	176	111	8.9	29.2
Randomization	2/1/2024	90.89	176	164	8.9	29.3
3 Month Visit	5/2/2024	88.1	176	130	6.8	28.4
6 Month Visit	8/1/2024	86.9	176	144	6.9	28.1
9 Month Visit	10/31/2024	84.8	176	134	6.9	27.4
12 Month FINAL	1/23/2025	79	176	121	6.8	25.5

Medication	Start	End	Dose	Unit	Freq	Route	Indication

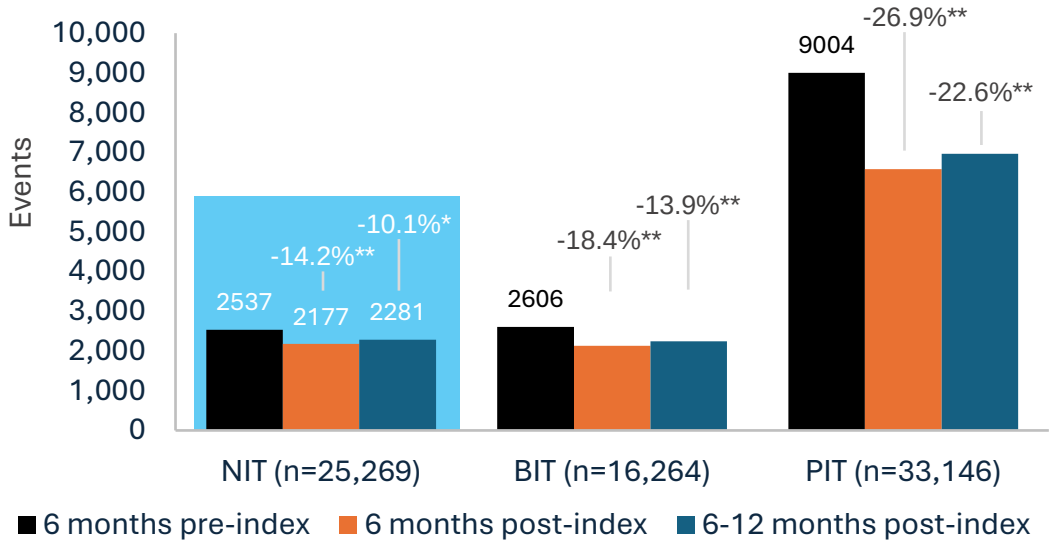
Real-World Clinical Data on CGM with Regional Washington State Data*

Reference	Type of Study	Duration (months)	Number of Participants	Type of Diabetes Medications	Baseline HbA1C	% HbA1C Change
Grace et al. (2)	Single arm prospective study	6	237	Insulin (42%) Non-insulin (58%)	9.4%	2.4%
Garg et al. (3)	Retrospective cohort study	3	74,679 (6030 HbA1c analysis)	Basal insulin (60%) Non-insulin (40%)	8.8%	1.1%
Shields et al. (4)	Prospective cohort study	3	182 (CGM=91 C=91)	Basal insulin (35%) Non-insulin (65%)	9.2%	CGM 1.4% C 0.8% (Difference 0.6%)
*Ehrhardt et al. (5)	Randomized control trial	3	120 (CGM=61 ED=59)	Basal insulin (26%) Non-insulin (74%)	10.7%	CGM 2.4% ED 1.5% (Difference 0.9%)
*Vidovic et al. (9)	Dual arm prospective study	6	66 (CGM=30 C=36)	Insulin (≥1 injections)	9.0%	CGM 1.4% C 0.8% (Difference 0.6%)

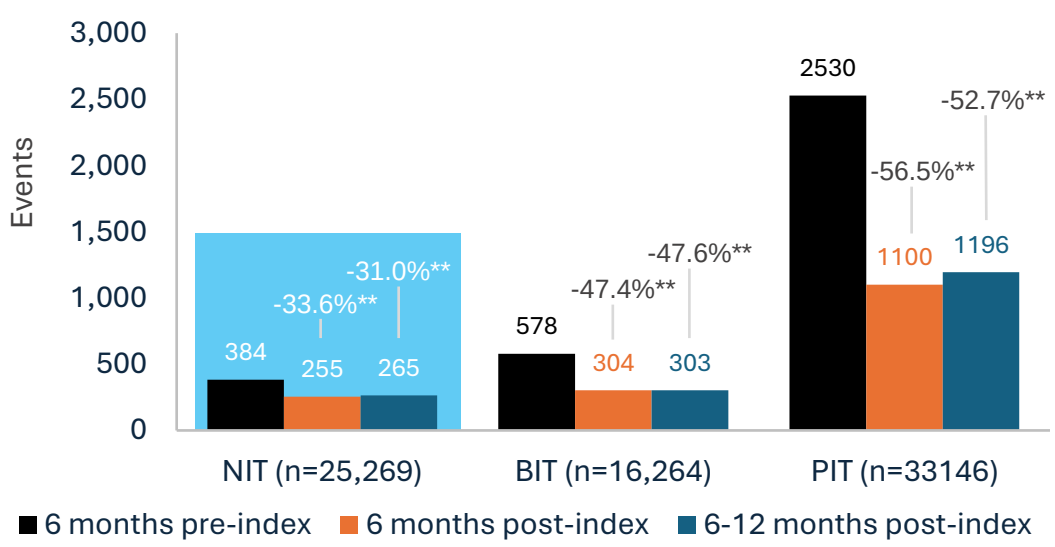
ED= Education only, C=Control, CGM= Continuous Glucose Monitor

CGM use led to significant reductions in hospitalizations in all treatment groups: Real world analysis of 74,679 adults with T2D

All-cause hospitalizations (ACH)



Acute diabetes-related hospitalizations (ADH)



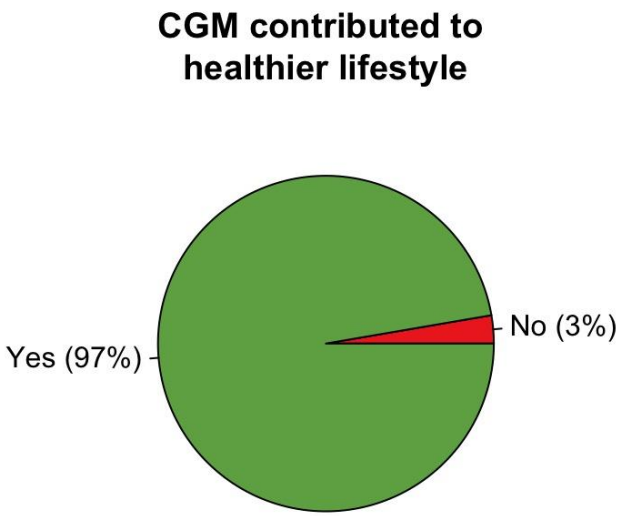
* p<0.01; ** p<0.0001

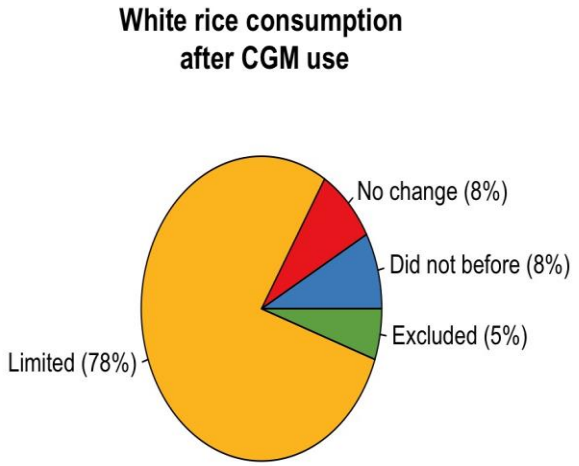
- CGM use led to significant reduction in ACH and ADH across all groups, with larger reductions in ADH
- ADH reductions accounted for a large proportion of the ACH reductions
- Costs associated with hospitalization of people with T2D are high; CGM use could reduce these costs

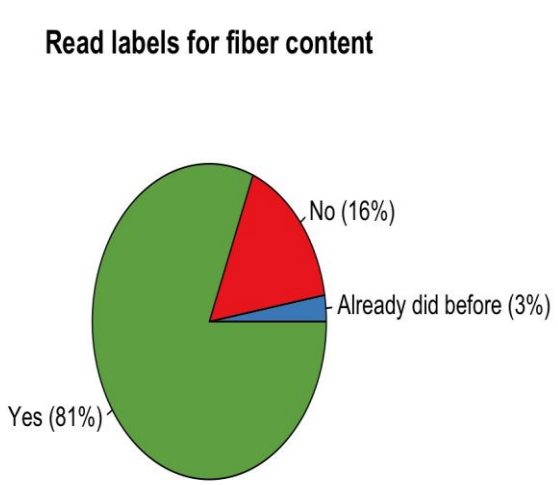
- ACH, all-cause hospitalizations; ADH, acute diabetes-related hospitalizations; BIT, basal insulin therapy; CGM, continuous glucose monitoring; NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes
- Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

