Washington State Health Care Authority

November 15, 2024 Meeting Materials
Health Technology Clinical Committee

Petition materials:

Contents

- ☐ Petition and supplemental materials – FAI
- ☐ Director's 2024 topic selection letter
- ☐ Updated 2023 signal search/literature scan – FAI
- ☐ Current 2019 HTCC findings and decision – FAI

Washington State Health Care Authority

Submit competed petition to: shtap@hca.wa.gov; **or**
Atten: Health Technology Assessment
PO Box 42712**,** Olympia, Washington 98504-2712; **or**
FAX (360) 586-8827

Petition for technology review or re-review

Your name:	Mia S. Hagen, M.D. for UWMC
Mailing address:	[redacted]
E-mail address:	[redacted]
Telephone number:	[redacted]

Note: Not all questions will apply to all technologies. For assistance email the HTA program at the address above, or phone (360) 725-5126 (TTY 711).

Technology topic Hip surgery for femoroacetabular impingement syndrome

If this topic has been reviewed by the health technology assessment program in the past, skip to question 7, below. See technologies HTCC has previously reviewed.

1. Background information

- Does this technology have FDA approval? ☐ Yes ☐ No
- When was this technology approved?
- For what indications has FDA approved this technology?
- Why do you believe this technology merits consideration for assessment?
- Proposed research questions.

N/A

2. Potential patient harm(s) or safety concerns

- What is the potential for patient harm, related to use of this technology?
- What are the likelihood and severity of the potential harms or adverse outcomes that may result from recommended use of this technology?
- Are there significant potential harms associated with this technology compared to alternatives?

N/A

3. Therapeutic efficacy, effectiveness or diagnostic accuracy

- What is the potential effectiveness of this technology on the indicated clinical condition? (e.g., prevent/reduce mortality; increase quality of life)
- How are indicated conditions diagnosed? Is there a consensus on diagnosis?

- For diagnostic technologies: Is this technology compared to a "gold standard" technology?
- What is the diagnostic accuracy or utility?
- What published, peer-reviewed literature documents the efficacy of this technology or the science that underlies it? Please enclose publications or bibliography.

N/A

4. Estimated total cost per year

- What are the direct health care costs of this technology (annual or lifetime)?
- What is the potential cost-effectiveness of this new technology compared with other alternatives?
- Which private insurers reimburse for use of this technology? Please provide contact information and phone numbers.

N/A

5. Secondary considerations

- **Number of persons affected** - What are the numbers of people affected by this technology in the State of Washington?
- **Severity of condition(s)** - What is the severity of the condition treated by this technology? Does it result in premature death; short or long term disability? How would this technology increase the quality of care for the State of Washington?
- **Policy-related urgency -** Is there a particular urgency related to this technology? Is it new and rapidly diffusing? How long has this technology been in use? Is there a standard of care? Is this technology or proposed use(s) controversial?
- **Potential or observed variation** - What is the observed or potential for under, or overuse of this technology? Are there any variations in use or outcomes by region or other characteristics?
- **Special populations and ethical concerns** - Is use limited to small populations; what characteristics are present (e.g., race, ethnicity, religion, rare condition, socioeconomic status) that may impact policy decision?

N/A

6. References

- List other organizations that have completed technology assessments on this topic (please provide date of technology assessments and links).
- Cite any Center for Medicare and Medicaid Services (CMS) national coverage decision on this topic and the date issued.
- Provide list of key references used in preparing this petition.

- Have any relevant medical organizations (e.g., American Medical Association) expressed an opinion on this technology? If so, please provide verification documents and contact names, numbers and links.
- Bibliography or reference list of requestor attached: ☐ Yes ☐ No

N/A

7. For re-review petitions only

Re-review of a technology requires new evidence that could change a previous decision. What new evidence should be considered? Please provide specific publication information and/ or references.

The HTCC decision to not authorize operative treatment for femoroacetabular impingement syndrome (FAI / FAIS) is outdated and contrary to the standard of care nationally and internationally. I am a hip preservation specialist at the University of Washington and a member of the ANCHOR (Academinc Network of Conservational Hip Outcomes Research) hip preservation group as well as a member of ISHA (International Society for Hip Arthroscopy). FAI is a globally recognized condition and the ANCHOR group's research in FAI is sponsored by a large grant from the United States Department of Defense. Multiple randomized controlled trials have demonstrated efficacy of the procedure over non surgical care and patient outcomes are excellent with minimal complications.

Training in hip arthroscopy has become a standardized part of sports medicine fellowship surgical training and is often included in standard orthopaedic resident training as well as incorporated in arthroscopic simulator and virtual reality training for residents (I am the Associate Program Director of our orthopaedic surgery residency and thus have a good understanding of the training tools used in program around the country for residents). The main procedure performed internationally and nationally via hip arthroscopy is osteoplasty and labral repair for FAI.

I have performed a large number of peer-to-peer conversations trying to get these surgeries approved for our patients with state-sponsored health insurance and even during these conversations the physicians employed by the insurance plans admit that the decision to leave this as an uncovered benefit is out-of-date but there is nothing they can do. The fact that this is still happening in Washington state discriminates against patients on state-run health care plans who have no financial means to acquire commercial insurance. Those patients under the Regence UMP plan with FAIS who desire surgery end up switching to Kaiser insurance (available through the University of Washington) or paying out of pocket for the procedure which delays care and creates unnecessary cost to these patients already paying high premiums for insurance. No other commercial plan has these restrictions on surgery for FAI.

Interestingly, insurance plans following the HTCC guidelines have historically approved hip arthroscopy for labral repairs of labral tears, but not osteoplasty (as "FAI" is not recognized as a diagnosis). As we know, isolated labral repair without osteoplasty leads to poorer patient outcomes as demonstrated in prospective cohort analyses as well as randomized controlled trials. As a high volume hip preservation surgeon I think it is almost malpractice at this point to do a labral repair without osteoplasty in a patient with clear radiographic hip impingement. In keeping with this line of thought, some Washington Medicaid plans are now denying isolated labral repairs, stating that they

cannot be performed without doing osteoplasty, but also won't approve osteoplasty because according to decision by HTCC, osteoplasty is an unnecessary procedure as FAI doesn't exist. So this feels a lot like saying FAI is both a real diagnosis and also not a real diagnosis, at the same time!

I participated in the review of this decision about 5 years ago. At the end of a long presentation on all the evidence demonstrating that FAI is a real condition and postoperative outcomes to osteoplasty and labral treatment are excellent, the committee agreed that it is a real condition and that surgery provides benefit to patients. However, the two parts of voting that prevented the decision from being overturned were: 1) "is surgery for FAI safer than non operative care?" and 2) "is surgery for FAI cheaper than non operative care?". The committee members felt that as a principle, surgery has inherently more risks than any non surgical intervention. So, by this narrow definition of risk, I don't think #1 above would ever get overturned. The second portion #2, was based on the committee decision that despite numerous strong studies that have demonstrated the cost effectiveness of surgery for FAI, the level of evidence still "wasn't strong enough" to overturn #2. To this, I would say, that most surgical cost analyses studies aren't even as well-performed as the ones that have been done for FAI and if this is the metric by which these decisions get overturned, this will probably never happen for this condition. In summary, I think that the method by which the HTCC currently considers surgical procedures for re-review is flawed and biased against surgery and other methods may need to be considered for surgical procedures.

I thus strongly urge the HTCC to overturn to outdated decision regarding FAIS as a non recognized pathology / uncovered benefit. Again this decision is out-of-date with the rest of the world in 2024, as all other commercial plans recognize FAI as a covered diagnosis and surgery for this condition as a covered benefit. The HTCC's current stance negatively impacts the poorest, most vulnerable members of our community who cannot get their insurance to approve surgical care for their hip pain that is recalcitrant to nonsurgical management. If not going to be widely approved, perhaps select approval for high-volume hip arthroscopists at secondary and tertiary referral centers in Washington state would be considered.

Here are a fewer newer publications since 2019 that may be of interest:

https://pubmed-ncbi-nlm-nih-gov.offcampus.lib.washington.edu/35400136/
Conclusion: This study demonstrated that for adults between the ages of 18 and 50 years with FAI, arthroscopic osteochondroplasty was associated with a 2.5-fold decrease in the hazard of reoperation at any point in time compared with arthroscopic lavage.

https://www-ncbi-nlm-nih-gov.offcampus.lib.washington.edu/pmc/articles/PMC8369620/
Conclusion:
The primary outcome of dGEMRIC showed no statistically significant difference between PHT and arthroscopic hip surgery at 12 months of follow-up. Patients treated with surgery reported greater benefits in symptoms at 12 months compared to PHT, but these benefits are not explained by better hip cartilage metabolism.

https://pubmed-ncbi-nlm-nih-gov.offcampus.lib.washington.edu/35229713/
Conclusion: Hip arthroscopy and personalised hip therapy both improved hip-related quality of life for patients with femoroacetabular impingement syndrome. Hip arthroscopy led to a greater improvement in quality of life than personalised hip therapy, and this difference was clinically significant at 12 months. This study does not demonstrate cost-effectiveness of hip arthroscopy

compared with personalised hip therapy within the first 12 months. Further follow-up will reveal whether or not the clinical benefits of hip arthroscopy are maintained and whether or not it is cost-effective in the long term.

https://pubmed.ncbi.nlm.nih.gov/30733197/
Conclusions: Patients with symptomatic FAI referred to secondary or tertiary care achieve superior outcomes with arthroscopic hip surgery than with physiotherapy and activity modification.

On PubMed on 5/23/2024, typing in “femoroacetabular impingement” yields 4,443 publications, perhaps this serves as additional evidence that this is a standardized, well-recognized diagnosis.

Washington State Health Care Authority

Health Technology Assessment Program

Selected technologies 2024

Contents

- ☐ Director's selection letter
- ☐ Topic selection background information
- ☐ Public comments received and HTA program response

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

April 17, 2024

To whom it may concern:

SUBJECT: Health Technology Assessment Topic Selection, 2024

As the Director of the Health Care Authority, I select technologies for review by Health Technology Clinical Committee in consultation with other agencies and the Committee itself (70.14 RCW). Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and when there is adequate evidence to conduct a review. Technologies are selected for rereview when new evidence is available that could change a previous determination.

For the current selection cycle, I reviewed the proposed topics and the comments received from interested individuals and groups who responded in the public comment period (March 20 to April 3, 2024). Based on this review I have selected the following technologies for assessment:

Technology	Primary Criteria Ranking		
	Safety	Efficacy	Cost
Endovascular intervention in lower extremity peripheral arterial disease and intermittent claudication	**Medium**	**Medium**	**High**

Endovascular intervention, including procedures such as angioplasty and stent placement, is commonly used in the management of lower extremity peripheral arterial disease (PAD).

Frenotomy and frenectomy with breastfeeding support	**Medium**	**High**	**Medium**

Procedures to cut the frenulum, a band of tissue in the mouth, often performed to address issues related to tongue-tie or lip-tie, which can affect breastfeeding.

Continuous Glucose Monitoring	**Medium**	**High**	**High**

New evidence identified that could change previous determination.

Hyperbaric Oxygen Therapy (HBOT)	**Medium**	**High**	**High**

New evidence identified for sensorineural hearing loss that could change previous determination.

At this time, **Optune/tumor treating fields (TTF)**, which was first reviewed in 2016 with a formal updated literature scan in 2017 and rereview in 2018, is not selected for rereview after public petition was reviewed. The information provided does not support that there is new evidence likely to change the previous determination. At this time, **hip surgery for femoroacetabular impingement syndrome (FAI)**, is not selected for rereview. The HTA program monitors the literature on this topic with detailed literature

searches including a recently concluded search (December 2023). Based on these searches and consideration by the participating agencies and the Health Technology Clinical Committee, new evidence is not likely to change the previous determination.

Upon publication of the selected list of technologies, a 30-day comment period will begin whereby any interested person or group may provide information to be considered in the review of the selected topic(s).

Should you have any questions or concerns, please contact the HTA Program at shtap@hca.wa.gov.

Sincerely,

Susan E. Birch MBA, BSN, RN
Director

Enclosure(s)

By email

cc: Josh Morse, HTA Director, CQCT, HCA
Valerie Hamann, HTA Program Specialist, CQCT, HCA
Melanie Golob, HTA Program & FFS Operations Manager, CQCT, HCA

Washington State Health Care Authority

Technology assessment background summary

New proposed technologies

Technology	Primary criteria ranking: Safety	Efficacy	Cost
Endovascular intervention in lower extremity peripheral arterial disease and intermittent claudication	**High**	**Medium**	**High**
Endovascular intervention, including procedures such as angioplasty and stent placement, is commonly used in the management of lower extremity peripheral arterial disease (PAD).			
Frenotomy and frenectomy with breastfeeding support	**Medium**	**High**	**Medium**
Procedures to cut the frenulum, a band of tissue in the mouth, often performed to address issues related to tongue-tie or lip-tie, which can affect breastfeeding.			

Topics considered, not proposed

	Technology
1	Noninvasive vagus nerve stimulation
2	Left atrium occlusion device (Watchman)
3	Invasive coronary angiography/percutaneous coronary intervention in stable coronary artery disease
4	Peripheral nerve stimulation
5	Functional endoscopic sinus surgery and balloon ostial sinus dilation in chronic rhinosinusitis
6	Bronchial valves

Rereview technologies

Technologies are considered for rereview at least once every eighteen months based on availability of new evidence that may change the decision. All technologies with determinations beyond 18 months since the final determination previously reviewed by the Health Technology Clinical Committee (HTCC) are listed below, along with information on whether they have been selected for rereview.

Petitioners whose topic is not selected for rereview by the Director of HCA may request consideration for selection of the topic by the HTCC.

	Technology	HTCC review history	Rereview?
1	**Continuous Glucose Monitoring (CGM)** New evidence identified that could change previous determination.	HTCC first reviewed in 2011 with a rereview conducted in 2018.	Yes
2	**Hyperbaric Oxygen Therapy (HBOT)** New evidence identified for sensorineural hearing loss that could change previous determination.	HTCC first reviewed in 2013.	Yes
3	**Optune/Tumor Treating Fields (TTF)** Petition for rereview received. Information provided does not support that there is new evidence likely to change the previous determination.	HTCC first reviewed in 2016 with a rereview 2018. Literature scan in 2018.	No
4	**Femoroacetabular Impingement Syndrome (FAI)** Signal search completed in 2023. New evidence does not appear to support policy changes.	HTCC first reviewed in 2011 with a rereview in 2019. Literature scans in 2014, 2018, and 2023.	No
5	**Artificial Disc Replacement** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2008 with a rereview in 2017. Literature scan in 2016.	Pending
6	**Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA)** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2013.	Pending
7	**Functional Neuroimaging for Primary Degenerative Dementia and Mild Cognitive Impairment** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2015	Pending
8	**Gene Expression Profile Testing of Cancer Tissue** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2018	Pending

	Technology	HTCC review history	Rereview?
9	**Intensity Modulated Radiation Therapy (IMRT)** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
10	**Microprocessor-Controlled Lower Limb Prosthetics** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
11	**Robotic Assisted Surgery (RAS)** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
12	**Sleep Apnea Diagnosis and treatment in Adults** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
13	**Upper Endoscopy for GERD and GI Symptoms** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
14	**Upright/Positional MRI** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2007. Literature scan conducted in 2012.	Pending

For the current period, the program has not received or identified new evidence to support review of the following:

	HTA Decisions	Latest Review/ Scan
1	Applied Behavioral Analysis (ABA or ABA Therapy) Based Behavioral Interventions for the Treatment of Autism Spectrum Disorder	June 2011
2	Appropriate Imaging for Breast Cancer Screening in Special Populations	January 2015
3	Autologous Blood/Platelet-Rich Plasma Injections	July 2023
4	Bone Growth Stimulation	August 2009
5	Bone Morphogenic Proteins for Use in Lumbar Fusion	March 2012
6	Breast MRI	August 2010
7	Bronchial Thermoplasty for Asthma	May 2016
8	Cardiac Stents	January 2016
9	Carotid Artery Stenting	September 2013

	HTA Decisions	Latest Review/ Scan
10	Cell-Free DNA Prenatal Screening for Chromosomal Aneuploidies (cfDNA)	January 2020
11	Cervical Spinal Fusion for Degenerative Disc Disease	March 2013
12	Chronic Migraine and Chronic Tension-type Headache	March 2022
13	Cochlear Implants: Bilateral Versus Unilateral	May 2013
14	Computed Tomographic Colonography (CTC)	February 2008
15	Coronary Artery Calcium Scoring	May 2020
16	Discography	February 2008
17	Electrical Neural Stimulation (ENS)	October 2009
18	Extracorporeal Membrane Oxygenation Therapy (ECMO)	March 2016
19	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions	March 2017
20	Facet Neurotomy	June 2020
21	Fecal Microbiota Transplantation	November 2016
22	Genomic Microarray Testing	January 2018
23	Hip Resurfacing	November 2013
24	Hip Surgery for Femoroacetabular Impingement (FAI) Syndrome	December 2023
25	Imaging for Rhinosinusitis	May 2015
26	Implantable Drug Delivery System for Chronic Non-Cancer Pain	August 2008
27	Knee Arthroscopy for Osteoarthritis of the Knee	August 2008
28	Lumbar Fusion for Degenerative Disc Disease	November 2015
19	Negative Pressure Wound Therapy (NPWT) for Home Use	November 2016
30	Nonpharmacologic Treatments for Treatment Resistant Depression	March 2014
31	Osteochondral Allograft/Autograft Transplantation (OAT)	January 2018
32	Peripheral Nerve Ablation for Limb Pain	January 2019
33	Pharmacogenetic Testing for Patients Being Treated with Oral Anticoagulants	May 2018
34	Pharmacogenomic Testing for Selected Conditions	January 2017
35	Positron Emission Tomography (PET) Scans for Lymphoma	November 2018
36	Proton Beam Therapy	May 2019
37	Routine Ultrasound for Pregnancy	November 2010
38	Screening & Monitoring Tests for Osteopenia/Osteoporosis	November 2014
39	Selected Treatments for Varicose Veins	May 2017
40	Spinal Cord Stimulation	November 2023
41	Spinal Injections	March 2016

	HTA Decisions	Latest Review/ Scan
42	Stem Cell Therapy for Musculoskeletal Conditions	June 2020
43	Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy	June 2023
44	Surgery for Lumbar Radiculopathy/Sciatica	May 2018
45	Testosterone Testing	March 2015
46	Tinnitus: Non-Invasive, Non-Pharmacologic Treatments	May 2020
47	Total Knee Arthroplasty	October 2010
48	Transcranial Magnetic Stimulation for Selected Conditions	March 2023
49	Tumor Treating Fields (Optune)	November 2018
50	Tympanostomy Tubes in Children	November 2015
51	Vagal Nerve Stimulation for Epilepsy and Depression	May 2020
52	Vitamin D Screening and Testing	November 2012
53	Whole Exome Sequencing	November 2019

Disposition of public comments

Public comments were accepted from March 20 through April 3, 2024. Comments were received on four proposed topics: **frenotomy and frenectomy with breastfeeding support, continuous glucose monitoring (CGM), and Optune/Tumor Treating Fields (TTF).** All comments were considered by the Director.

	Commenter	Topic
1	**Erika Queen**	Frenotomy/Frenectomy
2	**Mary Francell**, MA, IBCLC, RLC	Frenotomy/Frenectomy
3	**Ashley Walden**	Frenotomy/Frenectomy
4	**Maria Walden,** ANLC, IBCLC, BSL, BSN **Bobak Ghaheri,** MD, The Oregon Clinic	Frenotomy/Frenectomy
5	**Eric Hemmen,** Legislative Assistant to State Senator Ron Muzzall **Ron Muzzall,** Washington State Senator	Optune/Tumor Treating Fields
6	**Shannon Kavanaugh,** President & CEO, Archbright	Optune/Tumor Treating Fields
7	**Richard and Michele Rollins**	Optune/Tumor Treating Fields
8	**Phoebe Greening,** Legislative Assistant to State Representative Amy Walen **Amy Walen,** Washington State Representative	Optune/Tumor Treating Fields
9	**Emma Watson,** Associate Director, State Government Affairs, Novocure	Optune/Tumor Treating Fields
10	**Lyda Hawes,**	Optune/Tumor Treating Fields
11	**Patrick Jones**	Optune/Tumor Treating Fields
12	**Carissa Kemp,** Director, State Government Affairs, American Diabetes Association	Continuous Glucose Monitoring
13	**Linda Castine,** MN, RN, CNL, DCES, Nurse Care Manager, Ambulatory and Allied Care Services, Harborview Medical Center	Continuous Glucose Monitoring
14	**Eugenia Lennon,** PhD, ARNP, CDCES	Continuous Glucose Monitoring
15	**Charlotte Lewis,** MD, MPH, Professor of Pediatric, UW School of Medicine, Multidisciplinary Infant Nutrition and Feeding Team, Seattle Children's Hospital	Frenotomy/Frenectomy
16	**Sarah Skidmore,** RN, CDCES, PMG SW Boldt Diabetes and Nutrition	Continuous Glucose Monitoring
17	**Dellann Elliott Mydland,** President, CEO & Chair, End Brain Cancer Initiative	Optune/Tumor Treating Fields

	Commenter	Topic
18	**Emma Watson,** Associate Director, State Government Affairs, Novocure, submitting for group of providers throughout Washington State	Optune/Tumor Treating Fields
19	**Shawn Drennan**	Optune/Tumor Treating Fields
20	**Greg Norman,** PhD, Seniro Director of Health Econ & Outcomes Research, Dexcom	Continuous Glucose Monitoring
21	**Carol Wysham,** MD	Continuous Glucose Monitoring
22	**Sarah Lee,** RN, Kaiser Permanente	Frenotomy/Frenectomy
23	**Jona Feinberg,** Executive Director, Washington State Lactation Collaborative	Frenotomy/Frenectomy
24	**Mariham Fahim,** PharmD, Contingent Medical Outcomes Managers, Abbott	Continuous Glucose Monitoring
25	**BreAnne Marcucci,** ARNP, submitting for group of providers	Frenotomy/Frenectomy
26	**Nicole Treanor,** MS, RD, Diabetes Education Program Coordinator, Franciscan Endocrine Associates	Continuous Glucose Monitoring

A summary of comments received and HTA responses are contained in the table below**.** The full text of all comments, references and attachments follows.

Commenter	Topic	Comment	HTA program response
Erika Queen	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Mary Francell, MA, IBCLC, RLC	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Ashley Walden	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment for this proposed rereview. All information provided will be considered in any future rereview of frenotomy/frenectomy.
Bobak Ghaheri, MD, The Oregon Clinic	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Eric Hemmen, Legislative Assistant to State Senator Ron Muzzall **Ron Muzzall,** Washington State Senator	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Shannon Kavanaugh, President & CEO, Archbright	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Richard and Michele Rollins	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Phoebe Greening, Legislative Assistant to State Representative Amy Walen **Amy Walen,** Washington State Representative	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Emma Watson, Associate Director, State Government Affairs, Novocure	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.

Commenter	Topic	Comment	HTA program response
Lyda Hawes	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Patrick Jones	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Carissa Kemp, Director, State Government Affairs, American Diabetes Association	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed rereview. All information provided will be considered in any future rereview of continuous glucose monitoring.
Linda Castine, MN, RN, CNL, DCES, Nurse Care Manager, Ambulatory and Allied Care Services, Harborview Medical Center	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
Eugenia Lennon, PhD, ARNP, CDCES	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
Charlotte Lewis, MD, MPH, Professor of Pediatric, UW School of Medicine, Multidisciplinary Infant Nutrition and Feeding Team, Seattle Children's Hospital	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Sarah Skidmore, RN, CDCES, PMG SW Boldt Diabetes and Nutrition	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
Dellann Elliott Mydland, President, CEO & Chair, End Brain Cancer Initiative	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.

Commenter	Topic	Comment	HTA program response
Emma Watson, Associate Director, State Government Affairs, Novocure, submitting for group of providers throughout Washington State	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Shawn Drennan	Optune/Tumor Treating Fields	Complete comments included below.	Thank you for providing comments and for participating in the health technology assessment process.
Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
Carol Wysham, MD	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
Sarah Lee, RN, Kaiser Permanente	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Jona Feinberg, Executive Director, Washington State Lactation Collaborative	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.
Mariham Fahim, PharmD, Contingent Medical Outcomes Managers, Abbott	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.
BreAnne Marcucci, ARNP, submitting for group of providers	Frenotomy/Frenectomy	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of frenotomy/frenectomy.

Commenter	Topic	Comment	HTA program response
Nicole Treanor, MS, RD, Diabetes Education Program Coordinator, Franciscan Endocrine Associates	Continuous Glucose Monitoring	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of continuous glucose monitoring.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Frenectomy
Date: Thursday, March 21, 2024 6:49:44 PM

External Email

I'm writing regarding the buried language about investigating frenectomy for families on Medicaid. I'll cut to the chase, limiting access to quality providers who provide effective assessment and treatment of oral restrictions will ABSOLUTELY FAIL the babies and nursing parents in Washington.

My child has benefitted from multiple frenulum releases and other post-procedure intra-oral work by a very knowledgeable physician. I have referred hundreds of families to knowledgeable release providers and virtually ALL of them have had good results.

There ARE physicians and other providers who are under-educated, under-trained, and do preform these procedures with negative or less than positive outcomes. Addressing this would be reasonable, but using a wide brush to address a small problem is not going to benefit the babies, children, and families of Washington.

Thank you.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Frenulum release for those with state insurance
Date: Friday, March 22, 2024 2:38:57 PM

External Email

Please continue to support state insurance coverage for those parents seeking a frenulum release for their infants. Studies support the role of frenectomy in improved infant feeding when certain forms of ankyloglossia are present, as assessed by a trained lactation provider (IBCLC): https://pubmed.ncbi.nlm.nih.gov/31265153/

Frenectomy is most effective when assessed using a validated tool, such as the Hazelbaker Assessment Tool for Lingual Frenulum Function, and accompanied by support from a skilled lactation professional who can determined if ankyloglossia is causing maternal pain and/or restricted ability for the infant to consume milk. Access to this support, and frenectomy if necessary, is especially important for parents on state insurance, who are at risk for adverse health and financial outcomes if breastfeeding duration is cut short.

Thank you for supporting parents and babies in our state.

--
Mary Francell, MA, IBCLC, RLC
(she/her/hers)

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comment on Health Technology Assessment Program
Date: Saturday, March 23, 2024 8:15:27 AM

External Email

To Whom It May Concern,

My name is Ashley Walden, and I am a mother of two children; both of whom had Frenectomies performed as infants.