Perspectives from Patients with Diabetes in WA using CGM

Perception of Change after CGM USE:







Ehrhardt et al: CUT DM Study unpublished Data

T2D management in the 1st year matters

Legacy effect / metabolic memory

A1C ≥ 6.5% in the 1st year after diagnosis
associated with 20% higher risk for micro- and macrovascular events[1,*]

29% higher risk of mortality
associated with A1C levels 7.0 to <8.0% compared to A1C <6.5%[1]

Immediate, intensive treatment

25% reduced risk of microvascular disease
with early intensive-therapy sustained in UKPDS 30-year analysis[2]

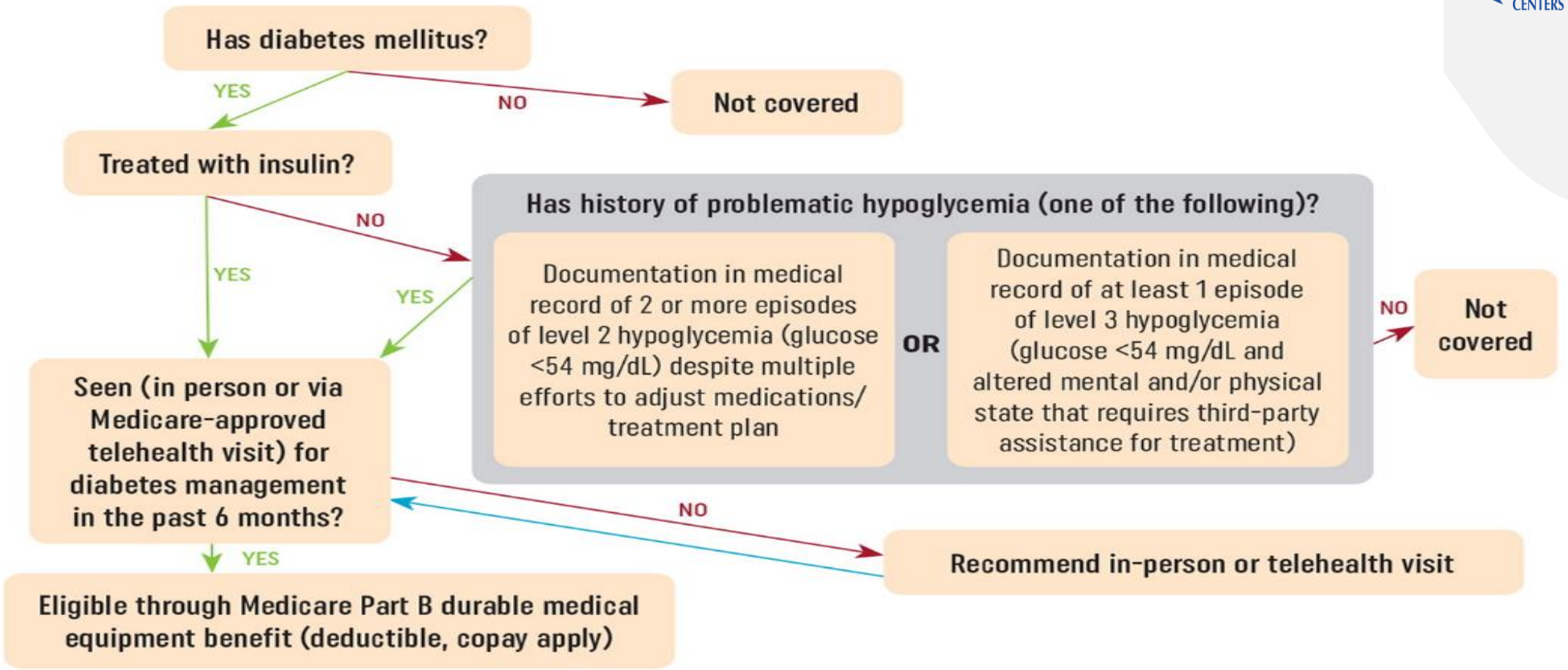
Post-trial risk reductions emerged in myocardial infarction and death from any cause[2]

Legacy effect persists up to 44 years[3]

Even if glycemic management declined over time[1,2]

- * Microvascular events: ESRD, diabetic eye disease, lower-extremity amputation; macrovascular events: cerebrovascular disease, heart disease, heart failure, vascular disease.
- A1C, glycated hemoglobin or HbA1C; ESRD, end-stage renal disease; T2D, type 2 diabetes; UKPDS, UK Prospective Diabetes Study.
- 1. Laiteerapong N, et al. *Diabetes Care*. 2019;42(3):416-426. 2. Holman RR, et al. *N Engl J Med*. 2008;359(15):1577-1589. 3. Holman R. Presented at: Hybrid 58th EASD Annual Meeting. Updated September 21, 2022. Accessed November 30, 2023. https://www.easd.org/media-centre/home.html#!resources/clinical-outcomes-at-44-years-do-the-legacy-effects-persist

WHCA recommendations do not match Medicare 2023 and Reduce CGM access to needed populations



Fam Pract Manag. 2024;31(1):17-18

Summary: Please reduce barriers to patients with diabetes having access to CGM

Empower our Patients living with Diabetes

- Let patient and provider decide if CGM is the correct tool for them through shared decision-making
- Lessen the paperwork burden for providers so they can focus on patient care

Actionable Items:

- Remove need to document finger-stick glucose checks
- Allow coverage for anyone with diabetes diagnosis on insulin
- Strongly consider covering for non-insulin requiring individuals with diabetes

Health Technology Clinical Committee Conflict of Interest Disclosure

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1 Applicant information

First name: Greg

Middle initial:

Last name: Norman

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

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Financial interest categories

Use these categories to indicate the nature of the financial interest:

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B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

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Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Dexcom, Inc		✓ Self	Family
C	Dexcom, Inc		✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Have published research on continuous gluocose monitors in peer-reviewed scientific journals.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

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To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Gregory Norman Digitally signed by Gregory Norman
Date: 2025.02.28 13:56:35 -08'00'

Date

2/28/2025

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

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Washington State Health Care Authority

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1 Applicant information

First name: Qaashif

Middle initial: A

Last name: Panjwani

Phone number: [redacted]

Email: [redacted]

2 Financial interests

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A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Abbott Diabetes Care	Salary	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Yes

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

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To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature Qaashif Panjwani

Qaashif Panjwani Digitally signed by Qaashif Panjwani Date: 2025.02.28 10:56:03 -06'00'

Date 2/28/25

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Washington State Health Care Authority
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FreeStyle

FREESTYLE LIBRE SYSTEMS

Improving Clinical and Economic Outcomes

Abbott

Important Safety Information

FreeStyle Libre 14 day, FreeStyle Libre 2 and FreeStyle Libre 3 systems:

Failure to use FreeStyle Libre systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury.

If glucose reading and alarms (if enabled) do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions.

Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.

Beta Bionics: iLet Pancreas

For full Beta Bionics safety information, please visit www.betabionics.com/safety.

Tandem: t:slim X2

For full Tandem safety information, please visit www.tandemdiabetes.com/safetyinfo.

Insulet: Omnipod 5

For full Omnipod safety information, please visit www.omnipod.com/safety.

The FreeStyle Libre systems are indicated across all types of diabetes, regardless of insulin usage

FreeStyle Libre 2 | FreeStyle Libre 2 PLUS

- An iCGM with optional alarms* that measures glucose accurately every minute[1]

FreeStyle Libre 3 | FreeStyle Libre 3 PLUS

- World's smallest[2,†] sensor proven to be accurate and is easy to wear comfortably[3] for up to 15 days

The **FreeStyle Libre systems** are broadly indicated for people with diabetes:

T1D	T2D MDI	T2D Basal	T2D Not on Insulin
AID Freestyle Libre 2 Plus and FreeStyle Libre 3 Plus	Ages 2 and Up FreeStyle Libre 2 Plus and FreeStyle Libre 3 Plus		

AID: automated insulin delivery system; iCGM: integrated continuous glucose monitor; MDI: multiple daily injection; T1D: type 1 diabetes; T2D: type 2 diabetes.

The FreeStyle Libre system apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the app. Use of the FreeStyle Libre systems apps may require registration with LibreView.

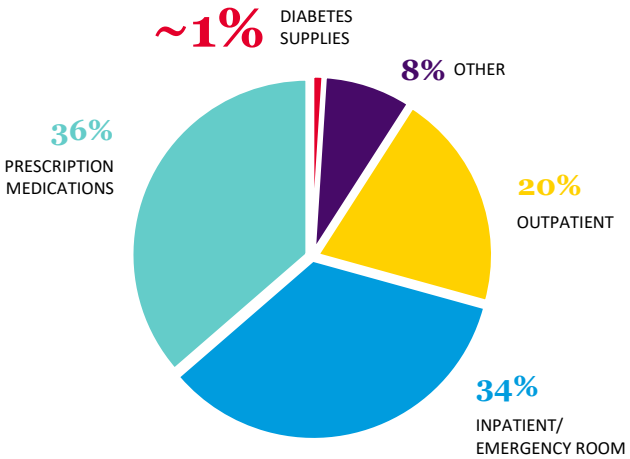
Medicare and other payor criteria may apply.

*Alarm notifications will only be received when alarms settings are enabled and turned on and sensor is within 20 feet unobstructed of the reading device.
†Among patient-applied sensors.

References: 1. Alva, S. (2020). Accessed September 11,2024 from: https://www.diabeteseducator.org/docs/default-source/dana-files/adc-23842v3-revised-august-3-2020cd070ee4-83cd-472c-a990-892684a26df3.pdf?sfvrsn=26ee6959_5.s
2. Data on file. Abbott Diabetes Care, Inc. **3.** Alva et al. Diabetes Ther (2023): https://link.springer.com/article/10.1007/s13300-023-01385-6

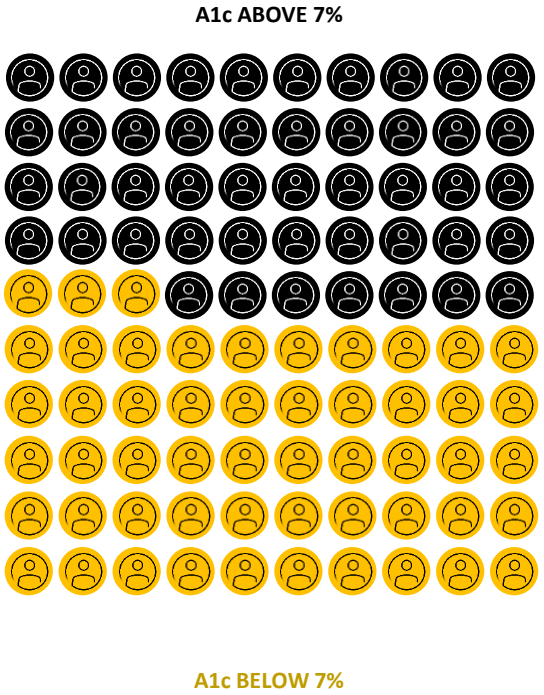
The total cost of diabetes in the US is ≈ $413 billion[1]

Total Diabetes Healthcare Expenditures[1]



Supplies for diabetes management (such as CGM) are only ~**1% of total costs** incurred by people with diabetes[1]

Despite Growing Costs, Only 53% of US Adults With Diabetes Met an A1c Goal of <7%[2]



CGM: continuous glucose monitoring.

References: **1.** Parker et al. Diabetes Care (2024): https://doi.org/10.2337/dci23-0085 **2.** Appendix | Diabetes | CDC. (n.d.). https://www.cdc.gov/diabetes/php/data-research/index.html

2025 ADA Standards of Care Recommendations on CGM Use[1]

American Diabetes Association®

Continuing Recommendations

Recommend **CGM for all individuals with diabetes on any type of insulin** therapy and should be used as close to daily as possible for maximal benefit

The **choice** of device should be made based on the individual's circumstances, preferences, and needs

People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM

Expanded Recommendations

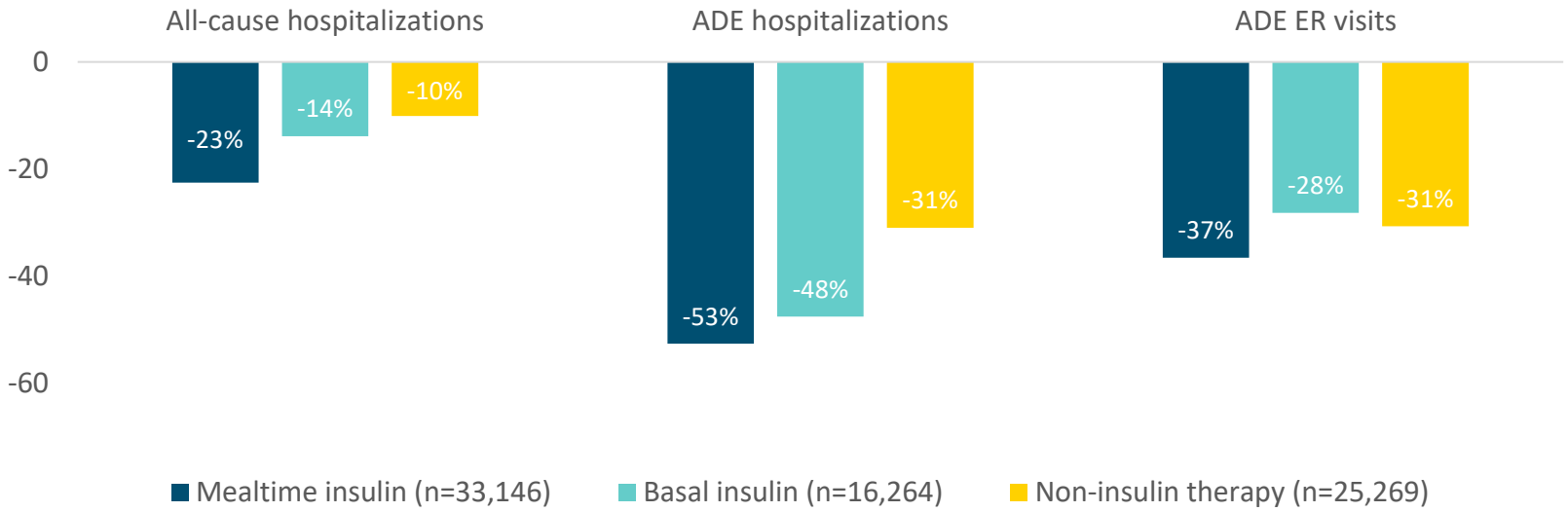
Consider using CGM in adults with type 2 diabetes **treated with glucose-lowering medications other than insulin** to achieve and maintain individualized glycemic goal

CGM can help achieve glycemic goals in **pregnancy**

Reference: 1. ElSayed, N. A., et al. (2024). 7. Diabetes Technology: Standards of Care in Diabetes—2025. Diabetes Care, 48(Supplement_1), S146–S166. https://doi.org/10.2337/dc25-s007

Use of CGM is associated with significant reductions in healthcare resource use in people with T2DM, including those managed with basal- or non-insulin therapy[1]

Change in healthcare resource use, 6-months pre-index vs 6-month post-index



Analysis of Optum's de-identified Market Clarity EMR and claims data; patients with T2DM with >1 CGM claim were included

Reductions in healthcare resource use associated with CGM use were sustained during 6–12 months post-index

*p<0.0001 vs pre-index; *ADE = acute diabetes event; CGM = continuous glucose monitoring; EMR = electronic medical records; ER = emergency room; T2DM = type 2 diabetes mellitus*

Reference: 1. Garg, SK. *Diabetes Obesity and Metabolism* (2024). https://doi.org/10.1111/dom.15866

FreeStyle Libre systems are supported by clinical evidence in patients with diabetes using basal insulin and not on insulin

Patients with T2DM on basal insulin experienced fewer adverse diabetes events and hospitalizations with the FreeStyle Libre systems[1,2]

T2DM patients not on insulin experienced fewer acute diabetes events with reductions in A1c with FreeStyle Libre systems[1,3-5]

Patients starting FreeStyle Libre systems in combination with a GLP-1 saw an incremental improvement in A1c[6]

GLP-1: glucagon-like peptide receptor agonist 1; T2DM: type 2 diabetes mellitus.