I am writing to you in earnest support of continued access and coverage for this procedure. Prior to my babies' frenectomies, breastfeeding was not sustainable. The tongue and lip ties my children had led to: 1. incredible pain for me during breastfeeding attempts, 2. Little to no transfer of milk from my breasts into my babies' mouths, 3. Short and insufficient breastfeeding sessions due to the prior reasons that left my babies hungry and exhausted and attempting feeds every 45 minutes to an hour, around the clock.

For my first child, I hesitated to have the Frenectomy performed for 3 weeks after she was born. Those were 3 of the most difficult weeks of my life. We tried everything. We utilized a lactation consultant and our pediatrician and I was tried using nipple shields, pumping around the clock in addition to the hourly feeds, weighing our baby before and after each feed to verify milk transfer, and ultimately hand feeding with a tube and syringe. When I finally took my first child to see a well reputed ENT surgeon for a Frenectomy evaluation and subsequent procedure, it was astonishingly simple and quick. It took all of 30 minutes, and my daughter was immediately handed to me to nurse, and she did so successfully on the first attempt, with no struggles, and was able to nurse effectively with zero pain for me. I never experienced pain when she was breastfeeding again, and she was finally able to eat and fill her belly. She was immediately able to go 3 hours between feeds, instead of the hourly struggles before. I was able to breastfeed for over 2 years, and it never would have been possible without the frenectomy. The procedure cost less than $1,000, which I paid for completely, without insurance coverage. I know I would have spent far more than that in formula alone had we not been able to receive that procedure, and I would have lost all of the health and psychological benefits of breastfeeding my daughter for 2 years.

When I was pregnant with my second daughter, I knew what to watch for. While the signs were slightly different, I knew with the confirmation of my lactation consultant that she had a tongue and lip tie within 24 hrs of her birth. I was able to call and schedule her with a more-local-to-us dentist in Spokane that was well-trained to treat these issues and she was treated at one-week of age. Again, we had to pay outside of insurance coverage, and again had the same experience as the first. She was immediately handed to me to nurse, and did so successfully, without any pain ever again. We are now nearly 2 years into our breastfeeding journey and I know I have these practitioners to thank.

Breastfeeding is something every mother should be able to try and do for their babies. The availability of lactation consulting for support, evaluation, and referrals for extra care when needed (like the Frenectomy) is essential to that possibility. As with all things in healthcare,

you may find a few providers who are looking to make a quick dollar and not provide well-researched and high quality care. This has not been my experience, nor the experience of many of my friends and acquaintances that needed similar care.

If we aren't willing to allow frenectomies to continue, you will force families into formula feeding. Instead of paying qualified professionals a truly reasonable amount of less than $1000 per child, families will have to shell out more than $300 per month from their pockets to purchase formula and it's accompanying accessories. Not only is the procedure more economical, it is giving that money to our local healthcare providers, who love and treat our families over many years of our lives, instead of further lining the corporate pockets of formula companies.

Frenectomies have been performed for nearly 200 years to help babies breastfeed successfully. It is better researched, trained and safely provided now than ever before. I encourage you to look at the work of Dr. Geheri in Portland, OR as the leader of standard of care for these procedures. He provides a great deal of information and data for absolutely free to anyone looking for more information on tongue and lip ties. He is not chasing patients down and persuading them into unnecessary procedures. Neither are most of these providers.

I beg you, please do not condemn frenectomies. They are a very necessary and most reasonable solution to allow more families to breastfeed comfortably and effectively. Please, don't take that opportunity away from us.

Most Sincerely,
Ashley Walden

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: COMMENTS 2024 Proposed Health Technologies Assessment Program
Date: Sunday, March 24, 2024 1:51:46 PM
Attachments: Letter to Washington State Healthcare AuthorityBGHAH.pdf

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External Email

Greetings:
Please accept the attached comments for the 2024-5 review on Frenectomy, submitted by Bobak Ghaheri MD.

Thank you kindly,

Maria Walden, ANLC, IBCLC, BSL, BSN
[redacted]

FROM THE DESK OF

Bobak Ghaheri MD

March 23, 2024

To whom it may concern:

It has come to my attention that there is a planned review of the efficacy of frenotomy and frenectomy in the clinical management of breastfeeding problems by the Washington State Healthcare Authority. As one of the leading authorities in the United States on this topic, I wanted to weigh in and give the clinical background for why this procedure must continue to be covered for mother/baby dyads of all socioeconomic backgrounds.

There has been concern nationally about the increased rates of this procedure. To give you context, there are numerous reasons for why this procedure has become more indicated and performed. First, the sheer number of mothers deciding to breastfeed has increased over the last 30 years, so there has been a concomitant increase in the incidence of pathology associated with breastfeeding. Second, we have more research and more technological analysis of how breastfeeding is impacted by tongue tie, specifically with how posterior tongue tie can impact breastfeeding adversely (Geddes 2008, Ghaheri 2022). Babies with posterior tongue tie were never previously candidates for a procedure; many of those babies would fail breastfeeding and would instead transition to bottle feeding. We now have an option to salvage that nursing relationship with a procedure that takes only seconds. Finally, we have increased education both in the medical realm, but also in the training of lactation consultants, occupational therapists, and speech pathologists who manage these patients frequently. We are simply more able to diagnose the problem due to better training.

There are many studies supporting the efficacy of this procedure, but I will highlight a few. There are three studies (Ricke 2005, Todd 2015, Donati-Bourne 2015) demonstrating that any delay in the diagnosis and treatment of tongue tie increases the rates of breastfeeding termination by 300 to 500%. There is a large study demonstrating the financial costs to the United States due to the lack of optimizing the rates of breastfeeding (Bartick 2016). There is also a recent meta-analysis that demonstrates the importance of frenotomy in the management of ankyloglossia (Cordray 2023). There are literally hundreds of other studies that I could provide you demonstrating the positive impact this procedure has on the well-being of both moms and babies. Even outside of the breastfeeding relationship from a nutritional standpoint, there are high quality studies demonstrating the positive impact breastfeeding has on craniofacial development, a critical precursor for the development of malocclusion and obstructive sleep apnea (Peres 2015).

Given the disparity of breastfeeding success rates and initiation rates already present in lower socioeconomic demographic groups, further complicating breastfeeding by refusing to cover a procedure covered by all commercial insurers seems unjust and clinically inappropriate. As a state healthcare authority that has to obviously cover the costs related to all procedures, it is very important that you consider the costs long-term if the procedure is not covered and if breastfeeding fails. Refusing to cover the cost of the procedure in infancy will result in a higher demanded cost later in life.

Please feel free to contact me if you need access to any of the available studies or if you need more clinical information in your decision-making. While I do not reside in Washington, I frequently see patients from Washington and would be happy to support you in your decision making.

Sincerely yours,

Bobak Ghaheri MD

The Oregon Clinic

Portland, Oregon

[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted])
Subject: Letter from Sen. Muzzall RE: Glioblastoma Treatment
Date: Monday, March 25, 2024 10:31:38 AM
Attachments: image001.png
Giloblastoma.pdf

External Email

Hello,
Attached, please find a letter from Sen. Muzzall to Director Fotinos RE: Tumor Treating Field technology. Please let me know if you need anything else from us.

Best,

Eric Hemmen
Legislative Assistant to
Senator Ron Muzzall
(360) 786-7618
PO Box 40410 , Olympia 98504
114 Legislative Modular Building (LMB)

SENATE REPUBLICANS
PEOPLE BEFORE POLITICS

Secure a Safer Washington | Fight for an Affordable Washington
Build a Better Future for Washington's Children

Click HERE to subscribe to Senator Muzzall's e-Newsletter

Washington State Senate

Senator Ron Muzzall
10th Legislative District

Olympia Address:
PO Box 40410
Olympia, WA 98504-0410
E-mail: Ron.Muzzall@leg.wa.gov

Telephone:
(360) 786-7618
Toll-Free: 1-800-562-6000
TTY#: 1-800-833-6388

March 25, 2024

Ms. Charissa Fotinos
Medicaid Director
Washington State Health Care Authority
626 8th Avenue SE
Olympia, WA 98501

Dear Ms. Fotinos,

I am writing to encourage coverage by the Washington State Healthcare Authority (HCA) of an innovative, FDA-approved and NCCN-recommended device that treats a rare form of aggressive cancer using Tumor Treating Field (TTFields) technology. TTFields utilize alternating electric fields to slow or stop dividing cancer cells without significantly affecting healthy cells. TTFields are FDA-approved to treat an aggressive form of brain cancer called Glioblastoma (GBM).

It has shown promise in extending the lives of those facing what is typically a terminal form of cancer with an average survivor timeline of 12 to 18 months. Although GBM is a rare form of cancer, around 13,000 Americans will receive a GBM diagnosis this year. These patients deserve access to any treatment that may extend their life.

Currently, a significant disparity exists in who has access to the TTFields technology in Washington State. WA State GBM patients who have Commercial, Medicare, TRICARE or VA coverage can access TTFields as an NCCN-recommended treatment; however, the Washington State HCA's denial of coverage for TTFields prevents Washington Medicaid patients, public and school employees, and some clinical trial patients, from accessing this innovative therapy.

The HCA policy negatively impacts the state's Medicaid population and tens of thousands of public and school employees. This includes individuals working in local and state government, higher education, and judicial agencies. TTFields are a safe and effective form of treatment and expanding access should be of the utmost importance to Washington State decision-makers.

I respectfully request the addition of TTFields to the covered treatments available to Washington State HCA beneficiaries. It provides comparable benefits to chemotherapy without the toxic side effects. Medicaid coverage should be granted for appropriate patients. At the very least, the HTCC should review new evidence since the last review in 2018.

Sincerely,

Ronald E Muzzall

Senator Ron Muzzall

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Request for a Re-Review of the Optune Gio/TTF Device for Coverage
Date: Thursday, March 28, 2024 12:44:49 PM
Attachments: archbright_email_logo_7d3f71c5-d83c-4f2c-8838-a2175e1cdb5b.png

External Email

I am writing you to urge you to reconsider the Optune Gio/TTF Device for Coverage. The options for patients with Glioblastoma, a devastating cancer, are limited. Patients need as many tools in their toolbox as possible to treat this disease. This treatment that has been approved by the FDA should be accessible for patients no matter their income level, what state they live in, or who their employers are. Extending the life of Glio patients gives us more time to find a more permanent cure, but more importantly improves the quality of life of those suffering a disease that has seen very little support over decades.

My husband died of Glioblastoma at the age of 53 in 2022. He used Optune and I am convinced it is why he not only had an improved quality of life, but that it extended his life to two years, which is much longer than most get with this disease. That extended time not only meant everything to us as a family, it allowed him to participate in treatments and studies to help the ongoing battle for treating this insidious disease. We need a cure. And in the meantime we need to treat the patients who battle GBM with every thing we have. Eliminating an FDA approved treatment is short sighted at best and cruel at its worst.

Shannon Kavanaugh

[redacted]

Archbright

Shannon Kavanaugh | she/her/hers | Archbright | President & CEO | direct [redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Re: Optune Device
Date: Thursday, March 28, 2024 1:02:35 PM

External Email

I would add my wife's and my thoughts on the Optune Technology which we used for almost a year. Michele at 72 was diagnosed with a 6 cm glioblastoma which was removed surgically November 14th 2022. Following 42 days of radiation she started using the Optune technology. Twice a week we would shave her head, attached the arrays, go to physical therapy, stop at Costco for a hotdog and return home.

Michele's cancer was treated with Chemotherapy during the last year which continues today. Concurrent with the onset of the Optune usage a second smaller glioblastoma was discovered 1 cm in February 2023.

November 10th 2023 Michele's recurrent tumor was gone. We discontinued the Optune device at the end of November 2023. On Feb 14th 2024 a third in operable tumor was discovered this one grew in two weeks.

Our decision to discontinue the Optune I believe was a mistake. Though the Optune device requires diligence and planning it extended Michele's life. We travelled to Alaska last year with the Optune Device and once we are able to get the Optune back we will restart its usage.

Now some folks question, the value of these life extending technologies. Michele taught 2nd grade for twenty years, retired and wearing the Optune returned as a very popular and in demand substitute teacher.

I believe it is the singular role of Government to protect its citizens from harm.

When Governments prioritize medical treatment, including experimental treatments below other societal needs, there is something wrong.

I can tell you there exists a community of Optune users that are successful and have extended the survival rate past 5 years. To deny them this tool condemns them to unnecessary suffering and death.

I hope you will reconsider your decision to deny your state this tool.

Thank you Richard and Michele Rollins

Sent from my iPhone
Sent from my iPhone

On Mar 28, 2024, at 1:02 PM, Richard Rollins [redacted] wrote:

I would add my wife's and my thoughts on the Optune Technology which we used for almost a year. Michele at 72 was diagnosed with a 6 cm glioblastoma which was removed surgically November 14th 2022. Following 42 days of radiation she started using the Optune technology. Twice a week we would shave her head, attached the arrays, go to physical therapy, stop at Costco for an richarderollins@hotmail.com dog and return home.

Michele's cancer was treated with Chemotherapy during the last year which continues today. Concurrent with the onset of the Optune usage a second smaller glioblastoma was discovered 1 cm in February 2023.

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I hope you will reconsider your decision to deny your state this tool.

Thank you Richard and Michele Rollins

Sent from my iPhone

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Glioblastoma Letter - House of Representatives, WA Leg
Date: Friday, March 29, 2024 9:07:22 AM
Attachments: Glioblastoma letterhead pdf.pdf

External Email

See attached from Rep. Walen for formal comment period.

Phoebe Greening *(She/Her/Hers)*
Legislative Assistant | House Democratic Caucus
Office of Representative Amy Walen | 48th Legislative District
Chair, Consumer Protection & Business Committee
Finance Committee | Civil Rights & Judiciary Committee
housedemocrats.wa.gov/walen
Olympia Office: 360-786-7848 [redacted]

Participate: watch session through TVW | look up bill information | see an overview of the legislative process | request accommodations

State of
Washington
House of
Representatives

January 23, 2024

Ms. Charissa Fotinos
Medicaid Director
Washington State Health Care Authority
626 8th Avenue SE
Olympia, WA 98501

Dear Ms. Fotinos

We are writing to encourage coverage by the Washington State Healthcare Authority (HCA) of an innovative, FDA-approved and NCCN-recommended device that treats a rare form of aggressive cancer using Tumor Treating Field (TTFields) technology. TTFields utilize alternating electric fields to slow or stop dividing cancer cells without significantly affecting healthy cells. TTFields are FDA-approved to treat an aggressive form of brain cancer called Glioblastoma (GBM).

It has shown promise in extending the lives of those facing what is typically a terminal form of cancer with an average survivor timeline of 12 to 18 months. Although GBM is a rare form of cancer, around 13,000 Americans will receive a GBM diagnosis this year. These patients deserve access to any treatment that may extend their life.

Currently, a significant disparity exists in who has access to the TTFields technology in Washington State. WA State GBM patients who have Commercial, Medicare, TRICARE or VA coverage can access TTFields as an NCCN-recommended treatment; however, the Washington State HCA's denial of coverage for TTFields prevents Washington Medicaid patients, public and school employees, and some clinical trial patients, from accessing this innovative therapy.

The HCA policy negatively impacts the state's Medicaid population and tens of thousands of public and school employees. This includes individuals working in local and state government, higher education, and judicial agencies. TTFields are a safe and effective form of treatment and expanding access should be of the utmost importance to Washington State decision-makers.

We respectfully request the addition of TTFields to the covered treatments available to Washington State HCA beneficiaries.

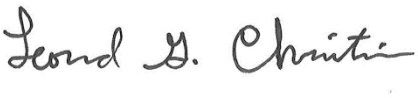
Sincerely,

Amy Walen
State Representative
48th Legislative District

Marcus Riccelli
State Representative
3rd Legislative District

Lisa Callan
State Representative
5th Legislative District

Suzanne Schmidt
State Representative
4th Legislative District



Leonard Christian
State Representative
4th Legislative District

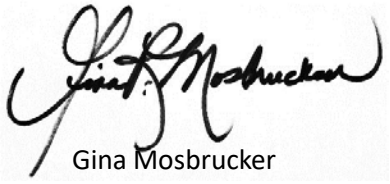
Stephanie Barnard
State Representative
8th Legislative District

Clyde Shavers
State Representative
10th Legislative District

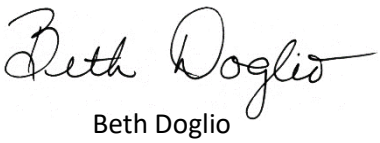
Dave Paul
State Representative
10th Legislative District

Tom Dent
State Representative
13th Legislative District

Stephanie McClintock
State Representative
18th Legislative District



Gina Mosbrucker
State Representative
14th Legislative District

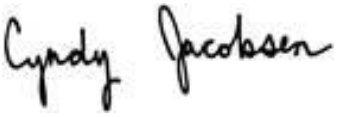


Beth Doglio
State Representative
22nd Legislative District

Jessica Bateman
State Representative
22nd Legislative District

Tarra Simmons
State Representative
23rd Legislative District

Greg Nance
State Representative
23rd Legislative District



Cyndy Jacobson
State Representative
25th Legislative District

Michelle Caldier
State Representative
26th Legislative District

Mari Leavitt
State Representative
28th Legislative District

Dan Bronoske
State Representative
28th Legislative District

Kristine Reeves
State Representative
30th Legislative District

Eric Robertson
State Representative
31st Legislative District

Cindy Ryu
State Representative
32nd Legislative District

Lauren Davis
State Representative
32nd Legislative District

Tina Orwall
State Representative
33rd Legislative District

Liz Berry
State Representative
36th Legislative District

Sharon Tomiko Santos
State Representative
37th Legislative District

Julio Cortes
State Representative
38th Legislative District

Mary Fosse
State Representative
38th Legislative District

Carolyn Eslick
State Representative
39th Legislative District

Tana Senn
State Representative
41st Legislative District

My-Linh Thai
State Representative
41st Legislative District

Alicia Rule
State Representative
42nd Legislative District

Nicole Macri
State Representative
43rd Legislative District

Brandy Donaghy
State Representative
44th Legislative District

April Berg
State Representative
44th Legislative District

Larry Springer
State Representative
45th Legislative District

Chris Stearns
State Representative
47th Legislative District

Vandana Slatter
State Representative
48th Legislative District

Sharon Wylie
State Representative
49th Legislative District

Monica Jurado Stonier
State Representative
49th Legislative District

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: Shawn Drennan
Subject: In Support To Request a Re-Review of the Optune Gio/TTF Device for Coverage
Date: Wednesday, April 3, 2024 12:26:50 PM
Attachments: WA State Optune GIO ReReview Letter of Support.docx

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External Email

I am writing this e-mail/letter to strongly request a re-review of the Optune Gio/TTF Device for coverage. I recently became aware of the decision to not cover the device in our great state, and I am shocked that anyone who understands the gravity of a diagnosis of this kind would make the decision to remove an FDA Approved and desperately needed treatment from the VERY SHORT list of available treatments for patients suffering from the devastating disease, Glioblastoma and other solid tumor cancers.

For any of you unaware of the impact of this disease, it is devastating to anyone who is diagnosed with it as well as their family, friends, co-workers, neighbors, and anyone that person has ever interacted with. I know this because my husband was diagnosed with Glioblastoma in January of 2018, a mere 2 months after we relocated from the East Coast to Seattle. After nearly a year of following the "Standard of Care" (SOC) treatment of surgery, radiation, and chemotherapy, it became evident that SOC was ineffective on his tumor - the SOC in the brain cancer space is ineffective for the majority of brain cancer patients - so we began to explore novel promising treatments. One of these was the Optune GIO Tumor Treatment Device. This device was finally able to slow down the growth of his tumor to allow him 1) time to try other treatments as well and 2) quality of life to spend as much time as possible with those that loved him. My husband passed away from Glioblastoma on March 24, 2020 after 26 ½ months of fighting. That was 4 years ago this week. He got to walk his daughter down the aisle, but he never met his 2 beautiful grandchildren.

This device has the potential to significantly impact many patients' lives and should absolutely remain on the covered treatments list in the state of Washington and beyond. The science is sound and now there is enough real-world evidence to clearly demonstrate its effectiveness.

I believe so strongly in the need to rethink this position that I will include my contact information below and absolutely encourage anyone with questions to please reach out. I am happy to expand on my personal experience and anything else that might prove helpful for you to make the right decision.

Shawn Drennan
[redacted]

Please, please, please do not take away even one person's chance for an improved prognosis.

In Good Health,

Shawn Drennan

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Novocure Comments to TTFields (Optune Gio) Proposed Technology Topics 2024
Date: Friday, March 29, 2024 8:59:47 AM
Attachments: image001.png
Novocure Comments to TTFields (Optune Gio) Proposed Technology Topics 2024.pdf

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External Email

Good morning,

Novocure appreciates the opportunity to submit the attached comments regarding the draft list of 2024 Prospective Technology Topics for review by the Health Technology Assessment program.

Thank you,

Emma Watson
Associate Director
State Government Affairs

[redacted]

novocure.com

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712

By Electronic Submission to: shtap@hca.wa.gov

RE: Novocure Comments to Tumor Treating Fields (Optune Gio) Prospective Technology Topics - 2024

To whom it may concern:

Novocure appreciates the opportunity to submit comments regarding the draft list of 2024 Prospective Technology Topics for review by the Health Technology Assessment program. We, as a company dedicated to advancing innovative therapies for cancer patients, are writing to respectfully request the inclusion of Optune Gio for the treatment of glioblastoma (GBM) in the 2024 review cycle.

There is considerable new data available since the HTCC rereview in 2018. We have provided a bibliography of new studies and evidence that demonstrates the efficacy, safety, and cost effectiveness of Tumor Treating Fields (TTFields) on glioblastoma and excluded anything that was considered in the 2016 and 2018 reviews.

We would like to draw your attention to a significant development in coverage policy regarding Tumor Treatment Field Therapy (TTFT) for newly-diagnosed GBM patients since the last HTCC review. In September 2019, the Centers for Medicare & Medicaid Services (CMS) have recognized the efficacy of this therapy by covering it under the Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823). This decision reflects the growing body of evidence supporting the effectiveness of TTFT, including its potential to extend the lives of patients with this aggressive form of brain cancer.

It is our understanding that Washington State Health Care Authority's decisions are to be consistent with those made under the federal Medicare program, as well as with expert treatment guidelines from specialty physician organizations and patient advocacy organizations. Therefore, we believe that the non-coverage of Optune Gio in Washington State creates a disparity in care for its beneficiaries.

Patients in Washington State, including those covered by Medicare, Tricare, VA, or commercial insurance, have access to this potentially life-extending therapy. However, beneficiaries under Washington State government plans, as well as School and Public Employee Benefit Board plans, are currently excluded from receiving Optune Gio. This exclusion not only hampers access to care but also erects additional barriers for members of employer-based beneficiary groups. Glioblastoma is a devastating disease and WA state residents should have access to all FDA-approved treatments that have been shown to extend life.

It is essential to address this disparity and ensure equitable access to Optune Gio for all GBM patients in Washington State. We urge the Washington State Health Care Authority to align its coverage policies with those of other payers and include Optune Gio as a covered therapy for the treatment of GBM.

Thank you for considering our request. We stand ready to provide any additional information or support needed to facilitate the inclusion of Optune Gio in Washington State's coverage policies.

Sincerely,

Emma Watson
Associate Director, State Government Affairs
Novocure

LITERATURE LIST

ECONOMIC

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: To Request a Re-Review of the Optune Gio/TTF Device for Coverage
Date: Saturday, March 30, 2024 12:37:04 PM
Attachments: WA State HCA_Public Comment_Optune Gio.pdf

External Email

I am sending this email to Request a Re-Review of the Optune Gio/TTF Device for Coverage. This device is FDA approved, standard of care, and is proven to extend the life of patients suffering with Glioblastoma, a form of brain cancer that is almost universally fatal. To deny coverage for Medicaid patients in WA state is essentially to say that if you are poor and without financial means, your life expectancy is not as important as those who have insurance or otherwise can pay for this treatment. In light of President Biden's own son succumbing to Glioblastoma, I am dismayed that a progressive state in both policy and med/tech research, such as Washington, would deny coverage for this device.

My then 51-year old husband was diagnosed with Glioblastoma on August 15, 2022. A few days prior, we thought he had a migraine or feared he might have had a stroke. Our world was ripped out from under us when we learned in the ER that he had a mass in his brain and had to be rushed to Tacoma for an emergency craniotomy a few days later. We were told that the life expectancy for this cancer was 12-14 months. He had surgery, then chemotheraphy and radiation, and later the Optune Gio tumor treating fields device. And wearing the device is not easy as it must be worn a minimum of 18 hours a day and requires 2 sets of hands to remove and replace the arrays, along with a heavy battery pack that must be carried at all times. But studies show that it extends both life expectancy and progression free survival for users. It is not a cure, but when you have been given only a year to live, anything that will give you more time with your family is a gift. Fortunately, my husband is still with us and so far his condition is stable, but we hold our breath with every follow-up MRI, knowing the day will come when the news is no longer good.

This is not a situation where lack of access results in a relative risk to patients' lives. Without access to the tumor treating fields device, patients with Glioblastoma die sooner. Not making this available to Medicaid patients with Glioblastoma in WA state literally shortens their lives. I am not writing this on our behalf, my husband is fortunate enough to have had access to the device through insurance. I am on my knees begging you to reconsider this position for those who do not have access and because of their financial situation cannot take advantage of this treatment.

Please feel free to contact me with any questions:

Lyda K. Hawes
[redacted]

[redacted]

A Washington resident since 1994,
Lyda

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: To Request a Re-Review of the Optune Gio/Tumor Treating Fields (TTF) Device for Coverage
Date: Saturday, March 30, 2024 1:35:28 PM
Attachments: Medicaid and Optune Gio.pdf

External Email

The Washington State Health Care Authority that's responsible for the health care of Washington Medicaid patients, public employees and teachers has wrongfully denied coverage for a FDA proved medical device, Optune Gio/TFF, that treats cancer patients, those diagnosed with brain cancer. The FDA approved this device over a decade ago.

My wife was diagnosed with Glioblastoma Multiforme (GBM) in the summer of 2018. A terminal form of cancer. This was after we both retired from our Navy service and our government service. Her neurooncologist suggested the use of Optune to prolong her life. She started Optune in the fall of 2018. She wore the device until the fall of 2022 when she had a second recurrence of the brain tumor. We believed this device allowed her to live well beyond the median life expectancy with GBM of 14 months. When she started using the device we had two insurances that shared the coverage, Tricare for Life and Blue Cross /Blue Sheild Federal employee. While on the device she further transitioned to Medicare. All approved coverage!!!! I strongly believe the use of the device allowed her to see her two grandchildren born and for them to briefly know her. She passed away just over a year ago, 5 March 2023.