References: 1. Miller et al. Am J Manag Care (2021): https://doi.org/10.37765/ajmc.2021.88780 **2.** Guerci et al. Diabetes Technol Ther (2022): https://doi.org/10.1089/dia.2022.0271 **3.** Wright et al. Diabetes Spectr (2021): https://doi.org/10.2337/ds20-0069 **4.** Miller et al. Diabetes (2020): https://doi.org/10.2337/db20-84-LB **5.** Aronson et al. Diabetes Obes Metab. (2022): https://doi.org/10.1111/dom.14949 **6.** Wright, E et al. Initiating GLP-1 therapy in combination with FreeStyle Libre provides greater benefit compared to GLP-1 therapy alone, The Official Journal of ATTD Advanced Technologies & Treatments for Diabetes CONFERENCE 6–9 MARCH 2024 I FLORENCE & ONLINE. (2024). Diabetes Technol Ther, 26(S2), https://doi.org/10.1089/dia.2024.2525.abstracts

All together, easier diabetes management

Abbott now has partnerships with four of the largest companies that develop automated insulin delivery systems—offering more choices with the technology of the FreeStyle Libre family of products[1]

FreeStyle Libre 2 PLUS Sensor

TANDEM Diabetes Care
t:slim X2 Insulin Pump

Insulet
Omnipod® 5 Automated Insulin Delivery System

FreeStyle Libre 3 PLUS Sensor

Beta Bionics
iLet Bionic Pancreas

Abbott

Medtronic
Partnership with Medtronic will enable sensors based on Abbott's FreeStyle Libre sensing technology to integrate with Medtronic's insulin delivery systems*,[1]

Product images are for illustrative purposes only. Not actual patient data.

*Partnership is not yet available in US market

Reference: 1. Abbott MediaRoom. https://abbott.mediaroom.com/2024-08-07-Abbott-Enters-Global-Partnership-to-Connect-Its-World-Leading-Continuous-Glucose-Monitoring-System-with-Medtronics-Insulin-Delivery-Devices. Accessed November 4, 2024.

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

I regularly speak about insulin rationing and our current crisis regarding access and affordability.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

I was on the WA Total Cost of Insulin workgroup and provide support for legislation concerning diabetes.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No.

4 Signature

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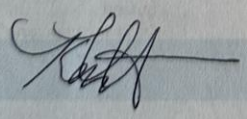
Signature 

Date 3/11/25

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Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.

Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name: Alyson

Middle initial: K

Last name: Blum

Phone number: [redacted]

Email: [redacted]

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
F	Dexcom - Speaker Bureau 1/24/25	[redacted]	✓ Self	Family
F	Dexcom Speaker Bureau 11/14/24		✓ Self	Family
F	Dexcom Speaker Bureau 7/15/24		✓ Self	Family
F	Dexcom Speaker Bureau 6/13/24		✓ Self	Family
F	Dexcom Speaker Bureau 2/24/24		✓ Self	Family
F	Dexcom Speaker Bureau 11/4/23		✓ Self	Family
F	Dexcom Speaker Bureau 10/18/23		✓ Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Yes, I have authored the following article about CGMs
Blum, A. (2018). Freestyle Libre Glucose Monitoring System. Clinical Diabetes: A Publication of the American Diabetes Association, 36(2), 203-204.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

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Signature [redacted]

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Continuous Glucose Monitors: New Populations

Washington State Health Technology Clinical Committee Meeting

March 11, 2025

Presented by Shauna Durbin, MPH

Acknowledgments

Report Authors

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Notices and Disclosures

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Conflict of Interest Disclosures: No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

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This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (Center). This document is intended to support the Washington HCA in making informed decisions about the provision of health care services. The document is intended as a reference and is provided with the understanding that the Center is not engaged in rendering any clinical, legal, business, or other professional advice. The statements in this document do not represent official policy positions of the Center, Washington HTA program, or Washington HCA. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Overview

- Background and context
- Evidence findings
  - Effectiveness of CGM
  - Device-related safety
  - Differential effectiveness and safety
  - Economic analyses
  - Ongoing studies
- Clinical practice guidelines and select payer policies
- Conclusions

Background

Terminology and review context

Key Abbreviations

Diabetes and glucose monitoring

- CGM: continuous glucose monitor(ing)
- GDM: gestational diabetes
- HbA1c: glycated hemoglobin
- isCGM: intermittently scanned CGM
- ODM: oral diabetes medication
- rtCGM: real-time CGM
- SMBG: self-monitoring of blood glucose
- T1D: type 1 diabetes
- T2D: type 2 diabetes

Additional abbreviations

- AE: adverse event
- CoE: certainty of evidence
- CPG: clinical practice guideline
- GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
- MA: meta-analysis
- QALY: quality-adjusted life year
- QoL: quality of life
- RCT: randomized controlled trial
- RoB: risk of bias
- SAE: serious adverse event

Glucose Monitoring Modalities

SELF-MONITORING OF BLOOD GLUCOSE (SMBG)
Manual measurement of blood glucose from fingerstick blood samples

INTERMITTENTLY SCANNED (isCGM)
CGM that automatically measure blood glucose levels, but patients must manually scan their sensor to see and track results

REAL-TIME (rtCGM)
CGM that automatically measure glucose levels and send results to a separate device for display

CONTINUOUS GLUCOSE MONITORING (CGM)
Devices that automatically measure and track blood glucose levels every few minutes

PROFESSIONAL OR RETROSPECTIVE
CGM that are managed by clinicians for assessment purposes, but glucose levels are not visible to patients

THERAPEUTIC
CGM that can be used to make treatment decisions without the need for SMBG testing to confirm glucose levels

NONTHERAPEUTIC*
CGM that require users to verify their glucose levels with SMBG testing before making treatment decisions

Blue text indicates included CGM modalities; Gray text indicates excluded CGM modalities
**No longer commercially available*

Review Objective and Context

To evaluate the effectiveness, safety, and cost-effectiveness of CGM for populations who do not currently have coverage under the 2018 Washington Coverage Determination

ADULTS

T2D not on intensive insulin regimens:

- Nonintensive insulin*
- ODM, but no insulin
- No insulin, no ODM

CHILDREN

T2D not on intensive insulin regimens:

- Nonintensive insulin*
- ODM, but no insulin
- No insulin, no ODM

PREGNANT PEOPLE

- T2D not on insulin
- GDM not on insulin

*Note: * Requiring 1 to 3 insulin injections or fewer than 4 SMBG tests per day.*
Abbreviations. CGM: continuous glucose monitor(ing); GDM: gestational diabetes; ODM: oral diabetes medications; T2D: type 2 diabetes.

Methods

EVIDENCE-BASED POLICY CENTER FOR

Key Questions

1. Effectiveness of CGM
2. Device-related harms of CGM
3. Differential effectiveness or harms
4. Cost-effectiveness of CGM

Also reviewed

- Ongoing studies
- Clinical practice guideline recommendations
- Select payer criteria

PICOS

- Populations
  - Adults and children with T2D using
    - Nonintensive insulin therapy (1 to 3 injections per day)
    - No insulin but on oral diabetes medication (ODM)
    - No insulin and no ODM
  - Pregnant people with T2D who are not using insulin
  - Pregnant people with GDM who are not using insulin
- Interventions
  - FDA-approved rtCGM and isCGM

PICOS

- Comparators
  - SMBG
  - Attention control
  - Blinded or sham CGM
  - Routine lab monitoring
  - Usual care
- Outcomes (next slide)
- Study design
  - RCTs from very-high HDI countries (KQs 1–3)
  - Formal economic studies based on US data (KQ4)

PICOS

- Outcomes
  - Change in HbA1c
  - Achieving target HbA1C level
  - Maintaining target HbA1C level
  - Acute episodes of hypoglycemia requiring intervention
  - Quality of life (validated instruments only)
  - Mortality
  - Perinatal mortality
  - Severe perinatal morbidity
  - Safety related to the device itself
  - Cost-effectiveness and resource use

Risk of Bias Assessment for Published Studies

- *Low*

  Clear reporting of methods and mitigation of potential biases and conflicts of interest

- *Moderate*

  Incomplete information about methods that might mask important limitations or a meaningful conflict of interest

- *High*

  Clear flaws that might introduce serious bias

GRADE Certainty of Evidence

Outcomes rated: change in HbA1c, achieving or maintaining target HbA1c levels, QoL, severe perinatal morbidity and mortality, cost-effectiveness

- **High** *(RCTs start here)*
  Very confident that the estimate of effect of intervention on outcome lies close to the true effect
- **Moderate**
  Moderately confident in estimate of effect of intervention on outcome; true effect is likely close to estimate, but possibly different
- **Low** *(nonrandomized studies start here)*
  Little confidence in estimate of effect of intervention on outcome; true effect may be substantially different from estimate
- **Very Low**
  No confidence in estimate of effect of intervention on outcome; true effect is likely substantially different from estimate

Abbreviations. GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HbA1c: glycated hemoglobin; QoL: quality of life; RCT: randomized controlled trial.