I am requesting this re-review so that those not so fortunate to have the insurance coverage we had are able to utilize all available treatments, possibly extending their life for and thereby giving them hope. Hope is so important to the patient and caregiver in their journey.

I believe it is my responsibility to help those that have this diagnosis, so I am working as a volunteer with at least three different Brain Tumor National Brain Tumor Society, American Brain Tumor Association and End Brain Cancer Initiative.

Please re-review your decision and give this technology as an option for brain tumor patients no matter what their income.

Respectfully,

Patrick W. Jones
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public comment for proposed topics - CGM
Date: Monday, April 1, 2024 11:27:34 AM
Attachments: image001.png
HTCC CGM Rereview.pdf

External Email

Hi,

Please find attached our public comment and letter of support for inclusion of CGM in the HTCC list of technologies for review.

Carissa

American Diabetes Association.
Connected for Life

Carissa Kemp
Director, State Government Affairs
(AK, ID, KS, MN, MT, NE, ND, OR, SD, WA, WY)
[redacted]

American Diabetes Association.
Connected for Life

Thank you for the opportunity to express our support and appreciation for adding continuous glucose monitors to the list of technologies for rereview by HTCC. For people living with diabetes, continuous glucose monitors (CGM) provide significant, potentially life-changing benefits for diabetes management through avoidance or delay of serious complications, hospitalizations and even death. This technology provides greater information to patients and their health care providers than traditional blood glucose meters do by continuously monitoring an individual's blood glucose levels. The information the devices provide can result in better blood glucose management and reduce the risk for premature death and disabling complications including heart disease, stroke, kidney failure, new cases of blindness among adults, and non-traumatic amputation of the lower extremities.

On April 16, 2023 Medicare updated its coverage criteria for Continuous Glucose Monitors (CGM). The changes included the following:

1. Medicare eliminated the requirement that a person with diabetes needs to administer insulin multiple times a day. Approaches to diabetes management and technology access should accommodate a variety of clinically appropriate strategies. The American Diabetes Association believes requirements specifying that an individual must be on intensive insulin therapy or minimum number of daily administrations of insulin limits access to CGM for patients who need it, and thus urge that this requirement be eliminated. The Medicare requirement now requires that the "beneficiary is insulin-treated" or "has a history of problematic hypoglycemia."

Additionally, in 2021 CMS removed the following requirement:

1. Medicare eliminated the requirement for four times a day blood glucose checks. We believe that requirements specifying a minimum number or "frequent" blood glucose monitoring (BGM) limits access to CGM for patients who need it, and thus we recommend the removal of this requirement. Specifically, current standards of clinical practice do not support a restriction on CGM coverage that limits access to patients with a demonstrated history of "frequent" BGM self-testing. Eliminating the requirement will better align with current Medicare coverage criteria for CGMs, with peer-reviewed clinical evidence, and standards of practice recommended by the American Diabetes Association. This revision acknowledges that coverage criteria, and the regulatory landscape more broadly, should reflect the diversity of diabetes management practices utilized for individuals living with this condition. We strongly encourage a review and elimination of minimum daily testing requirement to ensure CGM access to individuals with diabetes who would clinically benefit.

CMS's decision was based off a review of evidence to determine if CGM technology could improve health outcome for beneficiaries who do not administer insulin 3 or more times per day. Improvements had to be evidenced by a clinically significant reduction in HbA1c, increased time in range, or a reduction in rate or severity of hypoglycemic events compared to self-monitoring of

blood glucose.[1] In our original request we submitted a list of evidence that supports eliminating these burdensome criteria and further expanding access to this treatment. Thank you for the opportunity to express our support for rereviewing continuous glucose monitors based on new evidence and expanded indications for use. We urge the committee to move forward with aligning with CMS criteria.

Carissa Kemp
Director of State Government Affairs, American Diabetes Association

[1] https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: expanding medicaid access to CGM
Date: Monday, April 1, 2024 1:02:39 PM
Attachments: Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf

External Email

Good Afternoon,

The purpose of this email is to advocate that all people with diabetes on insulin have equal access to life changing tools and technology such as CGM. There is strong evidence of improved outcomes for both people living with diabetes and cost savings for their health plans.

As a diabetes care and education specialist for > 30 years, I am reaching out to the state diabetes state leaders to discuss concerns around disparities in access to continuous glucose monitors (CGM) through Washington State Medicaid health plans. Medicaid policies mandate that people living with diabetes treated with insulin check their blood glucose 4 times a day while most plans cover 3 strips a day. Many denials for CGM are related to people unable to meet this unrealistic requirement. During the pandemic Medicare has dismissed this mandate allowing people on insulin greater access to CGM.

Health care providers are spending valuable time trying to appeal denials by State Medicaid health plans for vulnerable people with diabetes treated with insulin who are at higher risk for costly, acute complications related to hypo and hyperglycemia., ED visits, and other costly complications related to their uncontrolled diabetes.
Additionally, the costs on health care providers and state health plan employees time on calls attempts to appeal a denial for 1 person today would cover more than 1 year of CGM sensors for every appeal.

Attached is an article outlining the variability in state coverage for CGM with evidence for use of CGM in people with diabetes treated with insulin.

Sincerely,
Linda Castine

Linda Castine MN, RN, CNL, DCES
Nurse Care Manager
Ambulatory and Allied Care Services
Harborview Medical Center

[redacted]

[redacted]

Center for Health Care Strategies

Expanding Medicaid Access to Continuous Glucose Monitors

January 2022

By Greg Howe and Jennie Chavis, Center for Health Care Strategies

Made possible through support from The Leona M. and Harry B. Helmsley Charitable Trust.

Contents

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- Jessie Trice Community Health System
- JDRF
- MassHealth (Massachusetts Medicaid)
- Medtronic
- National Minority Quality Forum
- Nebraska Department of Health and Human Services, Medicaid and Long-Term Care
- North Carolina Department of Health and Human Services, Medicaid
- North Dakota Department of Human Services, Medicaid
- Ohio Department of Medicaid
- Open Door Community Health Centers
- Pennsylvania Department of Health Services, Office of Medical Assistance Programs
- Stanford University Department of Pediatrics
- Steve Fitton, retired Medicaid Director, Michigan Department of Health and Human Services
- T1D Exchange
- Texas Department of Health and Human Services, Medicaid and CHIP Services
- University of Southern California Keck School of Medicine
- Virginia Department of Medical Assistance Services
- Washington State Health Care Authority

CHCS also thanks Anne Peters, MD, and Osagie Ebekozien, MD, who reviewed and provided valuable feedback for the paper.

ABOUT THE CENTER FOR HEALTH CARE STRATEGIES

The Center for Health Care Strategies (CHCS) is a policy design and implementation partner devoted to improving outcomes for people enrolled in Medicaid. We support partners across sectors and disciplines to make more effective, efficient, and equitable care possible for millions of people across the nation. For more information, visit **www.chcs.org**.

Introduction

Approximately 14 percent of Medicaid beneficiaries have diabetes.[1] Medical expenditures associated with diabetes by Medicaid programs were roughly $25.7 billion in 2013.[2] In five years, from 2012 to 2017, the cost of diabetes grew by 26 percent because of an increase in the prevalence of diabetes and cost of care per person with diabetes.[3] As these medical expenditures continue to rise, related indirect costs are also rising such as reduced productivity, inability to work, and absenteeism.[4] Compared to people with commercial insurance, Medicaid beneficiaries have higher rates of suboptimal diabetes management, worse glycemic control, experience more barriers to care, and have more acute- and long-term diabetes-related complications.[5] Within Medicaid, health care costs for people with diabetes are 1.5 to 4.4 times more than for those without diabetes.[6]

TAKEAWAYS

- Continuous glucose monitors (CGMs) are the standard of care for treating people with type 1 diabetes and people with type 2 diabetes on insulin pumps or multiple daily insulin injections, and a recommended tool for people with type 2 diabetes on any form of insulin.
- Studies demonstrate that CGMs can: (1) improve clinical quality, health outcomes, and quality of life; (2) reduce health care costs; and (3) support broader efforts by state Medicaid agencies and their partners to address structural and systemic racism and related health inequities.
- There is no consistent Medicaid CGM policy in the U.S., with 40 states and the District of Columbia, providing some level of CGM fee-for-service coverage with wide variations in coverage. Ten states do not have published fee-for-service CGM coverage except through medical necessity.
- This paper explores the current landscape of state Medicaid CGM coverage, highlights state approaches to CGM coverage, identifies state opportunities to expand Medicaid coverage of and access to CGMs, and provides recommendations to the diabetes community to support increased access and coverage across the states.

Continuous glucose monitors (CGMs) are an accepted standard of care for treating people with type 1 diabetes and people with type 2 diabetes on insulin pumps or multiple daily insulin injections, and a recommended tool for people with type 2 diabetes on any form of insulin.[7,8] In contrast to fingerstick blood glucose monitoring, which reveals data for one moment in time, CGMs provide people with diabetes access to continuous data on their glucose levels so they can better manage their disease. It is the equivalent of a movie versus a still photo. CGMs can also alert people when their glucose level is too high or too low. Depending on the type of CGM, studies have shown that the use of CGMs can lead to better health outcomes and quality of life.[9,10] In addition to improvements in health outcomes and quality of life, the work absenteeism rate and diabetes-related hospital admission rate can decrease significantly.[11] Additionally, data suggest that CGM devices are cost effective.[12,13,14,15] Studies show reductions in rates of acute diabetes-related events and rates of hospitalization in people with type 2 diabetes with insulin

therapy.[16] Retrospective data from Kaiser Permanente Northern California showed reductions in Hemoglobin A1c (A1c) levels — a key indicator of blood glucose management — and lower rates of emergency department visits and hospitalizations for hypoglycemia for people with diabetes receiving insulin therapy.[17]

Additionally, diabetes disproportionately affects communities of color and populations with lower socioeconomic status.[18,19] The COVID-19 pandemic uncovered and exacerbated these disparities, increasing vulnerability to complications and associated mortality for people with COVID-19 and uncontrolled diabetes, particularly among patients who are Black and Latino.[20] Activities to increase access to recommended approaches to managing diabetes — including CGMs plus patient and provider education[21] — can support broader efforts by state Medicaid agencies and their partners to address structural and systemic racism and related health inequities.[22,23,24]

Medicaid coverage for CGMs, which was identified through interviews with state Medicaid agencies and publicly available information, varies significantly across state Medicaid programs. As of December 1, 2021, 13 states are covering certain CGMs for any patient for which it is ordered under preferred drug lists or preferred diabetic supply lists, 28 states are covering CGMs for specified populations when conditions have been met, and ten states do not have published coverage and are covering CGMs only as a medical necessity or as a value-added service voluntarily provided by a Medicaid managed care plan. CGM coverage criteria may be based on population and age, and may require prior authorization and diabetes-specific requirements and documentation that may limit beneficiary access or even harm beneficiaries in some cases.[25,26]

With support from The Leona M. and Harry B. Helmsley Charitable Trust, this paper explores the current landscape of state Medicaid coverage of CGMs, highlights state approaches to CGM coverage, identifies opportunities for states to expand Medicaid coverage for and access to CGMs, and provides recommendations to support state expansion. It is intended to inform state Medicaid leaders, as well as stakeholders in the diabetes community.

To develop the paper, the Center for Health Care Strategies (CHCS) conducted 24 interviews with patients, health care providers, diabetes peer support coaches, diabetes organizations, CGM manufacturers, and state Medicaid officials. The interviews explored current CGM coverage policies in Medicaid programs, decision making and implementation of policy changes, and barriers and opportunities for expanding access to CGMs for Medicaid beneficiaries. Except where explicitly noted, observations about the processes and drivers of state Medicaid coverage decisions come from interviews with state leaders who participated in this project.

Why Access to CGMs Matters

Technological advances such as CGMs have significantly improved the ability of providers to treat diabetes and for patients to manage their blood glucose levels. CGMs allow for improved glucose control because patients can see in real time what their glucose levels are without the burden of performing a fingerstick, and the use of CGMs can eliminate the need for finger stick blood glucose monitoring.[27] Even more importantly, CGMs provide immediate information on whether glucose levels are rising, falling, or staying the same. This information allows for safer glucose management. Finally, some CGM systems provide alerts, not only to alert for a low or high glucose levels, but to predict that a glucose level is falling too low. This allows a person with diabetes to act before developing hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar).

For Medicaid agencies that can cover and increase access to CGMs for their beneficiaries, and for the larger health care system, there is strong evidence that supports the benefits of CGM use for all people who are insulin-treated with an insulin pump or multiple daily insulin injections, and emerging evidence is showing the benefit of CGMs in patients on basal insulin. Existing studies, both randomized control trials and observational studies, demonstrate that CGMs can: (1) improve clinical quality, health outcomes, and quality of life; (2) reduce health care costs; and (3) support broader efforts by state Medicaid agencies and their partners to address structural and systemic racism and related health inequities. The evidence provided through the research described in this section can help facilitate pathways to implementing or expanding CGM coverage across Medicaid state agencies.

What is a CGM?

A CGM is a medical device including: (1) a small sensor; (2) a transmitter; and (3) a monitoring system that automatically tracks glucose levels continually and as often as every five minutes. The sensor is inserted by the patient just beneath the skin (usually on a patient's arm or stomach), which is connected to a transmitter that sends information to a monitor. The CGM can either be attached to an insulin pump that triggers an insulin injection when needed or transmit information to a separate small handheld device or app on a smartphone.

CGMs Can Improve Clinical Quality, Health Outcomes, and Quality of Life

CGMs generally include the following types: (1) real-time CGMs (rtCGMs) with alerts that automatically transmit data to a smart phone or receiver; and (2) intermittently scanned CGMs (isCGMs), which require scanning for a result and do not have predictive alerts. Randomized controlled trial (RCT) data demonstrates improved disease management and outcomes such as the glycemic benefits of rtCGMs in people with type 1 and type 2 diabetes on insulin pumps or multi-daily injection, in adults, including seniors.[41,42] RCT data also exist showing the benefit of rtCGMs in people with type 2 diabetes on basal insulin.[43] Much of the data supporting the use of isCGMs comes from observational and longitudinal studies that show improvement in A1c levels and reduction in diabetes-related complications and work absenteeism.[44] In nearly all studies with any CGM system, people show a high level of satisfaction with the device compared to fingerstick blood glucose monitoring. Some studies show improvements in patient-reported outcomes, including health-related quality of life[45] and reduction in diabetes distress.[46]

The Benefits of CGMs At-a-Glance

Studies have shown that CGMs can:

- ✓ Serve as the standard of care for insulin-treated people with diabetes.[28]
- ✓ Reduce an elevated A1C level.[29]
- ✓ Reduce the frequency and severity of episodes of hypoglycemia.[30,31]
- ✓ Improve patient satisfaction compared to fingerstick monitoring.[32,33]
- ✓ Improve patient-reported outcomes, including health-related quality of life.[34]
- ✓ Reduce hospitalizations for acute diabetes-related issues.[35]
- ✓ Reduce work absenteeism.[36]
- ✓ Facilitate communication of data with health care providers.
- ✓ Provide health care cost savings.[37,38,39,40]

The ability to monitor continuous day and night patterns in blood glucose levels provides an opportunity for patients to better react to their diabetes in real-time and for providers and patients to retrospectively analyze the data to search for trends. CGMs allow providers to remotely monitor their patients and/or download a detailed report of their patients' glucose profile data. Fingerstick blood glucose monitoring alone, a clinical practice that is still frequently used in Medicaid settings,[47] involves finger sticks multiple times per day and obtaining an A1c measure. This method is not as safe for treating diabetes because it only provides a single measure in a moment in time without immediate trend information.[48] By comparison, CGMs allow providers to improve their delivery of care and manage their patients' diabetes through better understanding of patients' 24/7 behaviors and blood glucose levels and for patients to better self-manage their diabetes.

Patient Success Story: Back in Control with CGM

Laura, a 28-year-old working mom with type 1 diabetes, arrived for her first appointment at our health center. She was recently discharged from the emergency department after she developed significant diabetic retinopathy, a diabetes complication that left her blind in one eye.

As we talked, I learned that living with type 1 diabetes was nothing new to Laura. Diagnosed at the age of seven, Laura received care at a local children's hospital. Her treatment, which was covered by Medicaid, included CGM and was instrumental in keeping her diabetes under control throughout her early life.

However, when Laura aged out of pediatric coverage, she faced a health care crisis. She couldn't afford the infusion sets that had previously been covered by Medicaid. Instead of the local children's hospital, she now relied on the emergency department for her care. As a result, Laura was admitted several times for diabetic ketoacidosis, a serious diabetes complication.

At our first appointment, my top priority was to help Laura obtain Medicaid and get her back on CGM, so that she could return to continuously tracking her A1c levels and be alerted when she was out of a healthy range. In our follow-up appointments, Laura shared the relief she felt to be back in control of her diabetes for the first time since childhood. Today, her CGM and access to diabetes education empowers Laura to better manage her diabetes and improve her diabetic retinopathy.

If it wasn't for the CGM and the care she received at our clinic, Laura would continue to turn to the emergency department for care and be at risk for serious diabetes complications that would significantly affect her quality of life and ability to work and take care of her children.

- Anne Peters, MD, professor of clinical medicine at the Keck School of Medicine and the University of Southern California (USC) and the Director of the USC Clinical Diabetes Programs

CGMs Can Reduce Health Care Costs

There can be health care savings associated with CGM use for people with type 1 diabetes. While CGMs have upfront and ongoing costs, the use of them can lead to cost savings through a reduced number of non-severe hypoglycemic events.[49] CGMs can also reduce costs associated with daily test strip use. Over a lifetime, CGMs have been shown to be cost-effective at $100,000 per quality-adjusted life years,[50] and key drivers of this cost-effectiveness can include improved quality of life associated with the decrease in experiencing diabetes distress and fear of hypoglycemia, reduction or elimination in fingerstick testing, and change in A1c.[51] Because CGM use can reduce short- and long-term complications for people with diabetes, there can also be associated reductions in hospitalizations, emergency department visits, and outpatient visits and procedures for people with type 1 diabetes.[52] One study shows that patient adoption of CGMs for just nine months results in health care costs savings of $4,000 compared to a patient without a CGM.[53]

CGMs Can Support State Medicaid Agencies' Efforts to Address Health Disparities

Diabetes disproportionately affects communities of color and people with lower incomes. According to the American Diabetes Association, diabetes prevalence is highest in Native Americans (14.7 percent), Latinos (12.5 percent), and Black people (11.7 percent) compared to white people (7.5 percent).[54] With twice as many Black, Latino, and Native American beneficiaries covered by Medicaid/Children Health Insurance Program (CHIP) as compared to white beneficiaries,[55] the higher prevalence of diabetes for these populations is an important consideration.

Compared to people with commercial insurance, Medicaid beneficiaries have higher rates of poor diabetes management, worse glycemic control, experience more barriers to care (including access to and coverage of continuous glucose monitors and other diabetes technologies), and experience more acute- and long-term complications related to diabetes.[56,57,58] CGM use is the standard of care for insulin-treated people with diabetes,[59] and more widespread use of and access to CGMs can help to improve both health and racial equity.

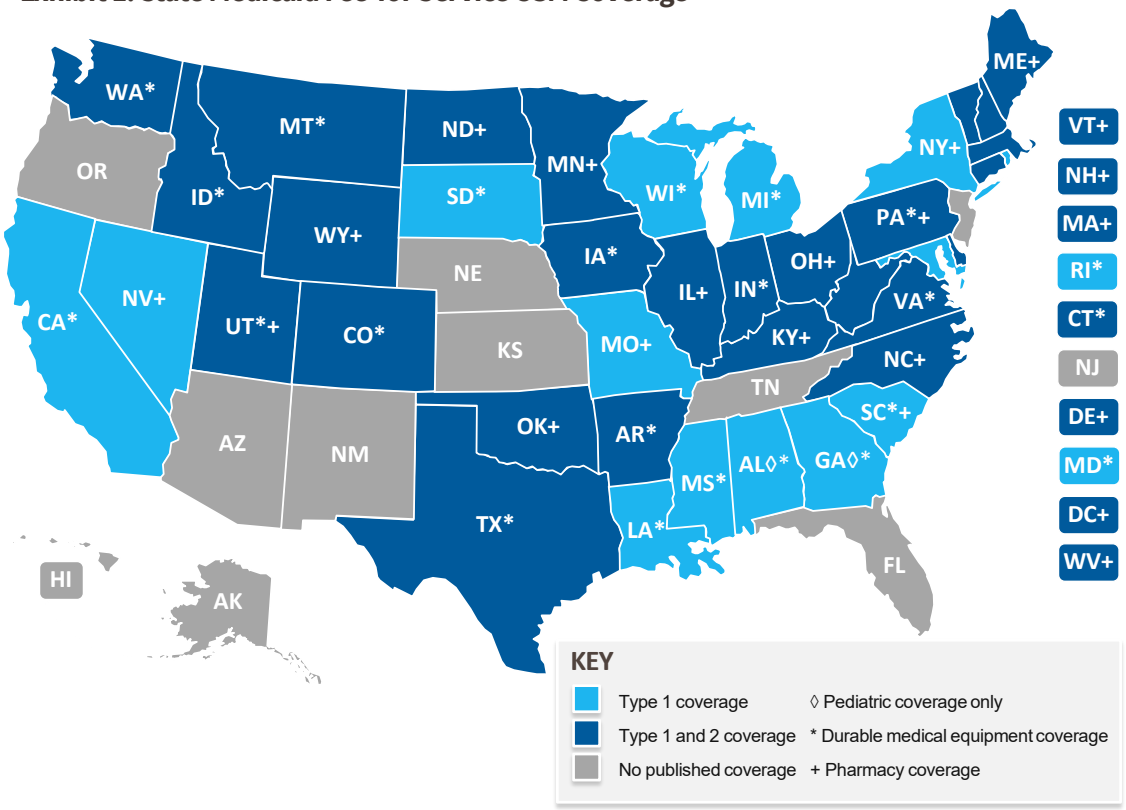
The Current Medicaid Coverage Landscape

Medicaid coverage decisions are made on a state-by-state basis, subject to minimum federal standards. While there is no consistent Medicaid CGM policy across all states, there are common components among state Medicaid agencies that cover CGMs.

Across the U.S., 40 states and the District of Columbia, provide some level of CGM fee-for-service coverage with variations in coverage that include: (1) classification as a durable medical equipment (DME) versus pharmacy benefit; (2) coverage for people with type 1 versus type 2 diabetes; (3) coverage for children versus adults; (4) prescriber requirements; (5) need for prior authorization; and (6) diabetes-specific requirements and medical documentation.

A detailed overview of these coverage components is described in **Appendix A** (see **Exhibit 1** for a summary) and an at-a-glance summary of policies is outlined in **Appendix B**. Ten states do not have published fee-for-service CGM coverage. In these states, CGMs may be covered through medical necessity (see "Medical Documentation" on page 13) or as a value-added service voluntarily provided by a managed care plan.

Exhibit 1. State Medicaid Fee-for Service CGM Coverage



Durable Medical Equipment or Pharmacy Benefit

Of the 40 states and the District of Columbia that provide coverage, 20 cover CGMs as a DME benefit and 21 cover CGMs as a pharmacy benefit. The DME benefit generally includes medical equipment, supplies, and appliances used for medical purposes (e.g., wheelchairs, oxygen equipment and accessories, and infusion pumps). A few states that cover CGMs as a pharmacy benefit, also provide the option for coverage through DME, or require nonpreferred CGMs to be approved and billed through DME. For states that offer coverage as a DME benefit, patients connect with DME distributor companies once their provider orders the CGM. DME companies can have their own separate set of exclusionary criteria that makes it challenging to navigate, and processing can take up to four to six weeks. Moreover, even once an order for a CGM is placed, getting refills can require frequent (as often as monthly) prior authorizations to obtain more supplies. For states that offer CGM coverage as a pharmacy benefit, CGMs are covered the same way as prescription drugs. Once a provider prescribes a CGM, the patient can pick up the CGM through their local pharmacy along with their other medications or supplies to manage their diabetes.

CGMs were initially covered as a DME benefit in all states, most likely because of Medicare's policy of classifying CGMs under Part B, which includes DME. In recent years, more states are changing their policies to cover CGMs as a pharmacy benefit due to increasing affordability and availability.

Despite the advantages for patients in providing CGMs as a pharmacy benefit, interviewees noted a few concerns about the adoption of CGMs as a pharmacy benefit. First, test strip coverage through local pharmacies under Medicare has become an increasingly cumbersome process, and providers fear that more complex processes in obtaining CGMs through pharmacies could be enacted in the future. Second, the pharmacy benefit can look different across states. While states have flexibility to expand access by putting certain CGMs on the preferred drug list or preferred

A Note about Pharmacy Benefits, Preferred Drug Lists, and Managed Care

When CGMs are covered as a pharmacy benefit, they can be included on the state's preferred drug list or preferred diabetic supply list for their fee-for-service (FFS) pharmacy program. For states with managed care programs where the managed care organizations (MCOs) provide the pharmacy benefits (pharmacy is "carved-in" to MCO contracts), federal law requires that prescription drug coverage under Medicaid MCOs be consistent with the FFS program. Further, MCOs are not allowed to have medically necessary criteria for prescription drugs that are more stringent than FFS.[60] A growing number of managed care states use a uniform preferred drug list, which requires all MCOs to cover the same drugs as the state.[61] In some cases in states where CGMs are not covered by Medicaid, MCOs cover CGMs for their members as a value-added benefit.

diabetes supply list, they can also limit access with restrictive criteria. Third, pharmacy benefit managers, who act as a third-party, might negatively affect rebates and affordability for states. Fourth, some providers find navigating pharmacies more challenging because of requirement to write prescriptions each month. Finally, either through pharmacy or DME benefits, use of CGM can be limited to one type, such as isCGM. Certain eligible patients who require rtCGMs, such as those experiencing hypoglycemia unawareness where the individual is unaware of his/her symptoms or experiencing frequent hypoglycemic events, also have the additional need for documentation and prior authorization. This can make these devices impossible for patients to obtain. Choice of CGM devices need to be individualized, particularly for patients on intensive insulin therapy.

What is the difference between type 1 and type 2 diabetes?

Type 1 diabetes and type 2 diabetes are very different. **Type 1 diabetes** is often diagnosed in children, teens, and young adults, but can also develop in adulthood. Symptoms in youth often develop quickly, while symptoms in adults usually develop slowly overtime. It is an autoimmune reaction that stops the body's ability to make insulin. Type 1 diabetes affects 5-10 percent of people with diabetes.[62] People with type 1 diabetes need to take insulin every day to survive, and there is no known prevention strategy or cure.

Type 2 diabetes affects 90-95 percent of people with diabetes.[63] People with type 2 diabetes experience both insulin resistance and insulin deficiency. It is often diagnosed in adults although can occur in youth. Unlike type 1 diabetes, type 2 diabetes can be prevented by engaging in healthy lifestyle changes (e.g., exercising, healthy eating, and maintaining a healthy weight).[64] In addition to lifestyle modification, people with type 2 diabetes often need treatment with both non-insulin and insulin therapies. Type 2 diabetes is particularly severe in youth who develop the disease.

Medicaid CGM Coverage for People with Type 1 versus Type 2 Diabetes

Medicaid CGM coverage criteria vary across states based on the type of diabetes. Of the 40 states and the District of Columbia that provide coverage, 27 currently cover CGMs for people with both type 1 and type 2 diabetes on intensive insulin therapy. Some cover CGMs for people with both type 1 and type 2 diabetes on intensive insulin therapy, while other cover CGMs only for people with type 1 diabetes. Originally, Medicaid agencies began covering CGMs for people with type 1 diabetes because CGMs were studied by researchers in this patient population due to their higher risk for hypoglycemia and hypo-unawareness. States' CGM coverage then expanded to include people with type 2 diabetes on intensive insulin therapy. More recently, CGMs have been found to be beneficial for people with type 2 diabetes on basal insulin, and even in people on non-insulin therapies. While CGMs are currently not covered for these populations, state Medicaid agencies continue to update coverage policies for CGMs as they are studied for efficacy in additional populations.

Coverage for Children Versus Adults

CGM coverage criteria that is inclusive of all ages is commonly found across state Medicaid agencies. There are only three states that provide coverage for only children or adults. Two states only cover children — one state only covers children with type 1, whereas the other state only covers children with type 1 and type 2 diabetes on insulin pumps or multiple daily insulin injections. Just one state covers only adults with type 1 diabetes and not children. Age restrictions can pose challenges for individuals whether that be losing coverage when they become an adult or only having coverage as an adult.

Prescriber Requirements

State Medicaid CGM coverage also specifies who is authorized to prescribe a CGM. The authorized prescribing physician varies across states and can be limited to endocrinologists, or can include primary care providers, nurse practitioners, physician assistants, or pharmacists. Of the 40 states and the District of Columbia that cover CGMs, seven require endocrinologists to prescribe or to provide consultation on a prescription. Other state Medicaid programs that do not have this requirement allow for primary care providers or other licensed care professionals to prescribe. Limiting prescriber requirements to only endocrinologists restricts access to CGMs, particularly in medically underserved communities where there are often shortages of specialists. Finally, interviewees noted that in some cases the documentation required for CGM approval is so detailed that it is beyond the knowledge base of many general practitioners.

Prior Authorization

Prior authorization, also known as pre-authorization, requires that the prescribing provider obtain approval by Medicaid before the CGM is covered and provide documentation to Medicaid that the CGM is medically necessary for the patient.[65] Although prior authorization can be an effective way for Medicaid agencies to reduce unneeded medications and manage costs, patients and providers interviewed for this paper noted that this process can be a barrier to receiving timely, evidence-based care.

Medical Documentation

Medicaid CGM policies, except for states with certain CGMs listed on their preferred drug lists or preferred diabetic supply lists, require meeting diabetes-specific medical documentation to provide evidence that the CGM is medically necessary. Diabetes providers interviewed for this paper suggested that most if not all medical documentation requirements present barriers to CGM access with limited clinical upside (see quoted perspectives below). While the extent of documentation varies across states, it can include that an individual experience one or more of the following:

EXAMPLES OF DIABETES-SPECIFIC MEDICAL DOCUMENTATION REQUIREMENTS	PERSPECTIVES FROM CLINICAL INTERVIEWEES ON REQUIREMENTS
Hypoglycemic episodes *(low blood sugar)*	*"This is a potentially dangerous requirement because it could provide an incentive for someone taking insulin to induce a dangerous low blood sugar reaction in order to qualify for a CGM."*
Nocturnal hypoglycemia *(low blood sugar at night)*	*"Similarly, this is a dangerous requirement because a patient can withhold a bedtime snack in order to go low to qualify, for example."*
Refractory postprandial hypoglycemia *(low blood sugar that occurs after a meal and for a long duration)*	*"This is a dangerous requirement because it can be completely inducible by the patient."*
Hypoglycemia unawareness or history of unawareness resulting in seizure, loss a of consciousness, or need for emergency care *(individual is not aware of their symptoms, but it may have been witnessed by others)*	*"Most individuals with type 1 diabetes have some element of hypoglycemia unawareness. Requiring a severe outcome to happen to qualify for a CGM may put patient safety in jeopardy."*
Recurring diabetic ketoacidosis *(a serious complication when an individual cannot produce enough insulin and there is a high production of ketones)*	*"Patients should not have to experience a serious complication more than once to get a CGM."*
Suboptimal glycemic control despite compliance with multiple daily injections of insulin — minimum of three per day	*"Any number of injections should qualify. Data show that rtCGMs can improve glycemia in people who receive a varying range of daily injections."*
Documented frequency of standard fingerstick monitoring of blood glucose *(self-monitoring blood glucose)*	*"There is no relationship between the ability to perform fingerstick monitoring of blood glucose and CGM outcomes. This is a barrier to CGM use, especially low-income populations who often have physically demanding jobs and less time to test and document than their higher socioeconomic status counterparts." (See sidebar on the next page for more information.). "Arguably, those who do not frequently test stand to benefit the most from continuous data because they need to do more monitoring."*
An insulin pump used for maintenance of blood sugar control	"*Pumps can be difficult to obtain through Medicaid.*"
Regular visits with an endocrinologist or another health care provider	"*As Medicaid beneficiaries may have more limited access to specialty care, this requirement can pose a barrier unrelated to clinical need."*

The diabetes-specific medical documentation commonly seen in policies often require patients with diabetes to demonstrate poor health to access a CGM. However, patients who have achieved excellent diabetes outcomes could also benefit from a CGM, and potentially improve their clinical success.[66,67]

More on Self-Monitoring Blood Glucose Disparities

The self-monitoring blood glucose (SBMG) requirement in many states is a barrier to CGM access. Of the 40 states and the District of Columbia that provide CGM coverage, 19 currently require beneficiaries to document blood glucose levels using finger sticks (at least 4 times per day) to demonstrate ongoing need for a CGM. Patients that are unable to afford or to access test strips may be denied CGM coverage because of this requirement. In July 2021, Medicare eliminated this requirement for beneficiaries given the barrier to access.[68] This specific eligibility criteria posed controversy for Medicare beneficiaries because coverage was only provided for three test strips per day for insulin- treated beneficiaries and required self-monitoring blood glucose four times per day. States may choose to revisit their policies given the Medicare precedent.

State Medicaid Approaches to Covering CGMs

Approval Process

The formal process for making Medicaid coverage decisions for CGMs shares similar elements across states, including agency staff involvement in reviewing relevant resources and conducting policy analysis, external advisory boards for evaluating clinical data, and legislative input and oversight. This section outlines state approaches to covering CGMs drawn from interviews with state Medicaid officials.

MEDICAID AGENCY STAFF

Staff at various levels of a state's Medicaid agency are involved in the CGM approval process, including policy analysts, pharmacy and medical directors, and senior agency leaders. Policy analysts collect publicly available resources on clinical outcomes, budgetary impact, and stakeholder input (see a description of these considerations beginning on page 16). After collecting publicly available resources, analysts and program staff prepare reports for external advisory groups, senior agency leaders, and interested legislative staff. Pharmacy and medical directors also review clinical and cost data, and often participate in external advisory groups to provide both clinical expertise and an agency perspective on the impact of a proposed coverage decision. Executive agency leaders, including the Medicaid director, review reports provided by their staff, consider stakeholder input, and make recommendations to and consult with department leaders and Governor's office staff.

EXTERNAL ADVISORY BOARDS

States typically engage external advisory boards to provide feedback for making CGM coverage decisions and advising agency leaders on administering pharmacy and DME programs. Federal law requires states to establish a Drug Utilization Review Board to guide pharmacy activities, including establishing standards for and conducting drug utilization review and identifying problems in pharmacy programs.[69] Thirty-nine states[70] also use a Pharmacy and Therapeutics Committee to provide clinical input on decisions related to the state's preferred drug list, including guidelines for drug placement and prior authorization and community prescribing standards.[71] External advisory boards are typically comprised of pharmacists and physicians that serve Medicaid beneficiaries, Medicaid agency pharmacy and medical directors, managed care plan representatives, and consumers. Although most states lean heavily on the input from

external advisory boards, there are no federal rules about how states process or use this input to make coverage decisions.

For example, **Washington State** uses an independent Health Technology Clinical Committee, comprised of community health care practitioners, to make coverage determinations for medical devices and procedures based on scientific evidence and public input. State purchased health care programs, including Medicaid, follow these determinations.[72]

LEGISLATURE

State legislatures play a significant role in the CGM decision-making process, both formally and informally. Some states have statutory requirements that the legislature needs to be consulted on pharmacy and device decisions if there is a significant projected budgetary impact. Other states recognize the informal influence that legislators have in impacting agency coverage decisions and choose to engage them in the decision-making process. One state noted that it maintains good relationships with legislators to monitor needs and concerns from constituents around the state.

Decision Drivers

States cited various factors in their consideration of coverage for CGMs, including clinical evidence, budget impact and alignment with the state's overall health priorities, stakeholder input, and coverage by other public and private insurers. While there are many common factors that drive state decision making, there is no single pathway for states that have approved coverage of CGMs, and there is no certain formula for gaining approval. Also, none of the factors discussed in this section would solely determine a state's coverage decision. While the importance of the factors varies among states, most states noted that clinical evidence and budget impact were the key decision drivers.

CLINICAL EVIDENCE

When considering coverage for new devices or therapies, states indicated that their primary concern is whether a proposed therapy has been proven effective in treating the disease. For CGMs, and other diabetes therapies, states indicated that they relied on information from reputable sources to determine clinical efficacy, such as:

- **Medical literature**: Peer-reviewed research studies that include randomized controlled trials.
- **Research organizations**: For example, the Institute for Clinical and Economic Review, a research program at Harvard Medical School, is an independent non-

profit organization that engages key stakeholders to evaluate clinical and economic evidence on prescription drugs, devices, medical tests, and delivery system innovations.[73] The Pacific Northwest Evidence-based Practice Center is a collaboration of the Oregon Health & Science University (OHSU), the University of Washington, and Aggregate Analytics that reviews clinical and quality evidence on health care topics for federal and state agencies, professional associations, and foundations.[74] Also housed at OHSU, the Center for Evidence-based Policy, through its partner collaborative,[75] the Medicaid Evidence-based Decisions Project, provides reports to a consortium of 21 participating states on the effectiveness and safety of treatments and services to inform their decision making, including a January 2021 report on rtCGMs and sensor augmented insulin pumps.

- **Disease-specific organizations**: The American Diabetes Association publishes the annual Standards of Medical Care in Diabetes, which includes clinical practice recommendations for the treatment of diabetes and the evaluation of the quality of care.[76] The Endocrine Society, comprised of clinicians and research scientists, publishes evidence-based recommendations for clinical care and practice to treat patients with endocrine disorders.[77] The American Association of Clinical Endocrinology publishes the Advanced Diabetes Technology Guideline, which is an evidence-based clinical practice guideline addressing the latest advancements in technology options, including CGMs, for patients with diabetes.[78]
- **Multi-state prescription drug purchasing pools**: Groups like the Sovereign States Drug Consortium, which is comprised of 13 state Medicaid programs, collectively solicit and evaluate offers from manufacturers for state supplemental and DME rebates.[79] They also provide information to their member states on clinical and administrative best practices on pharmacy and DME issues.
- **Providers**: States may consult with providers, both formally and informally, to learn about their experiences — both patient outcomes and effectiveness of new therapies — ordering devices under consideration for coverage. States with academic medical or research centers (e.g., a Diabetes Center of Excellence) receive requests from and consult with experts in these facilities about new therapies such as CGMs.
- **U.S. Food and Drug Administration (FDA)**: The FDA's Center for Devices and Radiological Health evaluates the safety and effectiveness of medical devices and will approve them if the product's benefits outweigh the risks for patients.[80] Devices approved by the FDA are considered more favorably by state decision makers.

BUDGET IMPACT

While documented clinical outcomes are a persuasive factor, the cost of covering new therapies weighs heavily in state decision making. State Medicaid leaders review data on costs and return on investment (ROI), often using analyses from sources described on the previous pages, to determine budget impact. Also important is the availability of state dollars to pay for upfront costs for implementing coverage changes. For CGMs, as noted earlier, cost savings, such as reductions of inpatient hospitalizations, are more likely seen in future budget years. While a positive ROI is a compelling argument, state budget officials are usually more interested in immediate cost savings and understand that any new coverage will increase costs in the near term.

States are faced with myriad health concerns and limited resources in their Medicaid budgets to address them. In almost every state, diabetes is one of the top health concerns and a significant cost driver for Medicaid. Therapies for managing diabetes, particularly those that have been proven to be clinically and cost effective like CGMs, present promising opportunities for states. Even a coverage change with a relatively small initial budget impact, however, can face approval challenges when considered with other critical state health needs.

Several states noted that although having evidence to make a compelling case for ROI is important, they made decisions to cover CGMs without this extensive evidence. These states felt confident that their clinical due diligence and experience approving other drugs and therapies was sufficient to project a positive ROI. One state, for example, noted that the cost of a CGM for a patient would be less than one emergency department visit.

STAKEHOLDER INPUT

State Medicaid leaders solicit formal input from stakeholders, including patients, providers, and others in the diabetes community, through external clinical and non-clinical advisory boards beyond those with a clinical focus. In **North Dakota**, which added coverage for CGMs in 2021, the Medicaid Medical Advisory Committee, which is a federally mandated committee to advise the state's Medicaid leaders, identified coverage for CGMs as one of the top issues for state action. In **Texas**, the Diabetes Council, which was created by state legislation to promote diabetes prevention and awareness throughout the state, focused its attention on state coverage for CGMs.

States also receive direct, unsolicited input from patients, providers, and others in the health care system. States also value input from providers who are on the front lines of diabetes care. Several states noted that before they decided to cover CGMs, state staff

reached out to specific community providers to get their input on the value of CGMs for their patients.

View from Stakeholders: California and Colorado

Colorado and California approved Medicaid coverage for CGMs in 2021. Members of the diabetes community involved in these states who were interviewed for this paper offered reflections on achieving coverage.

COLORADO: Interviewees in Colorado identified three key factors that helped sway decision-making around CGMs in the state:

- ***Data***. Presenting data to state Medicaid officials that highlighted a potential ROI was essential particularly because there would be an initial budget impact with expanding coverage.
- ***Health equity***. Without approving CGM coverage, Colorado would be perpetuating a two-tier health system in the state that could cause further inequities between Medicaid and commercial members.
- ***Patient voice***. Incorporating patient voice was critical in Colorado. Diabetes organizations facilitated discussions between Medicaid leaders and patients with type 1 diabetes so that they could directly share their personal experiences and how they benefitted from using a CGM.[81]

CALIFORNIA: California expanded its CGM coverage from including only children to covering both children and adults. Prior to approval in 2021, the State Assembly twice passed bills that were vetoed by two different governors. Interviewees pointed to several factors that contributed to the change in coverage:

- ***Health equity***. Black, Indigenous, Latino, and other people of color in California were and continue to be disproportionately impacted by COVID-19. Approving CGMs for coverage helped meet the needs of people with diabetes and provide a tool for effective diabetes management, especially during the COVID-19 crisis.
- ***Governor's priorities***. The Governor included Medicaid CGM coverage in his annual budget proposal.

In both states, forming relationships with state leaders was essential. The diabetes community and key stakeholders (e.g., patient organizations, state medical associations, providers, and social justice organizations) formed relationships and participated in ongoing dialogue with state leaders to discuss the importance and benefits of CGM coverage.

EXAMPLES OF OTHER PUBLIC AND PRIVATE COVERAGE

States often look at other states' Medicaid programs to find out how they cover a new therapy and what the states' experiences have been since adding coverage. Some states look to others with similar populations or program characteristics, while other states review coverage in every state, typically using resources from neutral organizations. Another source of information is the Medicaid Medical Directors Network, run by Academy Health,[82] which provides a forum for senior state clinical leaders to share best practices.

States also look at commercial insurance coverage practices, both within their state and nationally. State Medicaid medical directors often consult with their commercial peers, as well as review publicly available insurance policy information. In many instances, like with CGMs, commercial insurers cover new therapies earlier than state Medicaid programs.

While states are familiar with what Medicare covers with regard to pharmacy and DME, interviewees expressed different perspectives on the role of Medicare policy in making coverage decisions. Some states review Medicare policies, others noted that Medicare is generally not a major factor in state Medicaid coverage decisions, primarily because it serves a population with different age and demographic characteristics, except for dually eligible beneficiaries. While Medicare began covering some CGMs in 2017 and has expanded the types of covered CGMs and removed requirements for accessing them, states have not necessarily followed suit.

Recommendations

State Medicaid Agencies

Following are pathways for states that currently do not cover CGMs to do so, and opportunities for states that cover CGMs to eliminate barriers that make it harder for patients to access them.

For states considering CGM coverage:

- ***Include CGM coverage in the state's equity portfolio.*** Addressing racial health inequities is at the forefront of many state and federal priorities. Using proven, evidence-based interventions like CGMs, is a concrete way that states can move the needle on disparities in diabetes care. CGM data is useful for telemedicine visits, which benefits patients in rural settings. Providing CGMs to low-income beneficiaries, as well as Black, Indigenous, Latino, and other beneficiaries of color, also reduces disparities in access to technology.
- ***Align CGM coverage with other health priorities***. Improving care and reducing costs for chronic diseases like diabetes is a key priority for state policymakers. Linking CGM coverage to quality chronic disease care helps build the case for this proven technology. Other health priority areas where CGMs can drive better quality is maternal health (gestational diabetes) and for children with diabetes who are impacted by COVID-19. Separately, many states have advanced primary care initiatives that aim to bolster the capacity of primary care practices to provide better care. These initiatives, which often emphasize chronic disease management, such as diabetes, would align with efforts to expand access to CGMs.
- ***Understand the impact of CGMs on beneficiaries.*** States should seek opportunities to hear from beneficiaries directly about their experiences managing diabetes, including experiences related to CGMs. State advisory boards include consumers that may provide their own experiences or be able to point to other consumers. State and national diabetes organizations can connect state officials to patients with diabetes. Providers (primary care and specialists) and provider organizations can also offer feedback on their experiences helping patients manage diabetes.
- ***Address budget concerns.*** To build the case for covering CGMs, Medicaid agencies can review resources cited in this paper that highlight opportunities for cost savings.

- ***Connect with other states***. Medicaid staff and leaders in states that cover CGMs are a good source of information for building the case for CGM coverage and can provide lessons from their experiences implementing this benefit. Interested state leaders can contact peers in other states directly or leverage national forums such as the Medicaid Medical Directors Network.

For states with existing CGM coverage:

- ***Update diabetes measures to reflect current standards of care.*** States should consider adopting Time in Range (TIR) as a quality measure. TIR is defined as the amount of time a patient is in a clinically acceptable and healthy glucose range, which varies per patient. It provides actionable information for the patient and provider and was new to the Standards of Medical Care in 2021.[83] States with value-based payment programs that include diabetes targets could update measures, include additional measures, and develop incentives for providers and health plans to adopt and use CGMs to better manage patients with diabetes.

- ***Cover CGMs as a pharmacy benefit rather than a DME benefit***. Patients report that accessing a CGM and its components is more convenient through a pharmacy than through a DME supplier. Beneficiaries with diabetes who already access insulin and other pharmaceuticals through a pharmacy would not have to navigate the requirements of another entity. For states with a preferred drug list, Medicaid officials could also consider expanding the brands of CGMs that are available to beneficiaries, as some brands are not interchangeable with others. States may also benefit from rebates that would make covering CGMs more cost effective.

- ***Remove burdensome provider documentation***. Exclusions in the coverage criteria make it difficult for people who need CGMs to access them. Requirements that providers produce extensive documentation and that patients test blood glucose or inject insulin a certain number of times daily is inconsistent with widely accepted clinical guidelines. For states that require prior authorization by an endocrinologist, access to CGMs may be particularly limited by low numbers of endocrinologists.

- ***Allow providers to identify the CGM that is best for the patient***. CGM devices are not all the same. RCT data supports use of rtCGMs which provides predictive alerts for low and high blood glucose levels. Although more expensive, they are necessary for patients with type 1 diabetes who have episodes of any level of hypoglycemia and/or hypoglycemia unawareness. These devices are also necessary as part of automated insulin delivery systems. For others, particularly people with type 2 diabetes where rates of hypoglycemia are lower, isCGMs may be preferred. Finally,

some patients prefer one CGM device over another and patient preference is very important when it comes to selecting a device that is worn on the body 24/7/365 days a year.

- ***Include coverage for both type 1 and type 2 populations.*** While coverage is commonly seen for people with type 1 diabetes, people with type 2 diabetes who require insulin can also benefit from CGMs. States can potentially realize cost savings, better health outcomes for members, and reductions in disparities in this population.
- ***Include coverage for both children and adults***. Children who age-up to the adult population should not lose access to CGMs.

Diabetes Community

For the diabetes community — patients, providers, manufacturers, researchers, and diabetes-focused organizations — following are recommendations to support state Medicaid agencies in expanding coverage for and eliminating barriers to accessing CGMs.

- ***Develop pilot projects to demonstrate the value of CGMs.*** Before making programmatic changes, particularly those that involve financial investments, states often look favorably on pilot projects that demonstrate desired outcomes. States that do not cover CGMs could find value in seeing positive outcomes of CGM use in a population of beneficiaries. A pilot could focus on a discrete outcome, such as reducing disparities, or measuring impact on cost, health, and quality of life. Pilots could be for a geographic area or a specific population, like children with type 1 diabetes.
- ***Create resources for Medicaid staff.*** As described earlier, Medicaid staff and leaders often look to external resources from trusted sources to make decisions about coverage. In addition to resources that demonstrate clinical and cost outcomes, states could benefit from resources that are tailored to the state's Medicaid population and unique health needs and priorities.
- ***Evaluate data to demonstrate the value of Medicaid coverage of CGMs.*** While states review CGM utilization data, most states lack the resources to do robust evaluations of the effectiveness of policy changes. With state specific outcome or ROI data, states would be more likely to remove restrictions in their CGM policies, and states that do not cover CGMs would be more comfortable covering them.

- ***Leverage existing stakeholder groups and external boards.*** As noted on the previous page, states often look to external, independent sources for input on policy decisions. Existing boards are an opportunity to advance ideas for policy changes. Creating new task forces or groups within these existing entities to focus on CGMs and other diabetes supports can provide an additional source of credible information for state policymakers.
- ***Engage state Medicaid leaders by sharing experiences of patients with diabetes.*** Medicaid staff and leaders are often removed from direct, daily interactions with the individuals they serve. While most agencies value input from people with lived experience, particularly on policy changes that are under current consideration, they do not always have immediate access to those people. People with diabetes can uniquely speak to the value of CGMs, and their experiences make an impact on decision-makers.

Conclusion

CGMs have become the standard of care for people with diabetes who are insulin-treated. Observational studies and RCT data show that CGMs can help improve patient-reported outcomes including health-related quality of life, reduce hospitalizations for acute diabetes-related issues, reduce work absenteeism, and provide health care cost savings. Widespread use of and access to CGMs, along with education and follow-up, can also help to improve health equity.

Medicaid coverage for CGMs currently varies significantly across state Medicaid programs and strict requirements for initial and ongoing coverage can interfere with access to CGMs and the ability to improve diabetes management. Recommendations in this paper for both state Medicaid programs and the diabetes community aim to facilitate increased coverage for and access to CGMs.

Appendix A. 50-State Overview of Fee-for-Service CGM Coverage Policies

STATE	FFS COV.[1]	COVERAGE CRITERIA							ADDITIONAL COVERAGE NOTES
		T1	T2	PEDIATRICS ONLY	DME BENEFIT	RX BENEFIT	MIN. 4X/DAY FINGERSTK. BGM	ENDOCRIN. PRESCRIBER REQMNT.	
Alabama[2]	✓	✓		✓	✓		✓		*Covers children with type 1 diabetes who are 20 years old and younger with an EPSDT screening*
Alaska									
Arizona									
Arkansas[3]	✓	✓	✓		✓				*Legislature passed coverage of CGM in 2021; coverage criteria is not yet available; policy will go into effect in 2022*
California[4]	✓	✓			✓			✓	*Governor proposed to expand Medicaid CGM coverage to adults in 2021-2022 budget; legislation to expand Mediaid coverage to adult with type 1 diabetes passed and policy will go into effect in 2022*
Colorado[5]	✓	✓	✓		✓				*Has a 3x/day requirement for fingerstick BGM*
Connecticut[6]	✓	✓	✓		✓		✓		
Delaware[7]	✓	✓	✓			✓			
District of Columbia[8]	✓	✓	✓			✓			
Florida									
Georgia[9]	✓	✓	✓	✓	✓			✓	

[1] Among the ten states listed in this table as having no published CGM coverage, nine states (AZ, FL, HI, KS, NE, NJ, NM, OR, TN) provide benefits for at least 83% of their Medicaid beneficiaries through Medicaid managed care organizations (Share of Medicaid Population Covered under Different Delivery Systems, Kaiser Family Foundation), which have the option to cover CGMs for their members. One state, AK, only has a FFS program and no published coverage was found for CGMs.

[2] Alabama Medicaid. Provider Manual: Durable Medical Equipment, Supplies, Appliances, Prosthetics, Orthotics and Pedorthics. https://medicaid.alabama.gov/content/Gated/7.6.1G_Provider_Manuals/7.6.1.3G_July2021/Jul21_14.pdf. July 2021. Accessed 11/22/2021.

[3] Arkansas State Legislature. SB521 – To mandate that the Arkansas Medicaid program cover a continuous glucose monitor for an individual with diabetes. https://www.arkleg.state.ar.us/Bills/Detail?id=SB521&ddBienniumSession=2021/2021R. April 2021. Accessed 11/22/2021.

[4] DiaTribe Change. CGMs to be Covered Under California Medicaid's Medi-Cal. https://diatribechange.org/index.php/news/cgms-be-covered-under-california-medicaids-medi-cal. August 2021. Accessed 11/22/2021.