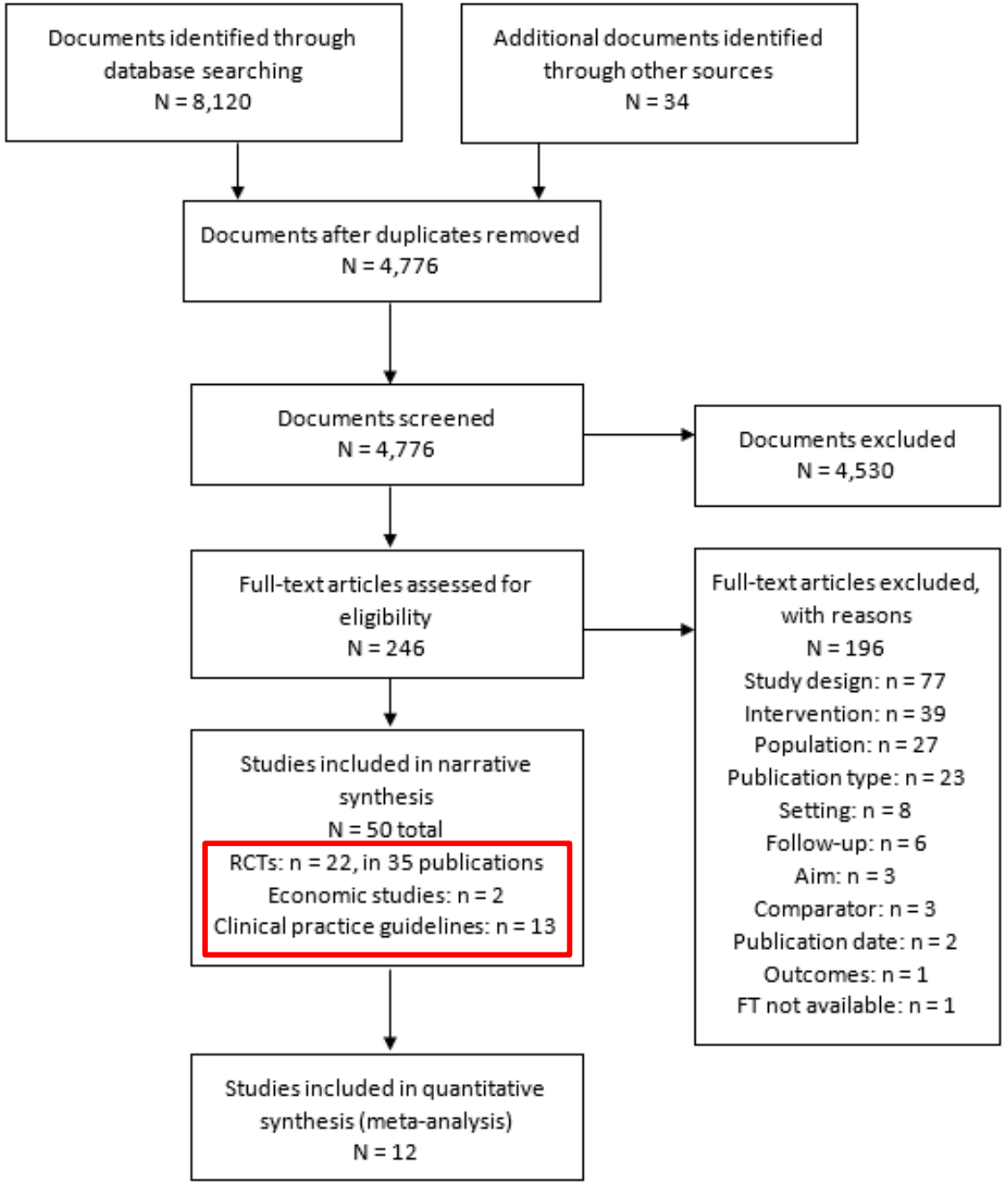
Evidence Findings

KQs 1-4 and Ongoing Studies

EVIDENCE-BASED POLICY CENTER FOR

Evidence Overview

Searches conducted in September 2024



Comparative Effectiveness

KQ1

EVIDENCE-BASED POLICY CENTER FOR

Bottom Line: RCT Availability

Review populations with eligible RCTs

- Adults with T2D not on intensive insulin regimens (18 RCTs)
  - On nonintensive insulin regimens (7)
  - On ODM therapy, but not on insulin (6)
  - On mixed diabetes regimens (5)
- Pregnant people with GDM not on insulin (4 RCTs)

Review populations with no eligible RCTs

- Adults with T2D not on insulin or ODM therapy
- Children with T2D not on intensive insulin
- Pregnant people with T2D not on insulin

Bottom Line: Change in HbA1c (1 of 2)

Population	Change in HbA1c
Adults with T2D using nonintensive insulin regimens	**CGM use resulted in a small (i.e., not clinically meaningful) but statistically significant reduction** in HbA1c from baseline compared with non-CGM controls (moderate CoE)
Adults with T2D using oral diabetes medications	**No consistent difference** in change in HbA1c from baseline with CGM versus non-CGM controls (low CoE)
Adults with T2D using no insulin or oral diabetes medications	No eligible RCTs identified
Adults with T2D using mixed diabetes regimens	**No consistent difference** in change in HbA1c from baseline with CGM versus non-CGM controls (very low CoE)

Bottom Line: Change in HbA1c (2 of 2)

Population	Change in HbA1c
Children with T2D not using intensive insulin (i.e., nonintensive insulin, ODMs, no treatment)	No eligible RCTs identified
Pregnant people with T2D not using insulin	No eligible RCTs identified
Pregnant people with GDM not using insulin	**CGM use was not associated with a significantly lower HbA1c** at the end of pregnancy (4 to 16 weeks of follow-up) compared with non-CGM controls (low CoE)

Adults Not Currently Covered for CGM Under the 2018 Washington Coverage Determination

CENTER FOR EVIDENCE-BASED POLICY

Adults With T2D Using Nonintensive Insulin Regimens (1 of 4)

Report pages 30-35

7 RCTs in 15 publications

- N = 802; follow-up range, 12 to 52 weeks
- Risk of bias: 4 *low*, 3 *moderate*

DEMOGRAPHICS

- Baseline means
  - Age, 51.0 to 61.5 years
  - HbA1c, 8.2% to 9.7%
  - Diabetes duration, 13.0 to 18.8 years
- 2 RCTs included US participants (N = 333)

CGM USE

- Modalities
  - rtCGM, 6 RCTs (3 of nontherapeutic devices)
  - isCGM, 1 RCT
- Duration of use
  - 100% of follow-up, 7 RCTs
- Comparators
  - SMBG, 7 RCTs

DIABETES REGIMENS

- Insulin regimens varied
  - Min, 1 to 2 injections of basal insulin per day
  - Max, MDI of basal and prandial insulin
- Most participants were also using ODMs (e.g., metformin) or GLP-1 agonists (e.g., semaglutide)

Adults With T2D Using Nonintensive Insulin Regimens (2 of 4)

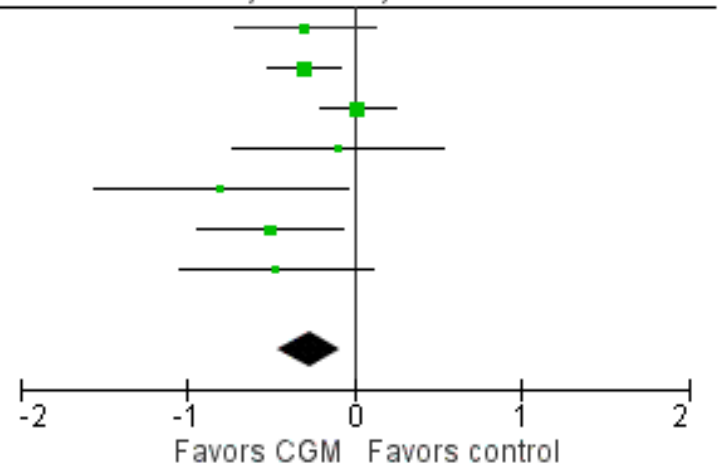
Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 802 7 RCTs	**CGM use resulted in a small, but statistically significant, reduction in HbA1c** from baseline • At final follow-up (range, 12 to 52 weeks), CGM use was associated with a significant reduction (pooled MD, −0.27%; 95% CI, −0.46 to −0.08; *P* = .005) • Difference was not clinically significant (MCID, 0.5%)	●●●○ Moderate	Downgraded 1 level • 1 for risk of bias (increased risk of selection bias; funding-related COI concerns)
Achievement of Target Hb1c Level			
N = 158 1 RCT	**No difference** between CGM and SMBG groups in the proportion of participants who achieved target HbA1c levels (i.e., 7.0%, 7.5%) at 12 or 24 weeks	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., small sample size, wide CIs) • 1 for indirectness (i.e., use of nontherapeutic CGM)

Adults With T2D Using Nonintensive Insulin Regimens (3 of 4)

Meta-Analysis: Change in HbA1c[a] at Final Follow-up

	CGM			No CGM				Mean Difference
Study or Subgroup	**Mean [%]**	**SD [%]**	**Total**	**Mean [%]**	**SD [%]**	**Total**	**Weight**	**IV, Random, 95% CI**
Ajjan 2016	8.4	0.68	30	8.7	0.68	15	13.5%	-0.30 [-0.72, 0.12]
Beck 2017 (DIAMOND)	-0.8	0.45	79	-0.5	0.89	79	26.4%	-0.30 [-0.52, -0.08]
Haak 2017 (REPLACE)	-0.29	0.85	149	-0.31	0.78	75	26.1%	0.02 [-0.20, 0.24]
Lever 2024 (2GO-CGM)	8	1.4	33	8.1	1.2	32	7.3%	-0.10 [-0.73, 0.53]
Lind 2024 (Steno2tech)	7.6	1.88	40	8.4	1.48	36	5.4%	-0.80 [-1.56, -0.04]
Martens 2021 (MOBILE)	-1.1	1.5	105	-0.6	1.2	51	12.9%	-0.50 [-0.94, -0.06]
Tildesley 2013	7.49	0.7	25	7.96	1.3	25	8.5%	-0.47 [-1.05, 0.11]
Total (95% CI)			**461**			**313**	**100.0%**	**-0.27 [-0.46, -0.08]**

Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 9.78$, df = 6 (P = 0.13); $I^2 = 39\%$
Test for overall effect: Z = 2.79 (P = 0.005)



Notes. Meta-analysis and corresponding forest plot prepared using Review Manager Desktop, version 5.4.1. [a] Mean HbA1c values at follow-up were compared when mean change from baseline by study group was not available.
Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; IV: inverse variance; SD: standard deviation.

Adults With T2D Using Nonintensive Insulin Regimens (4 of 4)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Quality of Life			
Diabetes-related QoL N = 503 4 RCTs	**No clear association** between CGM and improved diabetes-related QoL. • Mixed findings (no difference or improved QoL) • Where statistically significant differences were reported, it was unclear whether the differences were clinically meaningful • Follow-up scores generally indicative of low diabetes distress levels and high treatment-related satisfaction	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., increased risk of selection bias, funding-related COI concerns) • 1 for inconsistency (i.e., inconsistent direction of effect across and within studies)
General QoL N = 234 2 RCTs		●●○○ Low	Downgraded 2 levels • 1 for inconsistency (i.e., inconsistent direction of effect across and within studies) • 1 for indirectness (i.e., use of nontherapeutic CGM)

Adults With T2D Using Oral Diabetes Medications (1 of 4)

Report pages 35-40

6 RCTs in 8 publications

- N = 560; follow-up range, 12 to 52 weeks
- Risk of bias: 2 *low*, 2 *moderate*, 2 *high*

DEMOGRAPHICS

- Baseline means
  - Age, 50.7 to 60.9 years
  - HbA1c, 6.6% to 8.7%
  - Diabetes duration, 9.2 to 13.9 years
- 1 RCT included US participants (N = 70)

CGM USE

- Modalities
  - rtCGM, 3 RCTs (1 of nontherapeutic devices)
  - isCGM, 3 RCTs
- Duration of use
  - 100% of follow-up, 2 RCTs
  - < 50% of follow-up, 4 RCTs
- Comparators
  - SMBG, 4 RCTs
  - Attention control, 1 RCT
  - Blinded CGM, 1 RCT

DIABETES REGIMENS

- Insulin regimens varied
  - Min, 1-2 injections of basal insulin per day
  - Max, MDI of basal and prandial insulin
- Most participants were also using ODMs (e.g., metformin) or GLP-1 agonists (e.g., semaglutide)

Adults With T2D Using Oral Diabetes Medications (2 of 4)

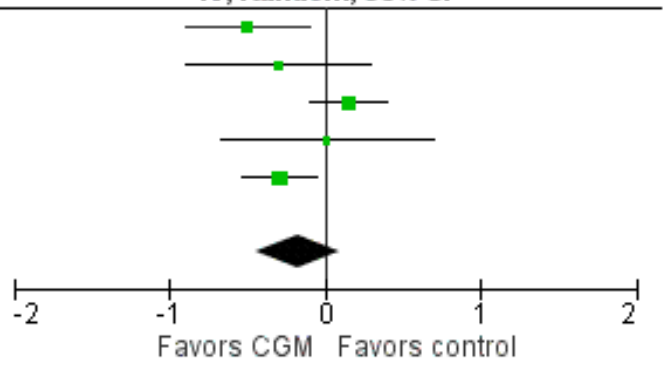
Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 560 6 RCTs	**No consistent difference** in change in HbA1c from baseline with CGM versus other non-CGM monitoring methods • Pooled analysis (MD, −0.18%; 95% CI, −0.45 to 0.09; *P* = .20) • Findings were significant (favoring CGM) when the GLiMPSE trial was removed during sensitivity testing, but the reasons for this effect are unclear	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, funding-related COI concerns, differential losses to follow-up, possible selection bias due to use of run-in periods) • 1 for inconsistency (i.e., unexplained heterogeneity)
Achievement of Target Hb1c Level			
N = 70 1 RCT	**No significant between-group differences** in the proportion of individuals randomized to CGM versus no CGM who achieved an HbA1c level below 7.0% or below 7.5%	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, funding-related COI concerns) • 1 for indirectness (i.e., limited CGM use relative to length of study follow-up) • 1 for imprecision (i.e., small study size)

Adults With T2D Using Oral Diabetes Medications (3 of 4)

Meta-Analysis: Change in HbA1c[a] at Final Follow-up

Study or Subgroup	CGM Mean [%]	CGM SD [%]	CGM Total	Control Mean [%]	Control SD [%]	Control Total	Weight	Mean Difference IV, Random, 95% CI
Aronson 2023 (IMMEDIATE)	7.6	0.9	54	8.1	1.2	54	20.1%	-0.50 [-0.90, -0.10]
Price 2021 (COMMITTED)	-0.2	0.9	44	0.1	1.3	23	13.2%	-0.30 [-0.89, 0.29]
Rama Chandran 2024 (GLiMPSE)	-0.3	0.8	87	-0.45	0.83	84	27.7%	0.15 [-0.09, 0.39]
Taylor 2019	-0.67	0.82	10	-0.68	0.74	10	10.9%	0.01 [-0.67, 0.69]
Wada 2020	-0.46	0.6	48	-0.17	0.6	49	28.0%	-0.29 [-0.53, -0.05]
Total (95% CI)			**243**			**220**	**100.0%**	**-0.18 [-0.45, 0.09]**

Heterogeneity: Tau² = 0.05; Chi² = 10.49, df = 4 (P = 0.03); I² = 62%
Test for overall effect: Z = 1.29 (P = 0.20)



Notes. Meta-analysis and corresponding forest plot prepared using Review Manager Desktop, version 5.4.1. [a] *Mean HbA1c values at follow-up were compared when mean change from baseline by study group was not available.*
Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; IV: inverse variance; SD: standard deviation.

Adults With T2D Using Oral Diabetes Medications (4 of 4)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Quality of Life			
Diabetes-related QoL N = 277 3 RCTs	**No clear association between CGM and improved diabetes-related QoL** • Mixed findings (no difference or improved QoL) • Mixed scales • Unclear whether the differences were clinically meaningful • Follow-up scores generally indicative of low diabetes distress levels and high treatment-related satisfaction	●○○○ **Very low**	Downgraded 3 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, high and differential LTFU, funding-related COI concerns) • 1 for indirectness (i.e., limited overlap in QoL outcomes and scales, limited CGM use) • 1 for imprecision (i.e., wide confidence intervals, lack of MCIDs)
General QoL N = 193 1 RCT	**No clear association between CGM and improved general QoL** • Mixed findings, depending on scale used	●○○○ **Very low**	Downgraded 3 levels • 1 for risk of bias (i.e., possible imbalances in key baseline characteristics, potential selection bias, author-related COI concerns) • 1 for imprecision (i.e., not assessable) • 1 for other reasons (i.e., mixed results on 2 related scales measuring overall well-being)

Adults With T2D Not Using Insulin or ODM

- No eligible RCTs

Adults With T2D Using Mixed Diabetes Regimens (1 of 3)

Report pages 40-45

5 RCTs in 7 publications

- N = 450; follow-up range, 12 to 52 weeks
- Risk of bias: 1 *low*, 1 *moderate*, 3 *high*

DEMOGRAPHICS

- Baseline means
  - Age, 54.6 to 63.0 years
  - HbA1c, 7.8% to 11.5%
  - Diabetes duration, not consistently reported
- 3 RCTs included US participants (N = 244)

CGM USE

- Modalities
  - rtCGM, 3 RCTs (2 of nontherapeutic devices)
  - isCGM, 2 RCTs
- Duration of use
  - 100% of follow-up, 2 RCTs
  - < 50% of follow-up, 3 RCTs
- Comparators
  - SMBG, 4 RCTs
  - Usual care, 1 RCT