[5] Colorado Medicaid. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. https://hcpf.colorado.gov/DMEPOS-manual#toc. Updated October 5, 2021. Accessed November 23, 2021.

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STATE	FFS COV.[1]	COVERAGE CRITERIA							ADDITIONAL COVERAGE NOTES
		T1	T2	PEDIATRICS ONLY	DME BENEFIT	RX BENEFIT	MIN. 4X/DAY FINGERSTK. BGM	ENDOCRIN. PRESCRIBER REQMNT.	
Hawaii									
Idaho[10]	✓	✓	✓		✓		✓		
Illinois[11]	✓	✓	✓			✓			
Indiana[12]	✓	✓	✓		✓		✓		
Iowa[13]	✓	✓	✓		✓		✓		
Kansas									
Kentucky[14]	✓	✓	✓			✓			
Louisiana[15]	✓	✓			✓				
Maine[16]	✓	✓	✓			✓			*CGMs are on the preferred drug list. There are age requirements based on the brand: 2 years of age or older for Dexcom G6, ≥ 14 years for Medtronic Guardian, or ≥ 11 years for Freestyle Libre*
Maryland[17]	✓	✓			✓		✓	✓	

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STATE	FFS COV.[1]	COVERAGE CRITERIA							ADDITIONAL COVERAGE NOTES
		T1	T2	PEDIATRICS ONLY	DME BENEFIT	RX BENEFIT	MIN. 4X/DAY FINGERSTK. BGM	ENDOCRIN. PRESCRIBER REQMNT.	
Massachusetts[18]	✓	✓	✓			✓			*In a November 2021 email, Dr. Mohammad Dar, Senior Medical Director, said the state removed clinical coverage guidelines requiring 4x/day of fingerstick BGM. Changes have been made to pharmacy-side billing and approved on the medical side. This has not been published yet, as this state is navigating the process of the intended changes. Changes can take several months before publication.*
Michigan[19]	✓	✓			✓				*The following language for fingerstick BGM criteria us used: "The beneficiary's treatment plan recommends testing blood glucose a minimum of four times per day."*
Minnesota[20]	✓	✓	✓			✓			
Mississippi[21]	✓	✓			✓		✓		
Missouri[22]	✓	✓				✓	✓		
Montana[23]	✓	✓	✓		✓		✓		
Nebraska									
Nevada[24]	✓	✓				✓			
New Hampshire[25]	✓	✓	✓			✓			*Dexcom CGMs are the preferred continuous glucose monitoring systems; does not cover non-preferred monitors unless the physician has requested an override*
New Jersey									

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STATE	FFS COV.[1]	COVERAGE CRITERIA							ADDITIONAL COVERAGE NOTES
		T1	T2	PEDIATRICS ONLY	DME BENEFIT	RX BENEFIT	MIN. 4X/DAY FINGERSTK. BGM	ENDOCRIN. PRESCRIBER REQMNT.	
New Mexico									
New York[26]	✓	✓				✓		✓	
North Carolina[27]	✓	✓	✓			✓	✓		
North Dakota[28]	✓	✓	✓			✓			
Ohio[29]	✓	✓	✓			✓			
Oklahoma[30]	✓	✓	✓			✓	✓		*Policy does not include children with type 2 diabetes*
Oregon									
Pennsylvania[31]	✓	✓	✓		✓	✓			*Dexcom products are a preferred pharmacy benefit, meaning prior authorization will not be required; all other CGMs products are available through DME*
Rhode Island[32]	✓	✓			✓		✓		
South Carolina[33]	✓	✓			✓	✓	✓	✓	*After July 1, 2019, certain CGMs are covered under the pharmacy benefit; however, CGMs are still offered as a DME benefit*
South Dakota[34]	✓	✓			✓		✓	✓	

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STATE	FFS COV.[1]	COVERAGE CRITERIA							ADDITIONAL COVERAGE NOTES
		T1	T2	PEDIATRICS ONLY	DME BENEFIT	RX BENEFIT	MIN. 4X/DAY FINGERSTK. BGM	ENDOCRIN. PRESCRIBER REQMNT.	
Tennessee[35]									
Texas[36]	✓	✓	✓		✓		✓		
Utah[37]	✓	✓	✓		✓	✓			*Covers Dexcom G6 CGM under preferred drug list; Freestyle Libre and Guardian Connect as non-preferred; non-preferred must be approved and billed through DME*
Vermont[38]	✓	✓	✓			✓			*Covers Dexcom G6 and Freestyle Libre CGMs under preferred drug list, and Medtronic CGMs as non-preferred*
Virginia[39]	✓	✓	✓		✓		✓		*Policy does not include children with type 2 diabetes*
Washington State[40]	✓	✓	✓		✓		✓		*Minimum 4x/day fingerstick blood glucose monitoring only required for adults with type 2 diabetes*
West Virginia[41]	✓	✓	✓			✓	✓		
Wisconsin[42]	✓	✓			✓		✓	✓	*CGMs are covered only for adults 25 years of age or older with type 1 diabetes*
Wyoming[43]	✓	✓	✓			✓			

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Appendix B. State Fee-for-Service CGM Coverage Policies At-A-Glance

CGMS COVERED UNDER[44]	STATES
• Preferred drug list[45] • Preferred diabetic supply list[46]	Delaware, District of Columbia, Illinois, Kentucky, Ohio, Pennsylvania,[47] Maine, Massachusetts,[48] Minnesota, New Hampshire, North Dakota, Utah,[49] Vermont, Wyoming

CGM COVERED FOR	STATES
• T1 & T2 on insulin pumps or multiple daily insulin injections • All ages • Pharmacy benefit • With prescriber and/or fingerstick monitoring requirements	Oklahoma, North Carolina, West Virginia
• T1 & T2 on insulin pumps or multiple daily insulin injections • All ages • DME benefit • Without prescriber and/or fingerstick monitoring requirements	Arkansas, Colorado, Virginia[50]
• T1 & T2 on insulin pumps or multiple daily insulin injections • All ages • DME benefit • With prescriber and/or fingerstick monitoring requirements	Connecticut, Idaho, Indiana, Iowa, Montana, Texas, Washington State
• T1 only • All ages	California, Louisiana, Maryland, Michigan, Mississippi, Missouri,[51] Nevada,[52] New York,[53] Rhode Island, South Carolina,[54] South Dakota
• T1 and/or T2 on insulin pumps or multiple daily insulin injections • Children or adults only	Alabama,[55] Georgia,[56] Wisconsin[57]
States with no published coverage[58]	Alaska, Arizona, Florida, Hawaii, Kansas, Nebraska, New Jersey, New Mexico, Oregon, Tennessee

[44] In states where CGMs is on the preferred drug list or preferred diabetic supply list there are not strict exclusionary criteria. While this is the easiest method for Medicaid patients to have access to CGM, it is not very common. Of these states, some include all CGM brands as preferred, while some only include one. There is no clear pattern, however, Dexcom and Abbott are the CGM manufacturers most seen as preferred products.
[45] Delaware, District of Columbia, Minnesota, New Hampshire, Pennsylvania, Vermont, Utah, Maine, Illinois, Wyoming, and Oregon have at least one CGM brand in their Preferred Drug List.
[46] North Dakota, Ohio, and Kentucky have at least one CGM brand in their Preferred Diabetic Supply List.
[47] Pennsylvania's non-preferred products must be approved and billed through DME.
[48] CHCS was unable to find CGMs included in a Preferred Diabetic Supply List or Preferred Drug List in Massachusetts, however, Massachusetts is the only other state that provides CGM coverage for people of all ages with type 1 and type 2 diabetes on insulin pumps or multiple daily insulin injections, as a pharmacy benefit, and without prescriber and fingerstick monitoring criteria.
[49] Utah's non-preferred products must be approved and billed through DME.
[50] Virginia does not include coverage for CGMs for children with type 2 diabetes on insulin pumps or multiple daily insulin injections.
[51] Missouri covers CGMs under pharmacy benefit.
[52] Nevada covers CGMs under pharmacy benefit.
[53] New York covers CGMs under pharmacy benefit.
[54] South Carolina covers CGMs as a DME and pharmacy benefit.
[55] Alabama covers CGMs for children with type 1 diabetes only.
[56] Georgia covers CGMs only for children with type 1 and type 2 diabetes on insulin pumps or multiple daily insulin injections.
[57] Wisconsin covers CGMs for adults with type 1 diabetes only.
[58] Arizona, Florida, Hawaii, Kansas, Nebraska, New Jersey, New Mexico, Oregon, and Tennessee provide benefits for at least 83% of their Medicaid beneficiaries through Medicaid managed care organizations (Share of Medicaid Population Covered under Different Delivery Systems, Kaiser Family Foundation), which have the option to cover CGMs for their members. Alaska's Medicaid population is covered under FFS.

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Revision of the Medicaid CGM Access Policy
Date: Monday, April 1, 2024 11:05:13 PM

External Email

Dear committee members of the WA HCA Health Assessment Technology Program.

I would like to offer some input regarding the revision of the Medicaid CGM Access Policy.

Thanks for revisiting the WA CGM prescription-covered guidelines. The 2018 criteria:

"HTCC coverage determination:
Continuous glucose monitoring is a covered benefit with conditions.
This determination does not pertain to a closed loop or artificial pancreas.
HTCC reimbursement determination:

Limitations of coverage:

Continuous glucose monitoring is covered for children/adolescents less than 19 years old, adults with Type 1 diabetes, and adults with Type 2 diabetes who are:

· Unable to achieve target HbA1C despite adherence to an appropriate glycemic management
plan (intensive insulin therapy; testing blood glucose 4 or more times per day), OR
· Suffering from one 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:
· 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 and/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."

These guidelines seemed straightforward at the time. Revising them to reflect the recommendations by the ADA and CMS is appropriate. I hear of folks clambering to have one of the CGMs because they don't want the inconvenience of "sticking" themselves. Although the CGMs are valuable tools for some patients. As the cost of

medical care continues to escalate, I feel there does need to be some constraints on the dispensing of them. I have found that within the first 3 months of use, I've been able to ascertain whether or not the CGM is used in such a way that the patient is actively working on getting the BS under better control. If there is no improvement in the blood sugar, then I favor discussing the issue with the pt. to determine how they use it. My non-insulin-dependent patients who look at the results and change their behavior often don't need to continue using them beyond 2-3 months. Likewise, I've had patients who demanded to have one, but then never took the time to look at the results. There should not be an automatic refill every 3 months without a repeated A1c and clinical visit/discussion. The issue of equity should focus on minimizing the cost while at the same time holding the patient responsible for improving their blood sugar control. Being good stewards of our resources could also include using a professional CGM before beginning a pt on an individual CGM.

Thank you for your consideration of these comments.

Eugenia Lennon, PhD, ARNP, CDCES

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: "Tethered oral tissues" and frenotomies
Date: Tuesday, April 2, 2024 12:30:36 PM

External Email

Hello,

I am responding to this query for feedback about frenotomies. I have been a pediatrician for 30 years and have worked with infants with craniofacial disorders and feeding problems for most of my career. I am professor of pediatrics at the University of Washington School of Medicine, attending physician in the UWMC Newborn and Progressive Care Nursery, and attending physician at Seattle Children's Hospital, where I lead the Multidisciplinary Infant Nutrition and Feeding Team (MINFT).

I have also led a clinic for the treatment of ankyloglossia at the University of Washington Maternal Infant Care Clinic for the last 9 years. I evaluate patients under 5 months of age referred to me for concerns about ankyloglossia, commonly referred to as tongue tie. If needed, I perform a sublingual frenotomy when the degree of ankyloglossia is interfering with breastfeeding effectiveness. I also perform sublingual frenotomies at Seattle Children's Hospital, in conjunction with the infant feeding therapists, who are highly qualified to identify which infants are most likely to benefit from a sublingual frenotomy to address feeding problems. Infant feeding therapist involvement offers the important advantage of specialty evaluation to identify other etiologies to infant feeding problems in which a frenotomy is not indicated and which require further evaluation and management of a different sort.

As part of my work as faculty in the school of medicine, I have conducted extensive literature reviews about these conditions and the evidence surrounding their treatment with frenotomy

and have provided education about evidence-based management of oral ties at CME conferences and in educational materials for the Washington Chapter of the American Academy of Pediatrics. The American Academy of Pediatrics is also concerned about the rush to frenotomy for any breastfeeding problem and the increasing involvement of dentists in performing these procedures. They are also preparing clinical guidelines for an evidence-based approach to treatment of ankyloglossia and I have reviewed these and made editorial/content recommendations to the authors.

Over time, there has been a growing trend of dentists offering to treat "tethered oral tissues" in young infants, often using laser technology and charging out-of-pocket payment, averaging $800-1200. What is referred to by tethered oral tissues are "buccal ties," "lip ties," and "tongue ties." Dentists have marketed their services to lactation consultants and primary care practices and have touted the advantages of laser treatment for these conditions. There is no well-designed study that supports laser over surgical scissors for surgical treatment of ankyloglossia. There are advantages and disadvantages to both, and the best option is what the operator is most comfortable with. I take a low-technology approach and use surgical scissors to perform a frenotomy. This is a procedure that takes literally 2 seconds to complete. In my hands, there is an approximately 1-2% risk of excessive bleeding when I perform a frenotomy. There may be a lower bleeding risk with laser however, pain with laser frenotomy is considered to be greater than with surgical scissors. I always have dental gelfoam available in case excessive bleeding occurs and after performing thousands of these procedures, I have found that dental gelfoam held under the tongue for 60 seconds has always worked to stop bleeding.

There is limited research evidence to support treatment of ankyloglossia to decrease maternal pain and improve breastfeeding self-efficacy. From an anecdotal perspective, there is a subset of infant-mother dyads who substantially benefit from sublingual frenotomy. The problem with the research to date is that it has mixed "apples and oranges," meaning these studies have included infant-mother dyads with a range of ankyloglossia severity, other breastfeeding challenges, and variable prior breastfeeding experiences—all factors that contribute to latch difficulties, maternal nipple pain, and breastfeeding efficiency. Thus, studies and metanalyses have reported mixed results because most studies are not adequately powered to identify improvement in select populations (ie, those with more severe ankyloglossia).

I rely on the TABBY (tongue assessment tool for tongue-tie in breastfed babies) tool developed by the University of Bristol to score severity of an infant's sublingual frenum (Ingram et al, 2019) as well as a functional assessment to make decisions (in addition to shared decision making with the infant's parents) about whether to perform a frenotomy. A study from New Zealand (Dixon et al, 2018) supports a multidisciplinary approach/evaluation (lactation consultant, speech and language pathologist or infant feeding OT/PT, and a specialist operator such as a pediatrician or an otolaryngologist) to identify infants with TABBY <= score of 4 (ie, more severe ankyloglossia) who would benefit from a sublingual frenotomy. I use the TABBY score of <=4 and a functional assessment to determine whether a sublingual frenotomy will be helpful in promoting breastfeeding for the infant-maternal dyad. If I am unsure of the potential benefit of a sublingual frenotomy, I refer patients to an infant feeding therapist at Seattle Children's Hospital for further evaluation. I bill medical insurance for my patient visits and procedures, including Medicaid, at the UWMC and Seattle Children's. I am frank with parents/caregivers when I do not believe, following my assessment, that a frenotomy will offer the benefit that they are hoping for.

The problem with the current situation is that lactation consultants increasingly refer patients to dentists and families self-refer (often based on social media ads and testimonials) when there are persistent breastfeeding problems, however the majority of breastfeeding

challenges are multifactorial in their etiology. Many patients undergo a sublingual frenotomy in a dental office as well as "release of lip and buccal ties" without an adequate understanding/evaluation of breastfeeding or infant feeding dynamics by the operator. To be clear, there have been no well-designed studies that support release (ie, surgical incision) of "buccal ties" or "lip ties" in infants. These structures appear differently in young infants that they do in older children and adults and because they may appear more prominent in infants, they have been made out to be "pathologic" and supposedly requiring costly, invasive treatment, which parents will pursue because **they are desperate for an answer to the-infant-maternal dyad breastfeeding challenges.**

I also lead the Multidisciplinary Infant Nutrition and Feeding Team (MINFT) at Seattle Children's Hospital. In this role I manage, along with my team, complex feeding problems including dysphagia, feeding refusal, and aspiration in infants with a variety of underlying conditions as well as typically-developing infants with isolated significant feeding disorders interfering with their ability to feed orally. I have observed a growing number of patients with significant dysphagia and other feeding disorders who, prior to making their way to MINFT at Seattle Children's, have been referred to a community dentist and undergone "release of tethered oral tissues" for their breastfeeding challenges.

Because dentists and many lactation consultants lack the expertise to identify more serious feeding issues, they resort to the one thing they are familiar with and have to offer, which is a surgical procedure to release the "tethered oral tissue." This is costly to families, painful for patients, delays appropriate evaluation and management, and potentially worsens oral aversion/feeding refusal. Unfortunately, it has become a regular component of the history I

obtain from patients followed by MINFT—that, at the first sign of a feeding problem. their baby was referred to a dentist for release of their "tethered oral tissues," underwent a surgical procedure, experienced no benefit, ultimately ended up being admitted to the hospital for failure to thrive and feeding refusal where a serious feeding disorder is identified and the infant requires placement of a feeding tube in order to receive adequate nutrition to grow well.

I cannot overemphasize how serious of an issue it is that health professionals, primarily dentists, who lack the expertise to determine the etiology of a feeding problem, are seemingly indiscriminately performing costly, painful procedures on infants that are not only ineffective but delay appropriate evaluation and management for more serious conditions. In addition, babies with more typical, less severe feeding problems are being subject to buccal tie and lip tie release, often paid for out-of-pocket, in the absence of *any* high-quality research evidence to support these practices. I believe that there is benefit to performing a sublingual frenotomy to address significant ankyloglossia interfering with effective breastfeeding but there should be a more selective, objective, expert approach to identifying appropriate candidates to undergo sublingual frenotomy.

Charlotte Lewis, MD, MPH
Professor of Pediatrics
UW School of Medicine

Multidisciplinary Infant Nutrition and Feeding Team
Seattle Children's Hospital

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Continuous Glucose Monitors (cgms)
Date: Tuesday, April 2, 2024 9:24:30 PM

External Email

To the WA HCA Health Assessment Technology Program:

I am writing as a RN and certified diabetes care and education specialist to advocate for the coverage of continuous glucose monitors (cgms) for WA state Medicaid patients. Currently, with our diabetes program, we have grant funding for enabling Medicaid patients to wear a professional use Dexcom G6 for 10 days and are tracking the progress of A1C's. It serves as a tremendous teaching tool for patients to learn how lifestyle choices affect blood sugar, and most often we seen measurable improvements when reviewing data. Medicare patients are now covered for cgms with one insulin injection a day and I have personally seen how valuable the devices are and how empowering they can be for lifestyle change and medication management. Seeing blood sugar patterns and trending in real time should be available to all people with diabetes, especially our more vulnerable populations. To give patients more control over a challenging chronic condition makes good health sense, as well as economic sense, often reducing the need for more medication and sometimes reducing doses.

With the health crisis that diabetes presents in our state and nationwide, I urge you to cover cgms for Medicaid patients.

Thank you,
Sarah Skidmore, RN, CDCES
PMG SW Boldt Diabetes and Nutrition

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: To Request a Re-Review of the Optune Gio/TTF Device for Coverage
Date: Wednesday, April 3, 2024 11:54:01 AM
Attachments: image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
image008.png
2024 WA State HCA Comment Period_ReReview Optune Gio Coverage 3 26 24 DEM pdf.pdf
Importance: High

External Email

March 25, 2024

TO: WA State Health Care Authority (HCA)
shtap@hca.wa.gov

RE: The End Brain Cancer Initiative (EBCI) Requests a Re-Review of Optune Gio/ Tumor Treating Fields

The Washington State Health Care Authority that's responsible for 2.5 million Washingtonians' health care, including Medicaid patients, public employees, including teachers, is wrongly denying coverage for new FDA-approved medical technologies, like Tumor Treating Fields, that treat cancer patients, including patients diagnosed with brain cancer.

From my personal experience of caring for my husband as he battled terminal cancer, specifically Glioblastoma Multiforme (GBM) a terminal type of cancer and from my day-to-day work with cancer patients, I know just how important immediate access to innovative treatments can be for a patient, their caregivers and their families. On behalf of all patients battling life-threatening diseases, I am urging the HCA to reverse this decision and ensure patients have access to innovative cancer care.

Glioblastoma brain cancer is terminal, and the options for patients with this devastating cancer are already extremely limited. From my personal experience in caring for my husband while he battled cancer, I have seen the positive impact medical innovation can have on a patient and their family. Patients need as many tools in their toolbox as possible to treat this disease. The Optune Gio/Tumor Treating Fields device which is approved by the FDA for treatment of Glioblastoma, is one of these vital tools. When you take away one of those options because it isn't covered, it serves as a second death sentence.

A treatment that has been approved by the FDA should be accessible for patients no matter their income level, what state they live in, or who their employers are. The HCA must reverse this decision for Washington's Medicaid patients.

From my perspective, the Washington State Health Care Authority issued a short-sighted ruling denying coverage for new FDA-approved medical technologies, like Tumor Treating Fields, that help extend the lives of patients living with cancer. This decision unfairly impacts the state's Medicaid population.

I beg the HCA to Re-Review its decision to not cover this treatment option for patients enrolled in Medicaid and government works as the financial weight of health care is a heavy burden. The reality is that without proper coverage, innovative care simply isn't accessible for most patients. The Washington State Health Care Authority's decision to deny coverage of innovative cancer treatments, like Tumor Treating Fields, to patients enrolled in Medicaid and government workers will leave many patients without HOPE.

I haven't been able to locate the reasons why this coverage was denied. The lack of transparency surrounding this decision raises concerns about fairness and ethical considerations in health care policies. Does the HCA want to be perceived as picking treatment winners and losers, thus forcing cancer patients into a one-size-fits-all approach because we science has identified, treating cancer is as a personalized and individual disease is most beneficial.

I also want to acknowledge WA State's healthy biomed/biotech industry. From this in growing industry in the State of WA, we can expect to see an increased number of biomed/biotech treatments and yes, additional devices used to treat cancer making their way to the HCA for coverage. Is it the HCA's plan to deny all coverage to devices used to treat cancer?

These are people who are fighting for their lives, and when opportunities to extend life are taken away, it can be devastating. From my personal experience of caring for my husband with Glioblastoma, which the Optune Gio/Tumor Treating Fields device is FDA approved for treatment, I know the real-world impact having immediate access to innovative treatments can have.

I ask the HCA to reverse its decision and ensure that patients are able to receive coverage for groundbreaking cancer treatments. These patients need and deserve access to any treatment that could extend their life.

If you would like to further discuss or if I can help to further your understanding on why coverage of this device is necessary to not only those diagnosed with Glioblastoma but for many solid tumor cancer patients, please do not hesitate to contact me. I have also attached my recent Op-Ed on this subject for your interest as this is an Advocacy area that I am deeply passionate about and will continue to advocate for.

Dellann Elliott Mydland
President, CEO & Chair
EndBrainCancer Initiative
(EBCI/Chris Elliott Fund)
[redacted]

[redacted]
endbraincancer.org

Download our disease education mobile app

I usually respond to emails w/in 72 hours, however, if this is urgent, pls. call or text me.

March 25, 2024

TO: WA State Health Care Authority (HCA)
shtap@hca.wa.gov

RE: The End Brain Cancer Initiative (EBCI) Requests a Re-Review of Optune Gio/ Tumor Treating Fields

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[redacted]

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If you would like to further discuss or if I can help to further your understanding on why coverage of this device is necessary to not only those diagnosed with Glioblastoma but for many solid tumor cancer patients, please do not hesitate to contact me. I have also attached my recent Op-Ed on this subject for your interest as this is an Advocacy area that I am deeply passionate about and will continue to advocate for.

Blessings,

endbraincancer

Download our disease education mobile app

Dellann Elliott Mydland
President, CEO & Chair
EndBrainCancer Initiative
(EBCI/Chris Elliott Fund)

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Health Care Provider Comments to TTFields (Optune Gio) Proposed Technology Topics 2024
Date: Wednesday, April 3, 2024 12:11:21 PM
Attachments: image001.png
WA TTFields ReReview HCP Letter of Support 4.3.pdf

External Email

Hello,

Please comments attached regarding the draft list of 2024 Prospective Technology Topics for review by the Health Technology Assessment program from WA health care providers.

Thank you,

Emma Watson
Associate Director
State Government Affairs

[redacted]

[redacted]

novocure®
patientforward

Ms. Charissa Fotinos
Medicaid Director
Washington State Health Care Authority
626 8th Avenue SE
Olympia, WA 98501

Dear Ms. Fotinos

We are writing to encourage coverage by the Washington State Healthcare Authority (HCA) of an innovative, FDA-approved and NCCN-recommended device that treats a rare form of aggressive cancer using Tumor Treating Field (TTFields) technology. TTFields utilize alternating electric fields to slow or stop dividing cancer cells without significantly affecting healthy cells. TTFields are FDA-approved to treat an aggressive form of brain cancer called Glioblastoma (GBM).

It has shown promise in extending the lives of those facing what is typically a terminal form of cancer with an average survivor timeline of 12 to 18 months. Although GBM is a rare form of cancer, around 13,000 Americans will receive a GBM diagnosis this year. These patients deserve access to any treatment that may extend their life.

Currently, a significant disparity exists in who has access to the TTFields technology in Washington State. WA State GBM patients who have Commercial, Medicare, TRICARE or VA coverage can access TTFields as an NCCN-recommended treatment; however, the Washington State HCA's denial of coverage for TTFields prevents Washington Medicaid patients, public and school employees, and some clinical trial patients, from accessing this innovative therapy.

The HCA policy negatively impacts the state's Medicaid population and tens of thousands of public and school employees. This includes individuals working in local and state government, higher education, and judicial agencies. TTFields are a safe and effective form of treatment and expanding access should be of the utmost importance to Washington State decision-makers.

We respectfully request the addition of TTFields to the covered treatments available to Washington State HCA beneficiaries.