DIABETES REGIMENS

- Mostly nonintensive insulin and ODM
  - 3 RCTs split participants evenly between insulin and ODM regimens
  - 2 included participants using any diabetes regimen less intensive than MDI insulin
- Outcomes not stratified by treatment regimen

Adults With T2D Using Mixed Diabetes Regimens (2 of 3)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 450 5 RCTs	**No consistent difference** in change in HbA1c from baseline with CGM versus other monitoring methods • At final study follow-up (range, 12 to 52 weeks), there were no between-group differences in change from baseline in 4 studies • CGM use was associated with a statistically and clinically greater reduction in HbA1c than SMBG in 1 study with a higher proportion of insulin users (−1.1% vs. −0.4%; *P* = .004) • All CGM groups experienced clinically meaningful reductions in HbA1c levels (i.e., 0.5%) from baseline (range, −0.8% to −5.2%) compared with only 3 of 5 control groups (range, −0.2% to −2.4%)	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., insufficient information about study group allocation procedures, high losses to follow-up, industry related funding concerns) • 2 for indirectness (i.e., high heterogeneity in terms of treatment regimen types, limited CGM use in most studies, higher-risk study populations)
Achievement of Target Hb1c Level			
No studies – not assessable			

Adults With T2D Using Mixed Diabetes Regimens (3 of 3)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Quality of Life			
Diabetes-related QoL N = 271 3 RCTs	**No between-group differences** at final study assessments (range, 12 to 52 weeks) in perceived diabetes burden, diabetes-related distress, and treatment satisfaction	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., insufficient information about study group allocation procedures, high LTFU) • 2 for indirectness (populations mostly high risk, limited overlap in QoL scales, limited CGM use across studies)
General QoL N = 141 1 RCT	**No difference** in overall QoL at 12 weeks among individuals using isCGM vs. SMBG for glycemic management	●○○○ Very low	Downgraded 3 levels • 1 for indirectness (i.e., limited to patients with recent acute MI) • 1 for imprecision (i.e., small sample size, wide CI) • 1 for other reasons (i.e., short-term data only, no within-group scores reported)

Children Not Currently Covered for CGM Under the 2018 Washington Coverage Determination

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Children With T2D Not Using Intensive Insulin

- No eligible RCTs

Pregnant People Not Currently Covered for CGM Under the 2018 Washington Coverage Determination

CENTER FOR EVIDENCE-BASED POLICY

Pregnant People With T2D Not Using Insulin

- No eligible RCTs

Pregnant People With GDM Not Using Insulin (1 of 3)

Report pages 46-50

4 RCTs in 4 publications

- N = 343; follow-up range, 4 to 16 weeks
- Risk of bias: 1 *low*, 1 *moderate*, 2 *high*

DEMOGRAPHICS

- Baseline means
  - Gestational age, 22 to 34 weeks
  - Maternal age, 29.9 to 34.5 years
  - HbA1c, 4.9% to 5.9%
  - Diabetes duration, all newly diagnosed
- 1 RCT included US participants (N = 40)

CGM USE

- Modalities
  - rtCGM, 3 RCTs (1 of nontherapeutic devices)
  - isCGM, 1 RCT
- Duration of use
  - 100% of follow-up, 1 RCT
  - < 50% of follow-up, 3 RCTs
- Comparators
  - SMBG, 3 RCTs
  - Blinded CGM, 1 RCT

DIABETES REGIMENS

- Some participants in each study received insulin during the study period due to rising blood glucose levels or risk of hyperglycemia
- Rate of new insulin use ranged from 17.4% to 31.3% at final follow-up

Pregnant People With GDM Not Using Insulin (2 of 3)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 270 3 RCTs	**No association of CGM with significantly lower HbA1c** at the end of pregnancy (4 to 16 weeks of follow-up) compared with non-CGM controls.	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., unclear group allocation procedures and reliance on completers-only analyses) • 1 for indirectness (i.e., nontherapeutic CGM models and limited CGM use)
Achievement of Target HbA1c Level			
No studies – not assessable			
QoL			
No studies – not assessable			

Pregnant People With GDM Not Using Insulin (3 of 3)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Severe Perinatal Morbidity and Mortality			
N = 343 4 RCTs	**No significant between-group differences in the incidence of severe perinatal outcomes** Very few severe perinatal events occurred and there were no statistically significant between-group differences in most reported outcomes, including: • Large for gestational age • Low birth weight • NICU admission • Perinatal death • Preeclampsia • Preterm birth • Shoulder dystocia • Unplanned cesarean delivery Results for macrosomia were mixed	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., unclear randomization and group allocation procedures, unclear or high losses to follow-up) • 1 for indirectness (i.e., nontherapeutic CGM models, limited CGM use) • 1 for imprecision (i.e., few events, small sample sizes for rare events, wide CIs)

Device-Related Safety

KQ2

EVIDENCE-BASED POLICY CENTER FOR

CGM-Related Harms in RCTs for All Populations

Report page 50

Incidence of CGM-related harms reported in 12 of 22 included RCTs

- All sensor insertion site-related symptoms (e.g., rash, pain, infection)
  - Majority were mild- to moderate-severity
  - Usually resolved through topical treatment or by moving the sensor to another site on the body
- Very few device discontinuations or study withdrawals associated with reported CGM issues
- No observed SAE were attributed to CGM use

Device-Related Harms in FDA MAUDE

Report pages 50-51

649 CGM-related events reported from January 2019 through November 2024 in the FDA MAUDE database*

- Mostly insertion site-related symptoms (e.g., rash, pain, infection)
- Various sensor malfunctions
  - Premature detachment
  - Failure to connect with receiver
  - Inaccurate blood glucose readings
- 2 deaths reported, but unclear if related to CGM use

MAUDE: Manufacturer and User Facility Device Experience

** Excluding reports from devices currently unavailable in US markets, those associated with an insulin pump malfunction, and those with an active product recall.*

Device Recalls

Report page 51

5 eligible open recalls of CGM systems reported in the FDA Medical Device Recalls database*

- Class 1 (most serious)
  - Extreme heat and fire from rechargeable lithium-ion batteries in handheld reader devices (3 recalls)
  - Inaccurately high blood glucose readings from certain sensors, increasing the risk of hypoglycemia (1 recall)
- Class 2
  - Incorrect readings due to overly thick glucose oxidase layers on some sensor batches, resulting in inconvenience or under- or over-administration of insulin (1 recall)

** Excluding recalls for discontinued devices or those posted more than 2 years ago without resolution.*

Differential Effectiveness and Safety

KQ3

EVIDENCE-BASED POLICY CENTER FOR

Differential Effectiveness or Safety

Report pages 51-54

- Change in HbA1c was the only outcome with available subgroup data
  - Reported in 6 RCTs of adults with T2D
  - No strong or consistent differences by age, gender or sex, race or ethnicity, baseline HbA1c, or CGM adherence
- No RCTs reported prespecified subgroup analyses for any other subgroup of interest

SUBGROUPS OF INTEREST

- **Age**
- **Gender or sex**
- **Race or ethnicity**
- Comorbidity status (e.g., hypertension)
- **Diabetes severity (e.g., baseline HbA1c)**
- **Adherence to CGM use**
- Type of CGM
- Duration of CGM use
- Timing of CGM initiation

Bold text indicates where relevant subgroups were reported.

Costs and Cost-Effectiveness

KQ4

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Costs and Cost-Effectiveness (1 of 2)

Report pages 54-58

- We identified 2 eligible studies reporting economic outcomes on the use of CGM from a US perspective
- However, only 1 study included a formal economic analysis and was eligible for CoE assessment

COST-EFFCTIVENESS ANALYSIS IN ADULTS WITH T2D USING BASAL INSULIN (Frank, 2024)

- N = 10,000 simulated patients (microsimulation model)
- isCGM vs. SMBG
- Perspective, Medicaid
- Glucose monitoring assumptions
  - SMBG: 1 test strip and lancet per day
  - CGM: 1 test strip and lancet per week, 26 sensors per year, and 1 isCGM reader every 3 years
- *Moderate* risk of bias

Costs and Cost-Effectiveness (2 of 2)

Number of Studies	Findings	Certainty of Evidence	Rationale
1 cost-effectiveness analysis[132]	Over a 10-year time horizon, from the Medicaid perspective • **CGM** (specifically, FreeStyle Libre systems) **was dominant to SMBG**, providing more QALYs and LYs at lower costs for people with T2D on basal insulin (i.e., nonintensive insulin)	●●●○ **Moderate**	Downgraded 1 level • 1 for RoB (i.e, role of funder in study publication)

Ongoing Studies

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Ongoing Studies

Report pages 58-59

We identified 37 ongoing RCTs

POPULATIONS

- 23 in adults with T2D not on intensive insulin
- 1 in children with T2D not on intensive insulin
- 3 in pregnant people with T2D not on insulin
- 10 in pregnant people with GDM not on insulin