Sincerely,

[redacted]

[redacted]

Herbert Wang, MD
Tacoma Valley Radiation Oncology
[redacted]

Christopher Lee, MD
Cancer Center Northwest
[redacted]

[redacted]

Jenn Maiorca, RN
Valley Medical Center/UW Medicine
Radiation Oncology
[redacted]

[redacted]

John Register, MD
Skagit Regional Health
Radiation Oncology
[redacted]

[redacted]

Nicholas Serrano, MD
Overlake Medical Clinics
Radiation Oncology
[redacted]

[redacted]

Robert M Douglas, MD
Valley Medical Center/UW Medicine
Radiation Oncology
[redacted]

[redacted]

Joon Lee, MD
Overlake Medical Clinics
Radiation Oncology
[redacted]

[redacted]

Deana Marienau, RN
Valley Medical Center/UW Medicine
Radiation Oncology
[redacted]

[redacted]

Monica Baca, R T (R)(T), CMD, AAS
Skagit Valley Hospital
[redacted]

[redacted]

Kristen Riegert, MD
Providence St. Marys Cancer Center
Walla Walla, WA

3 April 2024

To: Washington State Health Care Authority,

I am writing this e-mail/letter to strongly request a re-review of the Optune Gio/TTF Device for coverage. I recently became aware of the decision to not cover the device in our great state, and I am shocked that anyone who understands the gravity of a diagnosis of this kind would make the decision to remove an FDA Approved and desperately needed treatment from the VERY SHORT list of available treatments for patients suffering from the devastating disease, Glioblastoma and other solid tumor cancers.

For any of you unaware of the impact of this disease, it is devastating to anyone who is diagnosed with it as well as their family, friends, co-workers, neighbors, and anyone that person has ever interacted with. I know this because my husband was diagnosed with Glioblastoma in January of 2018, a mere 2 months after we relocated from the East Coast to Seattle. After nearly a year of following the "Standard of Care" (SOC) treatment of surgery, radiation, and chemotherapy, it became evident that SOC was ineffective on his tumor – the SOC in the brain cancer space is ineffective for the majority of brain cancer patients – so we began to explore novel promising treatments. One of these was the Optune GIO Tumor Treatment Device. This device was finally able to slow down the growth of his tumor to allow him 1) time to try other treatments as well and 2) quality of life to spend as much time as possible with those that loved him. My husband passed away from Glioblastoma on March 24, 2020 after 26 ½ months of fighting. That was 4 years ago this week. He got to walk his daughter down the aisle, but he never met his 2 beautiful grandchildren.

This device has the potential to significantly impact many patients' lives and should absolutely remain on the covered treatments list in the state of Washington and beyond. The science is sound and now there is enough real-world evidence to clearly demonstrate its effectiveness.

I believe so strongly in the need to rethink this position that I will include my contact information below and absolutely encourage anyone with questions to please reach out. I am happy to expand on my personal experience and anything else that might prove helpful for you to make the right decision.

Shawn Drennan
[redacted]

Please, please, please do not take away even one person's chance for an improved prognosis.

In Good Health,

Shawn Drennan

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: HTA re-review of Continuous Glucose Monitoring technology - public comments
Date: Wednesday, April 3, 2024 12:59:01 PM
Attachments: image001.png
WA HTA CGM Dexcom public comment.pdf

External Email

Please find attached public comment from Dexcom on the proposed 2025 HTA re-review of CGM technologies for diabetes management.

Greg Norman, PhD
Senior Director of Health Econ & Outcomes Research
Global Access & Evidence | Dexcom
[redacted]

dexcom

dexcom

Dexcom, Inc. | Corporate Headquarters
6340 Sequence Drive | San Diego, CA 92121
888.738.3646 | dexcom.com

April 3, 2024

RE: HTA Re-Review of Continuous Glucose Monitoring

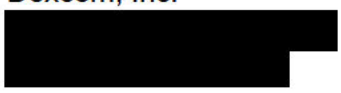
To the Washington State Health Care Authority,

Dexcom applauds the decision by the Washington State Health Care Authority Director to include a rereview of continuous glucose monitoring (CGM) in the Health Technology Assessment (HTA) program 2025 cycle. CGM technology was last reviewed in 2018, and a considerable body of additional evidence has accumulated demonstrating the clinical value of CGM for people with Type 1 and Type 2 diabetes. As a result, clinical practice guidelines from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) recommend CGM for adults and children with Type 1 or Type 2 diabetes on insulin therapy or with problematic hypoglycemia. Notably, Medicare coverage of CGM expanded on April 16, 2023 to more people with diabetes. CGM is now available through Medicare for people using any insulin (including those using only basal insulin) and those not using insulin who experience specified hypoglycemic events.

We anticipate that Washington State's HTA of the body of evidence for the clinical value of CGM will result in expanded coverage of CGM for people with diabetes in Washington, and we look forward to participating in the process.

Sincerely,

Greg Norman, PhD
Senior Director of Health Economics & Outcomes Research
Global Access & Evidence
Dexcom, Inc.



From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Medicaid coverage for CGM
Date: Wednesday, April 3, 2024 1:13:09 PM
Attachments: CGM Comments.docx

External Email

Please see attached comments.

Carol H Wysham, MD

To Whom it May Concern:

As an endocrinologist with 40+ years of experience treating patients with diabetes, I would like to have the opportunity to share some of my thoughts about access to CGM in the Medicaid population.

I would suggest that CGM should be available for all patients with T1D, all patients with T2D on any type of insulin, in all pregnant patients with type 1 diabetes and for any with high risk for hypoglycemia (even those not on insulin, such as older patients or those with renal failure on sulfonylureas)

The American Diabetes Association has updated the 2024 Standards of care. In this revision, they recommend :

1) CGM should be offered to people with T1D from diagnosis, based upon data from Barbara Davis Center seven-year real-world data demonstrating a 2.2% difference in A1c between CMG users and non users.
2) CGM should e offered for individuals at risk for hypoglycemia, based upon two studies that demonstrated a reduction in rates of hypoglycemia by revealing asymptomatic hypoglycemia and providing alarms to warn individuals of falling glucose.
3) CGM should be considered for older adults with T2D, related to article published in JAM which found that CGM users had significant decreases in A1c and reductions in emergency department visits and hospitalizations for hypoglycemia.
4) CGM is recommended for use in all pregnancies associated with type 1 diabetes

Dr Irl Hirsh recently presented results from a claims-based analysis demonstrating reductions in healthcare utilization for people with type 2 diabetes on basal insulin within 6 months after initiating CGM, including 18% reduction in hospitalizations, 12% reduction in ER visits and 6% reduction in outpatient visits. In those who had high rate of healthcare utilization, mean hospitalization visits fell from 4.8 to 1.5 per 6 months, a reduction of 68%.

Furthermore, real world studies, where CGM was offered to all patients in Findlay, OH should a mean reduction of A1c from 9.4% to 7.1%. The percent of participants with A1c < 7% went from 0% to 54% at 6 months. A1c<8% went from 19% to 83% at 6 months. A total of 34 patients were interviewed and all had increased confidence in managing their diabetes, every one of them noted that they had modified their diets based upon the CGM data. One-third noted changes in physical activity. About one-fourth changed medications – including increasing insulin or improving their adherence to taking their meds.

A summary of the important features of CGM that account for improvement in outcomes:

5) 1. Improved glycemic control: Several studies have shown that the use of CGM can lead to improved glycemic control in patients with type 2 diabetes. Better control of blood sugar levels can help reduce the risk of acute complications such as hyperglycemia-related emergencies and hypoglycemia-induced hospitalizations.

   2. Early detection and prevention of hypoglycemia and hyperglycemia. CGM systems can provide real-time alerts for low and high blood sugar levels, allowing patients to take prompt action to prevent severe hypoglycemia or hyperglycemia episodes that may require hospitalization.

   3. Reduction in severe hypoglycemic events. By providing continuous monitoring and alerts for hypoglycemia, CGM can help reduce the incidence of severe hypoglycemic events that may necessitate hospitalization.

   4. Enhanced patient engagement and self-management: CGM can empower patients to take an active role in managing their diabetes by providing them with real-time data and insights into their glucose levels. This increased engagement and self-management may lead to better adherence to treatment plans and lifestyle modifications, ultimately reducing the risk of diabetes-related complications .

I have been working with primary care practices to educate them on appropriate utilization of CGM and how to interpret and act upon CGM data.

Lastly, there is a real concern in the global healthcare community about the very large gap in utilization of diabetes technology between those in the higher vs lower socioeconomic strata. Healthcare equity must be eliminated in access to this important diabetes technology.

Thank you for allowing me to provide my comments on this topic.

Sincerely,

Carol H. Wysham, MD
Past President of Endocrine Society
Clinical Professor of Medicine
University of Washington
Clinical Endocrinologist
MultiCare/Rockwood Clinic
Spokane, Washington

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public comment on frenotomy in WA state
Date: Wednesday, April 3, 2024 3:02:41 PM
Attachments: image001.png

External Email

Hello,

I am a Registered Nurse practicing in WA State, International Board-Certified Lactation Consultant (IBCLC), and a mother of 4 children, 2 of whom were diagnosed with ankyloglossia and treated with scissor frenotomy. I would like to comment/propose questions related to the use of frenotomy in our state.

Questions to consider:

1. What is the global standard for diagnosis of ankyloglossia?
    a. Many systems exist for grading degrees of ankyloglossia and it is rare to find consensus on which tool should be utilized, which leads to disagreements in the medical community on the existence or prevalence ankyloglossia.
    b. The scope of practice for IBCLC's does not include diagnostic capabilities, and often when we send the findings of an oral assessment (grading the level of tongue restriction orally) to Pediatricians, they will come back with a conflicting opinion. This creates confusion for families, when both providers are explaining what they see, but the grading systems are not aligning (or, often, when a grading system is not even used by the Pediatrician – they simply document doing an oral assessment and 'finding' or 'not finding' ankyloglossia).
2. At which point is frenotomy needed in the presence of ankyloglossia?
3. What is the standard for post-frenotomy care and treatment of the infant? Should tongue mobility exercises be done? How often? Very little quality research exists on this topic.
4. How often are IBCLC's being involved in the immediate care and recovery of the infant undergoing frenotomy?
    a. One of the primary things an IBCLC can support families with is deep infant latch, which supports optimal functioning by supporting the infant in drawing in more mother's milk with each suck.
5. How are mothers being supported in protecting their milk supply in the presence of an infant with ankyloglossia? Whether the family elects to operate or not?
6. How soon is follow up happening with an IBCLC for families whose infant undergoes frenotomy?
7. Is there a difference in clinical outcome with scissor frenotomy vs laser frenotomy?

Sarah Lee
RN at Kaiser Permanente
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: public comment re: Health technology assessment of frenotomy
Date: Wednesday, April 3, 2024 4:18:37 PM
Attachments: WLC on HSA Frenotomy.pdf

External Email

Attached, please find my comments regarding the prospective inclusion of frenotomy in the 2025 cycle. Thank you for your consideration.

Jona

JonaRose Feinberg (she/her)
Executive Director, Washington State Lactation Collaborative
[redacted]

WASHINGTON STATE
Lactation Collaborative

April 3, 2024

To whom it may concern:

I am writing in response to the call for public comment regarding the Health Technology Assessment Program's initial review of frenotomy/frenectomy procedures and the impact on breastfeeding. As the Executive Director of the Washington State Lactation Collaborative, I wanted to share some information and resources that may be useful as your team reviews this issue.

Washington has breastfeeding rates higher than national averages on several indicators, but disparities remain.[1] We believe that it is important to *increase* access to skilled lactation support across the state as one means of addressing health inequities.

Tongue tie in a breastfeeding infant is a risk factor for premature termination of breastfeeding. Frenotomies/frenectomies performed by skilled, well-trained clinicians can improve comfort and increase milk transfer,[2] which can enable a breastfeeding parent to continue nursing and meet their lactation goals. Studies about the impact of tongue tie and the implications of frenotomy can be found in lactation literature, as well as pediatrics, otolaryngology, and dentistry.[3] [4] [5] While many such studies have concluded that frenotomy can help maintain breastfeeding, others were less conclusive.[6] The presence of a skilled lactation provider such as an IBCLC working as part of the health care team along with a clinician trained in tongue tie evaluation and frenotomy would enable a more thorough functional assessment, lactation support, and follow-up care if a procedure was deemed appropriate.

We encourage your assessment of this issue to take into consideration the importance of lactation support in all forms as one step toward addressing health inequities - racial, geographical, or otherwise. An abrupt decision on this matter could reduce access and limit opportunities for breastfeeding success.

Thank you for your consideration,

[redacted]

JonaRose Feinberg, MA, IBCLC
Executive Director, Washington State Lactation Collaborative
[redacted]

WASHINGTON STATE
Lactation Collaborative

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Abbott Submission to Washington State Health Care Authority Committee
Date: Wednesday, April 3, 2024 4:38:23 PM
Attachments: WA Medicaid evidence of CGM letter. 4.3.24 MF.pdf

External Email

Hello,

On behalf of Abbott Diabetes Care, please see the attached submission outlining clinical and economic value of Continuous Glucose Monitoring for your review and consideration.
Please feel free to reach out to me directly regarding any questions or inquiries you may have.

Thank you for your time and consideration.

Mariham Fahim, PharmD, RPh
Contingent Medical Outcomes Manager
Abbott Diabetes Care

April 1st, 2024

To: Washington State Health Care Authority Committee,

RE: Washington State Evidence of CGM Submission

Thank you for allowing us to submit the current health outcomes and economic data for the use of Continuous Glucose Monitoring (CGM) to help improve the lives of people living with Diabetes. Diabetes is a complex disease state that could be well managed with the help of advancing technology such as CGMs. With health equity being a concern for Medicaid population, expanding access to CGM for the Medicaid population can be not only beneficial for the patients, but also cost saving for the state. Below, please find relevant clinical and economic evidence for your considerations.

Prevalence of Diabetes in Washington State

Economic Impact of Diabetes in the US and Washington State

Health Equity in Washington State

Summary of CMS and National Guidelines for CGM

Clinical Outcomes in Micro/Macrovascular Disease, Kidney Disease, and Retinopathy

CGM Clinical Outcomes and HbA1c in T2D and DKA

CGM Clinical Outcomes in Pregnancy and Fetal Outcomes

CGM Economic Outcomes in T2D

Reduction of HbA1c Association with Cost Saving

The value of CGM over BGM

Randomized Controlled Trials (RCT) vs. Real World Evidence (RWE)

I would be happy to set up a time to discuss the impact of CGM, and any of these studies in greater detail.

Thank you,

Mariham Fahim, PharmD, RPh
Contingent Medical Outcomes Manager
Abbott Diabetes Care

Prevalence of Diabetes in Washington State[1]

- Diabetes is a costly, burdensome, and serious public health concern. Approximately 582,006 or 9.7% of adults in in the State of Washington have diagnosed diabetes.
- There are also 1.94 million or 33.7%, who have prediabetes, and an additional 164,000 people who have undiagnosed diabetes.
- It is estimated that 45,658 people are diagnosed with diabetes annually. This population is at an increased risk of complications such as heart disease, stroke, amputation, end-stage kidney disease, blindness and even death.

Economic Impact of Diabetes in the US and Washington State

- Type 2 Diabetes(T2D) accounts for 95% of the Diabetes epidemic in the US, with an estimated $412.9 billion in medical expenses for direct and indirect costs[2].
- As one of the fastest-growing chronic conditions in the state of Washington and across the country, the cost to provide care nears $10 billion annually in direct and indirect costs[3].

Health Equity in Washington State

- Health equity is a major contributor to poor diabetes outcomes[4], as the risk of other complications increases with the respective increase in Diabetes prevalence, the Medicaid population in Washington is more vulnerable to developing these complications.
- Despite annual American Diabetes Association (ADA) Medical Standards of Care publications and the increase in pharmacological options [5,6,7], there has been no statistically significant reduction in Chronic Kidney Disease (CKD) or Atherosclerotic cardiovascular disease (ASCVD) over the past 30 years[8], and most people living with diabetes fail to meet the glycemic recommendations of an HbA1c <7%[9].
- The Medicaid population with diabetes is 9 % less likely to test their glucose levels, 15% less likely to get an eye exam, and up to 18% less likely to have a kidney health evaluation[3].
- The ADA Health Equity bill of rights advocates access to medical technologies like CGM for people living with diabetes in the lowest income brackets to help improve outcomes and close the gap on inequalities[10].

Summary of CMS and National Guidelines for CGM

- Center of Medicare and Medicaid Services (CMS) Guidelines[11]
    - CMS revised coverage policy went into effect in April 2023 extending CGM eligibility for all beneficiaries with diabetes who use insulin (at least 1 administration/day) including those on basal only therapy, plus those documented to have at least 1 hypoglycemic event.
- American Diabetes Association (ADA)[5]
    - CGM can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely.

- The choice of device should be made based on patient circumstances, desires, and needs.
- CGM can be a useful tool for guiding medical nutrition therapy, physical activity, preventing hypoglycemia, and adjusting medications.
- Due to the limitations of HbA1c, clinicians should exercise judgement when using HbA1c as the sole basis for assessing glycemic control; recommend the inclusion of CGM metrics such as Glucose Variability (GV) and Time In Range (TIR).
- CGM users should have uninterrupted access through third-party payers.

- The American Association of Clinical Endocrinology (AACE)[6,7]
  - CGM may be recommended for individuals with T2DM who are treated with less intensive insulin therapy.
  - Lifestyle modification underlies all therapy and the need for on- going glucose monitoring with CGM preferred[6,7]
  - CGM is recommended for all insulin using patients and those at risk for hypoglycemia[6]
  - CGM is highly recommended for all patients to reach glycemic goals safely[6]
  - CGM metrics can be used as a surrogate to HbA1c[7]
  - Is-CGM could be helpful to newly diagnosed T2D patients and those at low risk for hypoglycemia[7]

- National Committee for Quality Assurance (NCQA)[12]
  - NCQA is recognizing the value of CGM metric and is considering incorporating glucose Management Indictor (GMI) alongside HbA1c in the blood sugar control measures.

Clinical Outcomes in Micro/Macrovascular Disease, Kidney Disease, and Retinopathy

- The CGM Metrics Time In Rage (TIR) and Time In Tight Range (TITR) have been associated with improvement in certain disease states.
- A study evaluated Time In Range (TIR) of 70–180 mg/dL (3.9–10 mmol/L) with the development or progression of Retinopathy and development of microalbuminuria using the Diabetes Control and Complications Trial (DCCT) data set in order to validate the use of TIR as an outcome measure for clinical trials. This study found that every 10% ↓in TIR associated with 64% ↑ risk of retinopathy, and each 10% ↓in TIR associated with 40% ↑ risk of microalbuminuria[13].
- The DEVOTE study[14] found that each 10% ↑ in TIR associated with 6% ↓ MACE; 10% ↓severe hypoglycemia. And also that TIR > 70% associated with 31% ↓ MACE; 40% ↓ microvascular complications; 46% ↓ severe hypoglycemia.
- The RESCUE study[15] found Less TIR associated with microvascular complications and that Less TIR associated with hospitalizations for hypoglycemia and Diabetic Ketoacidosis(DKA).
- Another study showed that for each 10 mg/dL ↑ in mean glucose and 5% ↓ in TIR associated with 22% ↑ and 18% ↑ risk of incident diabetic retinopathy, respectively. Also for each 5% ↓ in TITR and 5% ↑ in TAR associated with 28% ↑and 20% ↑ risk of incident diabetic retinopathy, respectively[16].

CGM Clinical Outcomes and HbA1c in T2D and DKA

- There is a large body of clinical evidence supporting the use of CGM in reducing (and maintaining reduction) of HbA1c, reducing time in (as well as the number of events) of hypoglycemia, as well as Diabetic Ketoacidosis (DKA).
- Three separate Randomized Controlled Trails (RCT) in poorly controlled noninsulin therapy consistently revealed improvement in outcomes:
    - CGM intervention group demonstrated modest weight loss and improved glycemic control without increasing the insulin dose or the number of antidiabetic medications when compared to self-monitoring blood glucose (SMBG) .[17]
    - A1c reduction of 0.46%, statistically significant improvement in Time In Range (TIR 70-180mg/dL) of 2.36h/day, reduction in Time Above Range (TAR > 180 mg/dL) by 2.66h/day as well as (TAR > 240mg/dL) by 1.23 hr/day, as well as greater treatment satisfaction compared to BGM[18]
    - Improved TIR of 9.9% (2.4 hours), a significantly lower TAR by 8.1% (1.9hours), and an A1c reduction of 0.3% at 16 weeks.[19,20]
- In addition, two separate real-world evidence studies reported an A1C reduction of 1.6%[19] and 0.9% with a sustained 0.7% reduction noted at twelve months[21]
- A retrospective cohort study sponsored by the National instate of Health (NIH) of 3,036 Medicaid adults with T2D showed that CGM use was associated with a statistically significant HbA1c reduction of 1.2%. This outcome was comparable between major racial/ethnic groups and those with higher fill adherence achieved greater HbA1c reduction (1.4% vs 1.0%). This study stated that elimination of CGM cost barriers can reduce racial/ethnic disparities in CGM uptake and improve glycemic control in this population. [22]
- The RELIEF study showed 75% fewer DKA admissions[23] , another analyses showed significantly lower incidence of admissions for DKA and for diabetes related coma with CGM[24]. Another study concluded that CGM monitoring is associated with significant improvements in HbA1c and fewer DKA admissions.

CGM Clinical Outcomes in Pregnancy and Fetal Outcomes

- ADA Guidelines Recommendations on CGM Use in Pregnancy include when used in addition to pre- and postprandial blood glucose monitoring(BGM), CGM can help to achieve the HbA1c target in diabetes and pregnancy[5].
- When used in addition to BGM, targeting traditional pre- and postprandial targets, real-time continuous glucose monitoring can reduce macrosomia and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes[5].
- The CONCEPTT trial was a Randomized Controlled Trial (RCT) conducted on 325 women in 31 hospitals, and compared BGM to CGM outcomes. The CGM arm showed pregnant CGM users spent more time in target range and less time hyperglycemia. It also showed Lower incidence of large for gestational age, fewer neonatal intensive care admissions lasting more than 24 hours, fewer incidences of neonatal hypoglycemia and 1-day shorter length of hospital stay[25].

- The FLAMINGO trail was another RTC that recruited 100 pregnant women diagnosed with GDM between 24 and 28 weeks of gestation. the CGM group showed significantly reduced fasting and postprandial glycaemia during the first 4 weeks following GDM diagnosis. Incidence of fetal macrosomia was significantly higher in SMBG as compared to CGM group[26].

CGM Economic Outcomes in T2D

- An observational study showed an associated 25% reduction in acute diabetes events within 6-months following CGM acquisition[27]
- A prospective non-randomized uncontrolled study of 111 people received CGM for 14 days. There was no change in anti-diabetic medications during this time. CGM users were able to change daily diet and exercise that resulted in a statistically significant reduction of mean plasma glucose and improved glycemic excursions and hypoglycemia.[28]
- The REFLIEF study[23] was conducted on 5,933 patients and showed overall 67% reduction in Acute Diabetes Events including 44% fewer severe hypoglycemia admissions. This sustained reduction in events persisted after 2 years.
- A retrospective cohort study assessed the association of CGM acquisition and healthcare resource utilization (HCRU) in 9,574 Medicaid beneficiaries with type 2 diabetes, among Managed Medicaid beneficiaries (<65 years) on basal insulin, ≥ 6 months pre-CGM and post-CGM data, and CGM purchase between January 1, 2017 and September 30, 2022. It was observed that there are significant reductions in HCRU when comparing the pre- and post-CGM periods. These reductions were seen with hospitalizations (0.37 vs. 0.31 $p<0.001$), emergency department visits (0.95 vs. 0.84, $p<0.001$) and outpatient visits (9.11 vs. 8.60, $p<0.001$)[29].
- Subgroup analyses were conducted and showed consistent trends across all subgroups, highlighting significant reductions in both emergency and inpatient hospitalizations[29].
- A study conducted to show Glycemic Control and Treatment Satisfaction in Patients With Type 2 Diabetes concluded that CGM improved Treatment Satisfaction (DTSQ) and statistical reduction of HbA1c[30].
- Another study showed reduced work absenteeism rate and improved patient reported outcome measures (improved wellbeing and decreased diseased burden)[31].
- CGM has also been associated with decreased anxiety and feeling depressed, in the FLARE-NL-6 study, 24% discontinued use of CGM mostly due to financial constraints, those that stopped using CGM consequently had higher HbA1c[32].A budget impact analysis for Medicaid patients suggests that the use of CGM can be associated with increased cost savings with expanded use. Increasing use of CGM by 10% was associated with a $19.4 million overall decrease in costs over the year and continued to reduce costs by $25.3 million in years 2 and 3[33].
- In the T2DM Intensive Insulin Treated (IIT) population, annual acquisition costs were $1,350 higher with CGM than with BGM. When all cost offsets were applied, the use of CGM was associated with cost savings of $278 PPPY[33]

Reduction of HbA1c Association with Cost Saving[34]

- For patients with Type 2 Diabetes, a study analysis revealed that a 1% reduction in HbA1c was associated with a 2% reduction in all-cause total health care costs and a 13% reduction in diabetes-related total healthcare costs (both $p < .0001$), and that these reductions resulted in annual cost savings of $429 and $736, respectively.
- For patients with an index HbA1c ≥7% , a 1% reduction in HbA1c was associated with a 1.7% reduction in all-cause total healthcare costs and a 6.9% reduction in diabetes-related healthcare costs (both $p \leq .0001$), with associated annual cost savings of $545 and $555, respectively.
- The analysis also found that having an index HbA1c <7% compared to HbA1c ≥7% or having an index HbA1c ≥7% and subsequently reducing HbA1c to below 7%, was associated with significant cost reductions.
- It is also important to note that this study was conducted in 2020, and with the rising medical costs and costs of inflation, current amounts might be higher.

The value of CGM over BGM

- Due to Blood Glucose Monitoring (BGM) being burdensome, only 1 out of 3 patients adhere to BGM testing as recommended by their health care provider[35] and only 1 out of 4 patients using insulin achieve HbA1c target (<7%)[36] .
- Accuracy of BGM meters do not always meet regulatory standards, The accuracy of 18 BGM systems that cleared FDA requirements represent currently 90% of commercially available BGMs. Only 6 BGM systems met predefined accuracy standards, which are more lenient than FDA requirements[37].
- The requirement changed from 20% (15 mg/dL) to the more stringent requirement of ± 15%, as the wide spectrum in accuracy of BGM devices put patients at risk of hyperglycemia and hypoglycemia events[37].
- A switch study examined HbA1c levels for people using BGM (at baseline) who switched to CGM, and HbA1c levels for people using CGM (at baseline) who switched to BGM . Of 18,169 BGM users, 7,709 that switched to CGM use, saw that CGM was associated with 0.6% lower HbA1c . On the other hand, BGM was associated with a 0.2% higher level of HbA1c[38].
- Studies also demonstrate no association between BGM frequency and glycemic outcomes, as reported in the DIAMOND study, only 48% of the rtCGM users (T1D and T2D) were preforming fingerstick testing ≥4 times per day at baseline; however, there was no association between HbA1c reductions at study end and baseline fingerstick frequency[39].
- In another study of adult T2D patients, the mean self-reported fingerstick frequency at baseline for the BGM and rtCGM groups was 3.2 and 3.3, respectively[40]. The mean change in HbA1c at 6 months, was significantly greater in the rtCGM group (−1.0) compared with BGM users (−0.6%).
- A post hoc analysis of the REPLACE study shows no association between baseline BGM frequency and rtCGM outcomes[41].
- Findings from a recent retrospective claims data analysis have also shown no association between prior BGM frequency and reductions in acute diabetes events (ADE) associated with CGM use.

- A cohort of 12,521 individuals with T1D and T2D experienced reductions in Adverse Drug Events (ADE) from 0.245 to 0.132 events/patient-year ($P < 0.001$), with similar reductions observed in patients testing <4 and ≥4 times per day[42].

Randomized Controlled Trials (RCT) vs. Real World Evidence (RWE) Studies

- RCTs and RWEs are the two most common forms for collecting data, and both forms have their value in assessing the initial and ongoing role of a drug or medical device[43].
- RCTs have limited set data for patient randomization, inclusion and exclusion criteria, and regulated follow-up protocols[43].
- Due to the limitation with RCTs, RWE may provide a more generalizable picture of treatment effects in clinical practice[43]
- RWE tend to have less constrained study designs (e.g. non-randomized treatment allocation, longer patient follow-up and broader patient populations) and can essentially provide longer term patient outcomes and include a broader population. [44].
- Consequently, the extrapolation of drug/device efficacy to drug/device effectiveness in clinical practice remains difficult when only assessing RCTs, hence the importance of RWE can not be ignored.
- Many payers and regulatory agencies such as the FDA now request pharmaceutical and medical device manufacturers to submit RWE in conjunction with findings from their RCTs when assessing the safety, effectiveness, and cost–benefit parameters of new medications and medical devices[45].
- The publication of FDA's RWE framework is expected to accelerate the use of RWE for approval and coverage decisions. 21st Century Cures Act mandated the US FDA to develop guidance for the use of RWE in regulatory decisions[46].
- It is also important to take into consideration that Diabetes technologies such as CGM continue to evolve at an increasingly rapid pace in comparison to drugs. Assessing RCTs alone poses major limitations of the current approach to clinical evidence assessment. Inclusion of RWE data presents a more appropriate method for evaluating rapidly evolving technologies such as CGM[47].

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public comment re: Frenectomy
Date: Thursday, April 4, 2024 8:11:25 AM

External Email

April 4th 2024

Washington State Healthcare Authority
Attention: Review Committee
P.O. Box 45502
Olympia, WA 98504-5502

Dear Review Committee,

Subject: re: Frenectomy Review 2025

As licensed healthcare providers, concerned parents, and engaged stakeholders in Washington State, we write with a deep commitment to the welfare of all families, especially those who rely on the support of WA State Medicaid. With the Healthcare Authority's (HCA) upcoming 2025 review of the frenectomy procedure in mind, we aim to contribute insights grounded in scientific research, breastfeeding/ infant feeding advocacy, personal experience as parents of infants and young children and our collective experience as healthcare providers in settings where infant frenotomy and frenectomy are performed. Our goal is to facilitate a well-rounded, science and evidence-based decision making process. **This correspondence emphasizes two principal concerns:**

1. **It is our firm position that the provision of accessible, timely, and high-quality healthcare services for families covered by Medicaid should not be encumbered by additional obstacles. We particularly oppose the imposition of Prior Authorization and restrictions on the categories of healthcare providers authorized to conduct frenectomies for infants with ankyloglossia (tongue-tie).**

2. **We advocate for the establishment of standard criteria for the assessment and management of infant tongue-tie. This should encompass a comprehensive standard evaluation, inclusive of an infant feeding assessment, before/in addition to consideration of lingual frenectomy for tongue-tie.**

Our advocacy is rooted in the belief that these measures are critical for maintaining the integrity and efficiency of healthcare services provided to our most vulnerable populations.

The ongoing discussion surrounding tongue-tie and frenectomy, fueled by opinion pieces labeled as investigative journalism, social media and public discourse has spotlighted the gaps in knowledge and lack of specific medical criteria for intervention. In addressing these concerns, especially as they relate to safety, efficacy and cost, it is critical to rely on rigorous scientific evidence, patient/client experience and expert experience to maintain a balanced and informed perspective.

We are particularly concerned about the potential for rapid policy changes to limit access to necessary care for families with Medicaid insurance. These families, often in vulnerable positions, must not face more barriers to receiving timely, high-quality healthcare services for their infants when it is medically indicated. Our State is fortunate to have a number of ethical, accessible clinics that accept Medicaid and offer lactation support and lingual frenectomy, performed by medical professionals, ensuring these essential services are available without imposing a financial burden on families. As the evidence listed at the bottom of this letter indicates, delay of frenectomy for symptomatic tongue tie has the potential to negatively affect breastfeeding success, exclusivity and duration. **Any broad or overly restrictive policy changes could undermine the health and well-being of numerous infants who stand to benefit from medically justified lingual frenectomy.**

Nonetheless, the necessity to formulate comprehensive standard criteria for the evaluation and treatment of infant tongue-tie stands paramount. **Frenectomy should be considered only after conservative measures, including supportive latch techniques and positioning guided by skilled and certified lactation support, prove insufficient.** This strategy highlights the indispensable role of the lactation consultant, specifically the International Board Certified Lactation Consultant (IBCLC), when considering escalating intervention, reinforcing the principle that surgery should not occur prior to a detailed infant feeding assessment and latching support.

Our advocacy is bolstered by six randomized controlled trials (RCTs), which demonstrate the safety, efficacy, and benefits of frenectomy for tongue-tie in addressing issues that include painful latching, inadequate milk transfer at breast/chest, and infant gastroesophageal reflux (GERD) affecting breastfeeding. These RCTs, embodying the highest standard of scientific research due to their design, effectively reduce bias and enhance the reliability of their outcomes, thereby affirming the value of frenectomy in the presence of tongue-tie.

Recognizing the urgent need for more standard assessment guidelines and evidence-based treatment protocols, we recommend assembling a multidisciplinary team of experts, including IBCLCs, Family Nurse Practitioners, Pediatricians, Pediatric Nurse Practitioners, Midwives, Obstetricians, Speech Language Pathologists, Occupational Therapists, Pediatric Dentists, and Pediatric Ear, Nose, and Throat Doctors. This team should be

tasked with developing and refining standards that cover the wide array of considerations involved in frenectomy procedures, from lactation and pediatric care to family practice and dental health.

Furthermore, we call for the creation of clear, standardized guidelines to determine when frenectomies are in the best interest of the infant and breastfeeding mother/parent. Such guidelines will not only ensure optimal patient care but also contribute to the efficient use of healthcare resources and the promotion of lactation, breastfeeding and healthful infant feeding practices.

The role of Medicaid in providing critical healthcare services to families in Washington State cannot be overstated. It is imperative that Medicaid coverage policies are guided by the latest evidence and best practices while also ensuring that care is not delayed or made less accessible. The ability to access medically necessary lingual frenectomy and quality lactation support in a timely and comprehensive manner is paramount for the health outcomes of our most at-risk populations.

We urge the HCA to carefully consider the evidence and the potential ramifications of delaying frenectomy procedures, which can perpetuate ongoing breastfeeding difficulties. By establishing science and evidence-based guidelines for the assessment and treatment of infant tongue-tie, we can safeguard and enhance access to essential care for Medicaid families in Washington State, thereby supporting successful breastfeeding and promoting healthy infant development for all families.

We are grateful for your attention to these significant concerns and are eager to provide further information or partake in additional discussions as needed to support the health and well-being of Washington State's families.

Sincerely,

BreAnne Marcucci ARNP, FNP-C, IBCLC, PMH-C
Kristina Chamberlain ARNP, CNM, IBCLC, PMH-C
Jennifer Millich ARNP, FNP-C, IBCLC
Gabriella Price LM, CPM, IBCLC
Elizabeth Jones ARNP, FNP-BC, CLE
Juliana Johnson ARNP, FNP-C, IBCLC

REFERENCES:

These RCTs determined that in the presence of tongue tie, frenectomy or frenotomy improved the infant's outcome related to breastfeeding, infant feeding, maternal painful latching, and/or infant GERD.

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Re: Public comment: Rereview for Continuous Glucose Monitoring
Date: Wednesday, April 3, 2024 5:00:23 PM
Attachments: VMFH_Logo_Hori_Full_Color_RGB-400px.png

External Email

Please let me include just a few more citations. Thank you.

Beck RW, Riddlesworth TD, Ruedy K, et al. (2017) Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med 167(6): 365-374. 10.7326/M16-2855

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Martens T, Beck RW, Bailey R, et al. (2021) Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA 325(22): 2262-2272. 10.1001/jama.2021.7444

On Wed, Apr 3, 2024 at 4:57 PM Nicole Treanor WA-TACOMA <[redacted]> wrote:

> To the HTA,
>
> I would like to support the rereview of Continuous Glucose Monitoring technology. I am a diabetes care and education specialist, working in an endocrinology practice, and previously in primary care. I am also the chair for the Washington State Coordinating Body for ADCES (the Association of Diabetes Care and Education Specialists).
>
> I am well versed in working with individuals using this technology, as well as those who would benefit from the technology, but have not had access to it. I would like to encourage the HTA to expand access to CGM technology, and to limit the burden to patient and provider in prescribing and receiving such devices.
>
> As it stands, there are significant burdens in paperwork (typically prior authorizations) which often lead to AI-generated denials, followed by appeals, which result in significant staff effort and a delay in receiving the device. This delay in care can have clinical consequences, and leads to additional healthcare costs.
>
> I've included the American Diabetes Association 2024 Standards of Care section on technology, which recommends use of CGM for all individuals on insulin, with uninterrupted delivery of supplies. As an example where these disruptions occur, is insurance companies asking for reapproval throughout the year. As diabetes is a chronic illness, and in the case of type 1 diabetes, patients will never be able to stop taking insulin, there should not be continual hoops for patients to stay on therapy.
>
> I would also like to advocate for exceptions to the standard criteria, for example, patients

with vision or dexterity deficits that prevent them from being able to use a standard glucometer.

While the evidence for CGM use in those treated with insulin is clear, I would like to add my professional opinion, which is that even in patients not treated with insulin, CGM provides an excellent educational tool that allows patients to understand and modify the factors affecting their glucose levels. My experience has often been that through use of CGM, patients will make diet changes on their own, even when those same diet recommendations have previously come from a health professional. This is where patient autonomy can lead to improved clinical outcomes through adjusted behaviors.

I would also like to highlight barriers to equitable access to CGM, in individuals with lower socioeconomic status, and those of minority race or ethnicity. I have provided two articles, detailing the lack of equity.

Please see additional evidence citations included in my attached petition.

I appreciate all efforts of the HTA and look forward to the rereview process.

--

Nicole Treanor MS, RD, CD, CDCES

Certified Diabetes Care and Education Specialist

Diabetes Education Program Coordinator

[redacted]

Virginia Mason Franciscan Health™

--

Nicole Treanor MS, RD, CD, CDCES

Certified Diabetes Care and Education Specialist

Diabetes Education Program Coordinator

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public comment: Rereview for Continuous Glucose Monitoring
Date: Wednesday, April 3, 2024 5:00:24 PM
Attachments: VMFH_Logo_Hori_Full_Color_RGB-400px.png
2024 SOC Technology.pdf
CGM in racial and ethnic minorities.pdf
ADA CGM Utilization White Paper.pdf
Petition for Rereview of CGM - Nicole Treanor.docx

External Email

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--

Nicole Treanor MS, RD, CD, CDCES

Certified Diabetes Care and Education Specialist

Diabetes Education Program Coordinator

[redacted]

[redacted]

Virginia Mason Franciscan Health™

7. Diabetes Technology: *Standards of Care in Diabetes—2024*

*American Diabetes Association Professional Practice Committee**

Diabetes Care 2024;47(Suppl. 1):S126–S144 | https://doi.org/10.2337/dc24-S007

The American Diabetes Association (ADA) "Standards of Care in Diabetes" includes the ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, an interprofessional expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA's clinical practice recommendations and a full list of Professional Practice Committee members, please refer to Introduction and Methodology. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

Diabetes technology is the term used to describe the hardware, devices, and software that people with diabetes use to assist with self-management, ranging from lifestyle modifications to glucose monitoring and therapy adjustments. Historically, diabetes technology has been divided into two main categories: insulin administered by syringe, pen, patch devices, or pump (also called continuous subcutaneous insulin infusion [CSII]) and glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM). Diabetes technology has expanded to include automated insulin delivery (AID) systems, where CGM-informed algorithms modulate insulin delivery, connected insulin pens, as well as diabetes self-management support software serving as medical devices. Diabetes technology, when coupled with education, follow-up, and support, can improve the lives and health of people with diabetes; however, the complexity and rapid evolution of the diabetes technology landscape can also be a barrier to implementation for people with diabetes, their care partners, and the health care team.

GENERAL DEVICE PRINCIPLES

Recommendations

7.1 Diabetes devices should be offered to people with diabetes. **A**

7.2 Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. **A**

7.3 Consider establishing competencies based on role in practice setting for health care professionals working with diabetes technology. **E**

7.4 The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **E**

**A complete list of members of the American Diabetes Association Professional Practice Committee can be found at https://doi.org/10.2337/dc24-SINT.*

Duality of interest information for each author is available at https://doi.org/10.2337/dc24-SDIS.

Suggested citation: American Diabetes Association Professional Practice Committee. 7. Diabetes technology: Standards of Care in Diabetes—2024. *Diabetes Care 2024;47(Suppl. 1):S126–S144*

7.5 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading/sharing data (if applicable), to monitor and adjust therapy. **C**

7.6 People with diabetes who have been using CGM, continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payers, regardless of age or A1C levels. **E**

7.7 Students should be supported at school in the use of diabetes technology, such as CGM systems, CSII, connected insulin pens, and AID systems, as recommended or prescribed by their health care team. **E**

7.8 Initiation of CSII and/or AID early, even at diagnosis, in the treatment of diabetes can be beneficial depending on a person's or caregiver's needs and preferences. **C**

Technology is rapidly changing, but there is no one-size-fits-all approach to technology use in people with diabetes. Insurance coverage can lag behind device availability, people's interest in devices and willingness for adoption can vary, and health care teams may have challenges in keeping up with newly released technology. An American Diabetes Association resource, which can be accessed at consumerguide.diabetes.org, can help health care professionals and people with diabetes make decisions as to the initial choice of devices. Other sources, including health care professionals and device manufacturers, can help people troubleshoot when difficulties arise (1–10).

Education and Training

In general, no device used in diabetes management works optimally without education, training, and ongoing support. There are multiple resources for online tutorials and training videos as well as written material on the use of devices. People with diabetes vary in comfort level with technology, and some prefer in-person training and support. Those with more education regarding device use have better outcomes (1,2); therefore, the need for additional education should be periodically assessed, particularly if outcomes are not being met. Better outcomes cannot be achieved, however, without the training and education of health care professionals. The assessment of competencies in diabetes technology is crucial for prescribers, certified diabetes and education specialists, pharmacists, nurses, and anyone involved in the care of people with diabetes. These competencies are described as basic, fundamental, intermediate, and advanced and are specific to the role of each health care team member (11). In addition, the health care team's knowledge and competency are even more relevant when people with diabetes are started on advanced diabetes technologies, such as AID systems. In such situations, training is vital and should include a discussion about realistic expectations for the ability of the initiated system to achieve glucose goals, the system's features and limitations, and the best way to utilize the new system to maximize the benefits it can offer (12).

Use in Schools

Instructions for device use should be outlined in the student's diabetes medical management plan (DMMP). A backup plan should be included in the DMMP for potential device failure (e.g., BGM, CGM, and/or insulin delivery devices). School nurses and designees should complete training to stay up to date on diabetes technologies prescribed for use in the school setting. Updated resources to support diabetes care at school, including training materials and a DMMP template, can be found online at diabetes.org/safeatschool.

Initiation of Device Use

The use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management (3,4). This allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent BGM. In addition, early CGM initiation after diagnosis of type 1 diabetes in youth has been shown to decrease A1C levels and is associated with high parental satisfaction and reliance on this technology for diabetes management (5,6). Training on alarm/alert settings when initiating CGM is crucial to avoid alarm overload. In appropriate individuals, early use of AID systems or insulin pumps may be considered. Interruption of access to CGM is associated with a worsening of outcomes (7,13); therefore, it is important for individuals on CGM to have consistent access to devices.

BLOOD GLUCOSE MONITORING

Recommendations

7.9 People with diabetes should be provided with blood glucose monitoring (BGM) devices as indicated by their circumstances, preferences, and treatment. People using CGM devices must also have access to BGM at all times. **A**

7.10 People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise, when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving. **B**

7.11 Health care professionals should be aware of the differences in accuracy among blood glucose meters. Only meters approved by the U.S. Food and Drug Administration (FDA) (or comparable regulatory agencies for other geographical locations) with proven accuracy should be used, with unexpired test strips purchased from a pharmacy or licensed distributor and properly stored. **E**

7.12 Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when altering meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program. **E**

7.13 Health care professionals should be aware of medications and other factors that can interfere with glucose

meter accuracy and provide clinical management as indicated. **E**

Major clinical trials of insulin-treated people with diabetes have included BGM as part of multifactorial interventions to demonstrate the benefit of intensive glycemic management on diabetes complications (14). BGM is thus an integral component of effective therapy for individuals using insulin. In recent years, CGM has emerged as a method for the assessment of glucose levels (discussed below). Glucose monitoring allows people with diabetes to evaluate their individual responses to therapy and assess whether glycemic goals are being safely achieved. Integrating results into diabetes management can be a useful tool for guiding medical nutrition therapy and physical activity, preventing hypoglycemia, or adjusting medications (particularly prandial insulin doses or correction bolus doses). The specific needs and goals of the person with diabetes should dictate BGM frequency and timing or the consideration of CGM use. As recommended by the device manufacturers and the U.S. Food and Drug Administration (FDA), people with diabetes using CGM must have access to BGM for multiple reasons, including whenever there is suspicion that the CGM is inaccurate, while waiting for warm-up, when there is a disruption in CGM transmission, for calibration (if needed) or if a warning message appears, when CGM supplies are delayed, and in any clinical setting where glucose levels are changing rapidly (>2 mg/dL/min), which could cause a discrepancy between CGM and blood glucose values.

Meter Standards

Glucose meters meeting FDA guidance for meter accuracy provide the most reliable data for diabetes management. There are several current standards for the accuracy of blood glucose meters, but the two most used are those of the International Organization for Standardization (ISO) (ISO 15197:2013) and the FDA. The current ISO and FDA standards are compared in **Table 7.1**. In Europe, currently marketed meters must meet current ISO standards. In the U.S., currently marketed meters must meet the standard under which they were approved, which may not be the current standard. Moreover, the monitoring of current accuracy postmarketing is left to the manufacturer and not routinely checked by an independent source.

People with diabetes assume their glucose meter is accurate because it is FDA cleared, but that may not be the case. There is substantial variation in the accuracy of widely used BGM systems (15,16). The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program provides information on the performance of devices used for BGM (diabetestechnology.org/surveillance/). In one analysis, 6 of the top 18 best-selling glucose meters met the accuracy standard (17). In a subsequent analysis with updated glucose meters, 14 of 18 glucose meters met the minimum accuracy requirements (18). There are single-meter studies in which benefits have been found with individual meter systems, but few studies have compared meters head-to-head. Certain meter system characteristics, such as the use of lancing devices that are less painful (19) and the ability to reapply blood to a strip with an insufficient initial sample, or meters with integrated speech that can read aloud glucose levels for visually impaired individuals (20), may also be beneficial to people with diabetes (21) and may make BGM less burdensome to perform.

Counterfeit Strips

People with diabetes should be advised against purchasing or reselling preowned or secondhand test strips, as these may give incorrect results. Only unopened and unexpired vials of glucose test strips should be used to ensure BGM accuracy.

Optimizing Blood Glucose Monitoring Device Use

Optimal use of BGM devices requires proper review and interpretation of data by both the person with diabetes and the health care professional to ensure that data are used in an effective and timely manner. In people with type 1 diabetes, there is a correlation between greater BGM frequency and lower A1C levels (22). Among those who check their blood glucose at least once daily, many report taking no action when results are high or low (23). Some meters now provide advice to the user in real time when monitoring glucose levels (24), whereas others can be used as a part of integrated health platforms (25). People with diabetes should be taught how to use BGM data to adjust food intake, physical activity, or pharmacologic therapy to achieve specific goals. The ongoing need for and frequency of BGM should be reevaluated at each routine visit to ensure its effective use (22,26,27).

People With Diabetes on Intensive Insulin Therapies

BGM is especially important for people with diabetes treated with insulin to monitor for and prevent hypoglycemia and hyperglycemia. Most individuals on intensive insulin therapies (multiple daily injections [MDI] or insulin pump therapy) should be encouraged to assess glucose levels using BGM (and/or CGM) prior to meals and snacks, at bedtime, occasionally postprandially, prior to, during, and

Table 7.1—Comparison of ISO 15197:2013 and FDA BG meter accuracy standards

Setting	FDA (287,299)	ISO 15197:2013 (300)
Hospital use	95% within 12% for BG ≥75 mg/dL 95% within 12 mg/dL for BG <75 mg/dL 98% within 15% for BG ≥75 mg/dL 98% within 15 mg/dL for BG <75 mg/dL	95% within 15% for BG ≥100 mg/dL 95% within 15 mg/dL for BG <100 mg/dL 99% in A or B region of consensus error grid‡
Home use	95% within 15% for all BG in the usable BG range† 99% within 20% for all BG in the usable BG range†	

BG, blood glucose; FDA, U.S. Food and Drug Administration; ISO, International Organization for Standardization. To convert mg/dL to mmol/L, see endmemo.com/medical/unitconvert/Glucose.php. †The range of blood glucose values for which the meter has been proven accurate and will provide readings (other than low, high, or error). ‡Values outside of the "clinically acceptable" A and B regions are considered "outlier" readings and may be dangerous to use for therapeutic decisions (301).

after physical activity, when they suspect hypoglycemia or hyperglycemia, after treating hypoglycemia until they are normoglycemic, and prior to and while performing critical tasks such as driving. For many individuals using BGM, this requires checking up to 6–10 times daily, although individual needs may vary. A database study of almost 27,000 children and adolescents with type 1 diabetes showed that, after adjusting for multiple confounders, increased daily frequency of BGM was significantly associated with lower A1C levels (−0.2% per additional check per day) and with fewer acute complications (28).

People With Diabetes Using Basal Insulin and/or Oral Agents and Noninsulin Injectables

The evidence is insufficient regarding when to prescribe BGM and how often monitoring is needed for insulin-treated people with diabetes who do not use intensive insulin therapy, such as those with type 2 diabetes taking basal insulin with or without oral agents and/or noninsulin injectables. However, for those taking basal insulin, assessing fasting glucose with BGM to inform dose adjustments to achieve blood glucose targets results in lower A1C levels (29,30).

In people with type 2 diabetes not taking insulin, routine glucose monitoring may be of limited additional clinical benefit. By itself, even when combined with education, this practice has shown limited improvement in outcomes (31–34). However, for some individuals, glucose monitoring can provide insight into the impact of nutrition, physical activity, and medication management on glucose levels. Glucose monitoring may also be useful in assessing hypoglycemia, glucose levels during intercurrent illness, or discrepancies between measured A1C and glucose levels when there is concern an A1C result may not be reliable in specific individuals (for more details, see Section 2, "Diagnosis and Classification of Diabetes"). It may be useful when coupled with a treatment adjustment program. In a year-long study of insulin-naive people with diabetes with suboptimal initial glycemic outcomes, a group trained in structured BGM (a paper tool was used at least quarterly to collect and interpret seven-point BGM profiles taken on three consecutive days) reduced their A1C levels by 0.3% more than that of the control group (35). A trial of once-daily BGM that included enhanced feedback from people with diabetes through messaging found no clinically or statistically significant change in A1C levels at 1 year (34). Meta-analyses have suggested that BGM can reduce A1C levels by 0.25–0.3% at 6 months (36–38), but the effect was attenuated at 12 months in one analysis (36). Reductions in A1C levels were greater (−0.3%) in trials where structured BGM data were used to adjust medications, but A1C levels were not changed significantly without such structured diabetes therapy adjustment (38). A key consideration is that performing BGM alone does not lower blood glucose levels. To be useful, the information must be integrated into clinical and self-management treatment plans.

Glucose Meter Inaccuracy

Although many meters function well under various circumstances, health care professionals and people with diabetes must be aware of factors that impair meter accuracy. A meter reading that seems discordant with the clinical picture needs to be retested or tested in a laboratory. Health care professionals in intensive care unit settings need to be particularly aware of the potential for incorrect meter readings during critical illness, and laboratory-based values should be used if there is any doubt. Some meters give error messages if meter readings are likely to be false (39).

Oxygen. Currently available glucose monitors use an enzymatic reaction linked to an electrochemical reaction, either glucose oxidase or glucose dehydrogenase (40). Glucose oxidase monitors are sensitive to the oxygen available and should only be used with capillary blood in people with normal oxygen saturation. Higher oxygen tensions (i.e., arterial blood or oxygen therapy) may result in false low-glucose readings, and low oxygen tensions (i.e., high altitude, hypoxia, or venous blood readings) may lead to falsely elevated glucose readings. Glucose dehydrogenase–based monitors are generally not sensitive to oxygen.

Temperature. Because the reaction is sensitive to temperature, all monitors have an acceptable temperature range (40). Most will show an error if the temperature is unacceptable, but a few will provide a reading and a message indicating that the value may be incorrect. Humidity and altitude may also alter glucose readings.

Table 7.2—Interfering substances for glucose meter readings

Glucose oxidase monitors
Uric acid
Galactose
Xylose
Acetaminophen
L-DOPA
Ascorbic acid
Glucose dehydrogenase monitors using pyrroloquinolinequinone cofactor (GDH/PQQ)
Icodextrin (used in peritoneal dialysis)

Interfering Substances. There are a few physiologic and pharmacologic factors that interfere with glucose readings. Most interfere only with glucose oxidase systems (40). They are listed in **Table 7.2**.

CONTINUOUS GLUCOSE MONITORING DEVICES

See **Table 7.3** for definitions of types of CGM devices.