CGM TYPES

- 8 of isCGM
- 22 of rtCGM
- 7 of unspecified type

OTHER

- Estimated study sample sizes range from 10 to 430 participants
- Most studies compare CGM with SMBG testing or usual care

Clinical Practice Guidelines and Select Payer Policies

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Summary of CPGs for Adults and Children With T2D

Report pages 60-62

Diabetes Treatment Regimen	CPGs Recommending CGM
Adults with T2D (7 CPGs from 6 organizations)	
Intensive insulin (i.e., MDIx3 or insulin pump)	ADA*, AACE, ES, NICE, OHQ, VA
Nonintensive insulin (e.g., basal only)	ADA*, AACE, ES, VA
ODM therapy	ES
Not on insulin or ODM	--
Children with T2D (2 CPGs from 2 organizations)	
Intensive insulin (i.e., MDI or insulin pump)	ADA*, NICE
Nonintensive insulin (e.g., basal only)	NICE
ODM therapy	--
Not on insulin or ODM	--

*Note. * This table reflects recommendations from the 2024 ADA Standards of Care. The 2025 Standards of Care were published after our systematic searches were conducted and, as such, were not eligible for inclusion.*
Abbreviations. AACE: American Association of Clinical Endocrinology; ADA: American Diabetes Association; CPG: clinical practice guideline; ES: Endocrine Society; MDIx3: multiple daily injections; NICE: National Institute for Health and Care Excellence; ODM: oral diabetes medications; OHQ: Ontario Health Quality; T2D: type 2 diabetes, VA: United States Veterans Administration.

Summary of CPGs for Pregnant People with T2D or GDM

Report pages 62-63

Diabetes Treatment Regimen	CPGs Recommending CGM
Pregnant People with T2D (6 CPGs from 4 organizations)	
Intensive insulin (i.e., MDIx3 or insulin pump)	AACE, NICE, SIGN
Nonintensive insulin (e.g., basal only)	AACE, NICE, SIGN
Not on insulin	SIGN
Insufficient evidence for a recommendation	ADA*
Pregnant People with GDM (2 CPGs from 2 organizations)	
Intensive insulin (i.e., MDI or insulin pump)	AACE, NICE
Nonintensive insulin (e.g., basal only)	AACE, NICE
Not on insulin	AACE
Insufficient evidence for a recommendation	ADA*, SIGN

*Note. * This table reflects recommendations from the 2024 ADA Standards of Care. The 2025 Standards of Care were published after our systematic searches were conducted and, as such, were not eligible for inclusion.*
Abbreviations. AACE: American Association of Clinical Endocrinology; ADA: American Diabetes Association; CPG: clinical practice guideline; GDM: gestational diabetes; MDI: multiple daily injections; NICE: National Institute for Health and Care Excellence; SIGN: Scottish Intercollegiate Guidelines Network; T2D: type 2 diabetes.

Select Payer Policies

Report pages 63-65

MEDICARE
Covered for adults with T2D on any insulin regimen –*OR*- who have a history of problematic hypoglycemia

OREGON MEDICAID
Covered for individuals with T2D and pregnant people with GDM on short- or intermediate-acting insulin regimens

PRIVATE PAYERS
Generally covered for adults and children with T2D on intensive insulin; not specified or not covered for pregnant people with T2D or GDM

- Policies included Aetna, Anthem, Cigna

Note. Most policies include additional provisional criteria for coverage (e.g., unable to reach glycemic targets, incidence of problematic hypoglycemia).

Changes in Medicare Coverage Criteria Since 2018

2021 — Eliminated requirement that individuals have a history of 4 daily SMBG tests to qualify for a CGM

2023 — Additional CGM coverage expansions

- CGMs for individuals who use insulin to treat their diabetes regardless of the type or amount of insulin used or the type of diabetes*
- Individuals with diabetes who do not take insulin but have a history of problematic hypoglycemia

** Before this change, individuals with diabetes had to take a certain amount of insulin daily to qualify for CGM coverage.*

In Summary

WHAT DO WE KNOW?

- CGM is effective for reducing HbA1c levels compared with SMBG testing in adults with T2D on nonintensive insulin
- CGM-related serious AEs and deaths are relatively rare
- CGM is cost-effective compared with daily SMBG testing in adults with T2D using nonintensive insulin

WHAT DON'T WE KNOW?

No clear or consistent evidence of effectiveness in:

- Adults with T2D on ODM or mixed diabetes regimens
- Pregnant people with GDM not on insulin

Review populations with no eligible evidence:

- Adults with T2D not using insulin or ODM
- Children with T2D not on intensive insulin regimens
- Pregnant people with T2D not using insulin

WHAT DO OTHER PROFESSIONAL GROUPS SAY?

- Clinical guidelines commonly recommend CGM coverage for patients with T2D or GDM who require insulin therapy
- Public and private payers generally align with major guidelines for patients with T2D who are on insulin, but criteria for pregnant populations is limited

Questions?


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HTCC Coverage and Reimbursement Determination

Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. ***Availability of evidence:***

   Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. ***Sufficiency of the evidence:***

   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - The amount of evidence (sparse to many number of evidence or events or individuals studied);
   - Consistency of evidence (results vary or largely similar);
   - Recency (timeliness of information);
   - Directness of evidence (link between technology and outcome);
   - Relevance of evidence (applicability to agency program and clients);
   - Bias (likelihood of conflict of interest or lack of safeguards).

   Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
    - Refer to evidence identification document and discussion.
    - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
    - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
    - What are the known conditions/criteria and evidence state
    - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Bleeding		
Bruising		
Erythema		
Skin Reactions/Rash/Skin irritation		
Pain		
Swelling		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
HbA1c		
QoL		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence

Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	**Low Risk** Safe	**Moderate Risk**	**High Risk** Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	**Less** Less effective	**Equivocal**	**More** More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	**Less** Less cost effective	**Equivocal**	**More** More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is *insufficient* to make a conclusion about whether the health technology is *safe, efficacious, and cost-effective*;
- Evidence is *sufficient* to conclude that the health technology is *unsafe, ineffectual, or not cost-effective*
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for all indicated conditions*;
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for some conditions or in some situations*

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	Covered unconditionally	Covered with conditions

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Medicare Coverage

[see page 63 of final report]

For adults with type 2 diabetes, continuous glucose monitors are covered if taking insulin of any kind or any amount, or have a history of problematic hypoglycemia. Not applicable to children or pregnant people with type 2 diabetes, or pregnant people with gestational diabetes mellitus.

Clinical Practice Guidelines

[see pages 60 and 61of final report]

Guideline Publication Year Methodological Quality	Guideline Recommendation
American Diabetes Association Standards of Care in Diabetes: Chapter 7 Diabetes Technology[25] 2024 Fair	CGM should be offered to adults with diabetes who: • Use multiple daily injections of insulin (number of injections not specified) or have an insulin pump OR • Use basal insulin
Blonde et al. American Association of Clinical Endocrinology Developing a Diabetes Mellitus Comprehensive Care Plan[19] 2022 Poor	CGM recommended for adults with T2D who: • Are treated with insulin therapy OR • Have high risk for hypoglycemia and/or with hypoglycemia unawareness
Grunberger et al. American Association of Clinical Endocrinology The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus[175] 2021 Poor	CGM recommended for: • All persons who take 3 or more insulin injections daily or have an insulin pump OR • Individuals with problematic hypoglycemia CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy
McCall et al. Endocrine Society Management of Individuals with Diabetes at High Risk for Hypoglycemia[176] 2023 Good	CGM is suggested for people with T2D who take insulin and/or sulfonylureas and are at risk for hypoglycemia
NICE Type 2 Diabetes in Adults: Management[181] 2022 Good	Offer CGM to adults with T2D who have multiple daily insulin injections if 1 of the following apply: • Recurrent hypoglycemia or severe hypoglycemia • Impaired hypoglycemia awareness • Learning disability or cognitive impairment impeding SMBG • Would otherwise have to self-measure at least 8 times a day

Guideline Publication Year Methodological Quality	Guideline Recommendation
Ontario Health Quality Flash Glucose Monitoring System for People with Type 1 or Type 2 Diabetes: Recommendations[177] 2019 Good	CGM recommended for people with T2D who use multiple daily injections of insulin or an insulin pump, and who experience recurrent hypoglycemia despite frequent self-monitoring of blood glucose and efforts to optimize insulin management
Veterans Administration/Department of Defense Management of Type 2 Diabetes Mellitus[184] 2023 Good	CGM is suggested for adults with T2D who are treated with insulin but are not achieving glycemic goals

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?
If yes, the process is concluded.
If no or unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

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.

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