Recommendations

7.14 Real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) **B** should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI) or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.15 rtCGM **A** or isCGM **B** should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.16 rtCGM **A** or isCGM **E** should be offered for diabetes management in youth with type 1 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.17 rtCGM or isCGM should be offered for diabetes management in youth with type 2 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver).

Table 7.3—Continuous glucose monitoring devices

Type of CGM	Description
rtCGM	CGM systems that measure and display glucose levels continuously
isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for visualization and storage of glucose values
Professional CGM	CGM devices that are placed on the person with diabetes in the health care professional's office and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes.

CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM.

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

7.18 In people with diabetes on MDI or CSII, rtCGM devices should be used as close to daily as possible for maximal benefit. **A** isCGM devices should be scanned frequently, at a minimum once every 8 h to avoid gaps in data. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **A**

7.19 When used as an adjunct to preprandial and postprandial BGM, CGM can help to achieve A1C targets in diabetes and pregnancy. **B**

7.20 Periodic use of rtCGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. **C**

7.21 Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices. **E**

7.22 People who wear CGM devices should be educated on potential interfering substances and other factors that may affect accuracy. **C**

CGM measures interstitial glucose (which correlates well with plasma glucose, although at times, it can lag if glucose levels are rising or falling rapidly). There are two basic types of CGM devices. The first type includes those that are owned by the user, unblinded, and intended for frequent or continuous use, including real-time CGM (rtCGM) and intermittently scanned CGM (isCGM). The second type is professional CGM devices that are owned by practices and applied in the clinic, which provide data that are blinded or unblinded for a discrete period of time. The types of sensors currently available are either disposable (rtCGM and isCGM) or implantable (rtCGM). **Table 7.3** provides the definitions for the types of CGM devices. For people with type 1 diabetes using CGM, frequency of sensor use is an important predictor of A1C lowering for all age-groups (41,42). The frequency of scanning with isCGM devices is also correlated with improved outcomes (43–46).

Some real-time systems require calibration by the user, which varies in frequency depending on the device. Additionally, some CGM systems are called adjunctive, meaning the user should perform BGM for making treatment decisions such as dosing insulin or treating hypoglycemia. Devices that do not have this requirement outside of certain clinical situations (see BLOOD GLUCOSE MONITORING, above) are called nonadjunctive (47–49).

One specific isCGM device (Freestyle Libre 2 [no generic form available]) and three specific rtCGM devices (Dexcom G6 [no generic form available], Dexcom G7 [no generic form available], and FreeStyle Libre 3 [no generic form available]) have been designated integrated CGM (iCGM) devices (50). This is a higher standard set by the FDA so that these devices can be integrated with other digitally connected devices. Dexcom G6 rtCGM, Dexcom G7 rtCGM, and a modified version of Libre 2 and Libre 3 are FDA approved for use with AID systems. At this time, Dexcom G6 is integrated with four AID systems (t:slim ×2 with control IQ, Omnipod 5, iLet, and Mobi). Similarly, the Medtronic Guardian 3 rtCGM (no generic available) and the Medtronic Guardian 4 rtCGM are FDA approved for use with the 670/770G and 780G AID systems, respectively.

Benefits of Continuous Glucose Monitoring

Data From Randomized Controlled Trials

Multiple randomized controlled trials (RCTs) have been performed using rtCGM devices, and the results have largely been positive in terms of reducing A1C levels and/or episodes of hypoglycemia, as long as participants regularly wore the devices (41,42,51–73). The initial studies were done primarily in adults and youth with type 1 diabetes on insulin pump therapy and/or MDI (41,42,51–54,57–67). The primary outcome was met and showed benefit in adults of all ages (41,51,52,57, 58,60,62,63,74–77), including seniors (59, 78,79). Data in children show that rtCGM use in young children with type 1 diabetes reduced hypoglycemia; in addition, behavioral support of parents of young children with diabetes using rtCGM showed the benefits of reducing hypoglycemia concerns and diabetes distress (41,66,80). Similarly, A1C level reduction was seen in adolescents and young adults with type 1 diabetes using rtCGM (65). RCT data on rtCGM use in individuals with type 2 diabetes on MDI (69), mixed therapies (70,71), and basal insulin (72,81) have consistently shown reductions in A1C levels and increases in time in range (TIR) (70–180 mg/dL [3.9–10 mmol/L]) but not a reduction in rates of hypoglycemia. The improvements in type 2 diabetes have largely occurred without changes in insulin doses or other diabetes medications. CGM discontinuation in individuals with type 2 diabetes on basal insulin caused partial reversal of A1C reduction and TIR improvements, suggesting that continued CGM use achieves the greatest benefits (13). In addition, rtCGM benefits were reported in a mixed population (including people not using insulin) of adults with

type 2 diabetes with reduction in A1C levels, increase in TIR, and reduction of time in hyperglycemia (>180 mg/dL [>10 mmol/L] and >250 mg/dL [>13.8 mmol/L]) (10).

RCT data for isCGM are fewer but increasing. One study was performed in adults with type 1 diabetes and met its primary outcome of a reduction in rates of hypoglycemia (55). In adults with type 2 diabetes using insulin, two studies were done: one study did not meet its primary end point of A1C levels reduction (82) but achieved a secondary end point of a reduction in hypoglycemia, and the other study met its primary end point of an improvement in the Diabetes Treatment Satisfaction Questionnaire score as well as a secondary end point of A1C level reduction (83). In a study of individuals with type 1 or type 2 diabetes taking insulin, the primary outcome of a reduction in severe hypoglycemia was not met and the incidence of severe hypoglycemia was not significantly different between isCGM users and the BGM group (84). One study in youth with type 1 diabetes did not show a reduction in A1C levels (85); however, the device was well received and was associated with an increased frequency of testing and improved diabetes treatment satisfaction (85). A randomized trial of adults with type 1 diabetes showed that the use of isCGM with optional alerts and alarms resulted in reduction of A1C levels compared with BGM use (9). The benefits of isCGM for adults with type 2 diabetes not using insulin were recently reported in an RCT. In this study, the use of isCGM plus diabetes education versus diabetes education alone showed decreased A1C levels and increased TIR as well as increased time in tight target range (70–140 mg/dL [3.9–7.8 mmol/L]) in the isCGM-plus-education group (8).

Observational and Real-world Studies

isCGM has been widely available in many countries for people with diabetes, and this allows for the collection of large amounts of data across groups of people with diabetes. In adults with diabetes, these data include results from observational studies, retrospective studies, and analyses of registry and population data (86,87). In individuals with type 1 diabetes wearing isCGM devices, most (46,86,88), but not all (89), studies have shown improvement in A1C levels. Reductions in acute diabetes complications, such as diabetic ketoacidosis (DKA), episodes of severe hypoglycemia or diabetes-related coma, and hospitalizations for hypoglycemia and hyperglycemia, have been observed (46,89,90), with persistent effects observed even after 2 years of CGM initiation (91). Some retrospective/observational data have shown an improvement in A1C levels for adults with type 2 diabetes on MDI (92), basal insulin (93), and basal insulin or noninsulin therapies (94). In a retrospective study of adults with type 2 diabetes taking insulin, a reduction in acute diabetes-related events and all-cause hospitalizations was seen (95). Results of self-reported outcomes varied, but where measured, people with diabetes had an increase in treatment satisfaction with isCGM compared with BGM.

In an observational study in youth with type 1 diabetes, a slight increase in A1C levels and weight was seen, but the device was associated with a high user satisfaction rate (87).

Retrospective data from rtCGM use in a Veterans Affairs population (96) with type 1 and type 2 diabetes treated with insulin showed that the use of rtCGM significantly lowered A1C levels and reduced rates of emergency department visits or hospitalizations for hypoglycemia but did not significantly lower overall rates of emergency department visits, hospitalizations, or hyperglycemia.

Real-time Continuous Glucose Monitoring Compared With Intermittently Scanned Continuous Glucose Monitoring

In adults with type 1 diabetes, three RCTs have been conducted comparing isCGM and rtCGM (97–99). In two of the studies, the primary outcome was a reduction in time spent in hypoglycemia, and rtCGM showed greater benefits compared with isCGM (97,98). In the other study, the primary outcome was improved TIR, and rtCGM also showed greater benefits compared with isCGM (99). A retrospective analysis also showed improvement in TIR with rtCGM compared with isCGM (100). A more recent 12-month real-world nonrandomized study compared rtCGM with isCGM in adults with type 1 diabetes. At 12 months, A1C levels, time in level 1 hypoglycemia (<70 mg/dL [<3.9 mmol/L]), and time in level 2 hypoglycemia (<54 mg/dL [<3.0 mmol/L]) were all lower in the rtCGM group than in the isCGM group; similarly, the TIR was higher in the rtCGM group than in the isCGM group (101).

Data Analysis

The abundance of data provided by CGM offers opportunities to analyze data for people with diabetes more granularly than previously possible, providing additional information to aid in achieving glycemic goals. A variety of metrics have been proposed (102) and are discussed in Section 6, "Glycemic Goals and Hypoglycemia." CGM is essential for creating an ambulatory glucose profile and providing data on TIR, percentage of time spent above and below range, and glycemic variability (103). Data analysis can be burdensome without a systematic approach to its review. Several efforts have been made to streamline the interpretation of CGM reports to assist health care professionals in their daily practice. These have various, but overall similar, approaches. The initial steps are focused on assessing the sufficiency and quality of data; subsequent recommendations include reviewing the presence and trends or patterns of hypoglycemia, followed by hyperglycemia patterns and trends. Some authors also suggest approaches to changing therapy plans based on the data reviewed that enable health care professionals to make a simple yet comprehensive review and plan of care even within the time constraints of office visits (104–108).

Real-time Continuous Glucose Monitoring Device Use in Pregnancy

Recently, CGM indication has been expanded to include pregnancy for Dexcom G7, FreeStyle Libre 2, and FreeStyle Libre 3, which will enhance care in this population (109,110). Prior data from one well-designed RCT showed a reduction in A1C levels in pregnant adults with type 1 diabetes on MDI or insulin pump therapy and using rtCGM in addition to standard care; CGM users experienced more pregnancy-specific TIR (63–140 mg/dL [3.5–7.8 mmol/L]) and less time in hyperglycemia (111). This study demonstrated the value of rtCGM in pregnancy complicated by type 1 diabetes by showing a mild improvement in A1C levels and a significant improvement in the maternal glucose TIR for pregnancy (63–140 mg/dL [3.5–7.8 mmol/L]), without an increase in hypoglycemia, as well as reductions in large-for-gestational-age births, infant hospital length of stay, and severe neonatal hypoglycemia (111). An observational cohort study that evaluated

the glycemic variables reported using rtCGM and isCGM found that lower mean glucose, lower standard deviation, and a higher percentage of TIR were associated with lower risks of large-for-gestational-age births and other adverse neonatal outcomes (112). Data from one study suggested that the use of rtCGM-reported mean glucose is superior to use of the glucose management indicator and other calculations to estimate A1C levels given the changes to A1C levels that occur in pregnancy (113). Two studies employing intermittent use of rtCGM showed no difference in neonatal outcomes in individuals with type 1 diabetes (114) or gestational diabetes mellitus (115). At this time, data are insufficient for recommending the use of CGM in all pregnant people with type 2 diabetes or GDM (116,117). The decision of whether to use CGM in pregnant individuals with type 2 diabetes or GDM should be individualized based on treatment plan, circumstances, preferences, and needs. Although CGM systems for use in pregnancy do not require calibrations and are approved for nonadjunctive use, when using CGM in diabetes and pregnancy, determination of glucose levels by finger stick may be necessary in certain circumstances, such as in the setting of hypoglycemia or hyperglycemia outside the recommended CGM targets (63–140 mg/dL [3.5–7.8 mmol/L]) during pregnancy.

Use of Professional and Intermittent Continuous Glucose Monitoring

Professional CGM devices, which provide retrospective data, either blinded or unblinded, for analysis can be used to identify patterns of hypoglycemia and hyperglycemia (118,119). Professional CGM can be helpful to evaluate an individual's glucose levels when either rtCGM or isCGM is not available to the individual or they prefer a blinded analysis or a shorter experience with unblinded data. It can be particularly useful in individuals using agents that can cause hypoglycemia, as the data can be used to evaluate periods of hypoglycemia and make medication dose adjustments if needed. It can also be useful to evaluate periods of hyperglycemia.

Some data have shown the benefit of intermittent use of CGM (rtCGM or isCGM) in individuals with type 2 diabetes on noninsulin and/or basal insulin therapies (70,120). In these RCTs, people with type 2 diabetes not on intensive insulin therapy used CGM intermittently compared with those randomized to BGM. Both early (70) and late improvements in A1C levels were found (70,120). Use of professional or intermittent CGM should always be coupled with analysis and interpretation for people with diabetes, along with education as needed to adjust medication and change lifestyle behaviors (121–123).

Side Effects of Continuous Glucose Monitoring Devices

Contact dermatitis (both irritant and allergic) has been reported with all devices that attach to the skin (18,124,125). In some cases, this has been linked to the presence of isobornyl acrylate, a skin sensitizer that can cause an additional spreading allergic reaction (126–128). It is important to ask CGM users periodically about adhesive reactions, as tape formulations may change over time. Patch testing can sometimes identify the cause of contact dermatitis (129). Identifying and eliminating tape allergens is important to ensure the comfortable use of devices and promote self-care (130–133). The Panther Program offers resources in English and Spanish at pantherprogram.org/skin-solutions. In some instances, using an implanted sensor can help avoid skin reactions in those sensitive to tape (134,135).

Substances and Factors Affecting Continuous Glucose Monitoring Accuracy

Sensor interference due to several medications/substances is a known potential source of CGM sensor measurement errors (**Table 7.4**). While several of these substances have been reported in the various CGM brands' user manuals, additional interferences have been discovered after the market release of these products. Hydroxyurea, used for myeloproliferative disorders and hematologic conditions, is one of the most recently identified interfering substances that cause a temporary increase in sensor glucose values discrepant from actual glucose values (136–141). Similarly, substances such as mannitol and sorbitol, when administered intravenously or as a component of peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose (142). Therefore, it is crucial to routinely review the medications and supplements used by the person with diabetes to identify possible interfering substances and advise them accordingly on the need to use additional BGM if sensor values are unreliable due to these substances.

INSULIN DELIVERY

Insulin Syringes and Pens

Recommendations

7.23 For people with insulin-requiring diabetes on MDI, insulin pens are preferred in most cases. Still, insulin syringes may be used for insulin delivery considering individual and caregiver preference, insulin type, availability in vials, dosing

Table 7.4—Continuous glucose monitoring devices interfering substances

Medication	Systems affected	Effect
Acetaminophen		
>4 g/day	Dexcom G6, Dexcom G7	Higher sensor readings than actual glucose
Any dose	Medtronic Guardian	Higher sensor readings than actual glucose
Ascorbic acid (vitamin C), >500 mg/day	FreeStyle Libre 14 day, FreeStyle Libre 2, FreeStyle Libre 3	Higher sensor readings than actual glucose
Hydroxyurea	Dexcom G6, Dexcom G7, Medtronic Guardian	Higher sensor readings than actual glucose
Mannitol (intravenously or as peritoneal dialysis solution)	Senseonics Eversense	Higher sensor readings than actual glucose
Sorbitol (intravenously or as peritoneal dialysis solution)	Senseonics Eversense	Higher sensor readings than actual glucose

therapy, cost, and self-management capabilities. C

7.24 Insulin pens or insulin injection aids are recommended for people with dexterity issues or vision impairment or when decided by shared decision-making to facilitate the accurate dosing and administration of insulin. C

7.25 Connected insulin pens can be helpful for diabetes management and may be used in people with diabetes taking subcutaneous insulin. E

7.26 FDA-approved insulin dose calculators/decision support systems may be helpful for calculating insulin doses. C

Injecting insulin with a syringe or pen (143–159) is the insulin delivery method used by most people with diabetes (149,160), although inhaled insulin is also available. Others use insulin pumps or AID devices (see INSULIN PUMPS AND AUTOMATED INSULIN DELIVERY SYSTEMS, below). For people with diabetes who use insulin, insulin syringes and pens are both able to deliver insulin safely and effectively for the achievement of glycemic targets. Individual preferences, cost, insulin type, dosing therapy, and self-management capabilities should be considered when choosing among delivery systems. Trials with insulin pens generally show equivalence or small improvements in glycemic outcomes compared with using a vial and syringe. Many individuals with diabetes prefer using a pen because of its simplicity and convenience. It is important to note that while many insulin types are available for purchase as either pens or vials, others may be available in only one form or the other, and there may be significant cost differences between pens and vials (see **Table 9.4** for a list of insulin product costs with dosage forms). Insulin pens may allow people with vision impairment or dexterity issues to dose insulin accurately (161–163), and insulin injection aids are also available to help with these issues. (For a helpful list of injection aids, see consumerguide.diabetes.org/collections/injection-aids). Inhaled insulin can be useful in people who have an aversion to injection.

The most common syringe sizes are 1 mL, 0.5 mL, and 0.3 mL, allowing doses of up to 100 units, 50 units, and 30 units, respectively, of U-100 insulin. Some 0.3-mL syringes have half-unit markings, whereas other syringes have 1- to 2-unit increment markings. In a few parts of the world, insulin syringes still have U-80 and U-40 markings for older insulin concentrations and veterinary insulin, and U-500 syringes are available for the use of U-500 insulin. Syringes are generally used once but may be reused by the same individual in resource-limited settings with appropriate storage and cleansing (163).

Insulin pens offer added convenience by combining the vial and syringe into a single device. Insulin pens, allowing push-button injections, come as disposable pens with prefilled cartridges or reusable insulin pens with replaceable insulin cartridges. Pens vary with respect to dosing increment and minimal dose, ranging from half-unit doses to 2-unit dose increments, with the latter available in U-200 insulin pens. U-500 pens come in 5-unit dose increments. Some reusable pens include a memory function, which can recall dose amounts and timing. Connected insulin pens are insulin pens with the capacity to record and/or transmit insulin dose data. Insulin pen caps are also available and are placed on existing insulin pens and may assist with calculating insulin doses and by providing a memory function. Some connected insulin pens and pen caps can be programmed to calculate insulin doses, can be synced with select CGM systems, and can provide downloadable data reports. These pens and pen caps are useful to people with diabetes for real-time insulin dosing and allow clinicians to retrospectively review the insulin delivery times and in some cases doses and glucose data in order to make informed insulin dose adjustments (164). A quantitative study showed that people with diabetes preferred connected pens because of their ability to log insulin doses and glucose levels automatically (164).

Needle thickness (gauge) and length are other considerations. Needle gauges range from 22 to 34, with a higher gauge indicating a thinner needle. A thicker needle can give a dose of insulin more quickly, while a thinner needle may cause less pain. Needle length ranges from 4 to 12.7 mm, with some evidence suggesting that shorter needles (4–5 mm) lower the risk of intramuscular injection with erratic absorption and possibly the development of lipohypertrophy. When reused, needles may be duller and thus injections may be more painful. Proper insulin injection technique is a requisite for receiving the full dose of insulin with each injection. Concerns with technique and use of the proper technique are outlined in Section 9, "Pharmacologic Approaches to Glycemic Treatment."

Bolus calculators have been developed to aid dosing decisions (165–170). These systems are subject to FDA approval to ensure safety and efficacy in terms of algorithms used and subsequent dosing recommendations. People interested in using these systems should be encouraged to use those that are FDA approved. Health care professional input and education can be helpful for setting the initial dosing calculations with ongoing follow-up for adjustments as needed.

Insulin Pumps and Automated Insulin Delivery Systems

Recommendations

7.27 AID systems should be offered for diabetes management to youth and adults with type 1 diabetes A and other types of insulin-deficient diabetes E who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. A

7.28 Insulin pump therapy alone with or without a sensor-augmented pump low-glucose suspend feature should be offered for diabetes management to youth and adults on MDI with type 1 diabetes A or other types of insulin-deficient diabetes E who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an AID system. The choice of device should be made based on the individual's circumstances, preferences, and needs. A

7.29 Insulin pump therapy can be offered for diabetes management to youth and adults on MDI with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. A

7.30 Individuals with diabetes who have been using CSII should have continued access across third-party payers. E

Insulin Pumps

Insulin pumps have been available in the U.S. for over 40 years. These devices deliver rapid-acting insulin throughout the day to help manage glucose levels. Most insulin pumps use tubing to deliver insulin through a cannula, while a few attach directly to the skin without tubing. AID systems, which can adjust insulin delivery rates based on sensor glucose values, are preferred over nonautomated pumps and MDI in people with type 1 diabetes.

Most studies that compare MDI with insulin pump therapy have been relatively small and of short duration. However, a systematic review and meta-analysis concluded that pump therapy has modest advantages for lowering A1C levels (−0.30% [95% CI −0.58 to −0.02]) and for reducing severe hypoglycemia rates in children and adults (171). Real-world data on insulin pump use in individuals with type 1 diabetes show benefits in A1C levels and hypoglycemia reductions as well as total daily insulin dose reduction (172). There is no consensus to guide choosing which form of insulin administration is best for a given individual, and research to guide this decision-making process is needed (171). Thus, the choice of MDI or an insulin pump is often based upon the characteristics of the person with diabetes and which method is most likely to benefit them. DiabetesWise (diabeteswise.org/) and DiabetesWise Pro (pro.diabeteswise.org/), for health care professionals, and the PANTHER Program (pantherprogram.org/device-comparison-chart) have helpful websites to assist health care professionals and people with diabetes in choosing diabetes devices based on their individual needs and the features of the devices. Newer systems, such as sensor-augmented pumps and AID systems, are discussed below.

Adoption of pump therapy in the U.S. shows geographical variations, which may be related to health care professional preference or center characteristics (173,174) and socioeconomic status, as pump therapy is more common in individuals of higher socioeconomic status, as reflected by private health insurance, family income, and education (173,174). Given the additional barriers to optimal diabetes care observed in disadvantaged groups (175), addressing the differences in access to insulin pumps and other diabetes technologies may contribute to fewer health disparities.

Pump therapy can be successfully started at the time of diagnosis (176,177). Practical aspects of pump therapy initiation include assessment of readiness of the person with diabetes and their family, if applicable (although there is no consensus on which factors to consider in adults [178] or children and adolescents with diabetes), selection of pump type and initial pump settings, individual/family education on potential pump complications (e.g., DKA with infusion set failure), transition from MDI, and introduction of advanced pump settings (e.g., temporary basal rates and extended/square/dual-wave bolus).

Older individuals with type 1 diabetes benefit from ongoing insulin pump therapy. There are no data to suggest that measurement of C-peptide levels or antibodies predicts success with insulin pump therapy (179,180). Additionally, the frequency of follow-up does not influence outcomes. Access to insulin pump therapy, including AID systems, should be allowed or continued in older adults as it is in younger people.

Complications of the pump can be caused by issues with infusion sets (dislodgement and occlusion), which place individuals at risk for ketosis and DKA and thus must be recognized and managed early (181). Other pump skin issues include lipohypertrophy or, less frequently, lipoatrophy (182,183) and pump site infection (184). Discontinuation of pump therapy is relatively uncommon today; the frequency has decreased over the past few decades, and its causes have changed (184,185). Current reasons for attrition are problems with cost or wearability, loss of insurance, dislike for the pump, suboptimal glycemic outcomes, or mood disorders (e.g., anxiety or depression) (186).

Insulin Pumps in Youth

The safety of insulin pumps in youth has been established for over 15 years (187). Studying the effectiveness of insulin pump therapy in lowering A1C levels has been challenging because of the potential selection bias of observational studies. Participants on insulin pump therapy may have a higher socioeconomic status that may facilitate better glycemic outcomes (188) versus MDI. In addition, the fast pace of development of new insulins and technologies quickly renders comparisons obsolete. However, RCTs that compared insulin pumps and MDI with rapid-acting insulin analogs demonstrated a modest improvement in A1C levels in participants on insulin pump therapy (189,190). Observational studies, registry data, and meta-analyses have also suggested an improvement in glycemic outcomes in participants on insulin pump therapy (191–193). Data suggest that insulin pumps reduce the rates of severe hypoglycemia compared with MDI (193–196).

There is also evidence that insulin pump therapy may reduce DKA risk (193,197) and diabetes complications, particularly retinopathy and peripheral neuropathy in youth, compared with MDI (178). In addition, treatment satisfaction and quality-of-life measures improved on insulin pump therapy compared with MDI (198,199). Therefore, insulin pumps can be used safely and effectively in youth with type 1 diabetes to assist with achieving targeted glycemic outcomes while reducing the risk of hypoglycemia and DKA, improving quality of life, and preventing long-term complications. Based on shared decision-making by people with diabetes and health care professionals, insulin pumps may be considered in all children and adolescents with type 1 diabetes. In particular, pump therapy may be the preferred mode of insulin delivery for children under 7 years of age (200). Because of a paucity of data in adolescents and youth with type 2 diabetes, there is insufficient evidence to make recommendations.

Common barriers to pump therapy adoption in children and adolescents are concerns regarding the physical interference of the device, discomfort with the idea of having a device on the body, therapeutic effectiveness, and financial burden (191,201).

Sensor-Augmented Pumps

Sensor-augmented pumps (or partial closed-loop systems) consist of three components: an insulin pump, a CGM system, and an algorithm that automates insulin suspension when glucose is low or is predicted to go low within the next 30 min, and these systems have been approved by the FDA. The Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial of 247 people with type 1 diabetes showed that sensor-augmented insulin pump therapy with a low-glucose suspend function significantly reduced nocturnal

hypoglycemia over 3 months without increasing A1C levels (61). In a different sensor-augmented pump, predictive low-glucose suspend reduced time spent with glucose <70 mg/dL from 3.6% at baseline to 2.6% (3.2% with sensor-augmented pump therapy without predictive low-glucose suspend) without rebound hyperglycemia during a 6-week randomized crossover trial (202). These devices may offer the opportunity to reduce hypoglycemia for those with a history of nocturnal hypoglycemia. Additional studies have been performed in adults and children that show the benefits of this technology (203–205).

Automated Insulin Delivery Systems

AID systems increase and decrease insulin delivery based on sensor-derived glucose levels to mimic physiologic insulin delivery. These systems consist of three components: an insulin pump, a CGM system, and an algorithm that determines insulin delivery. All AID systems on the market today adjust basal delivery in real time, and some deliver correction doses automatically. While insulin delivery in closed-loop systems eventually may be truly automated, currently used AID systems require the manual entry of carbohydrates consumed or qualitative meal estimation announcements to calculate prandial doses, and adjustments for physical activity must be announced in most systems. Multiple studies using various systems with varying algorithms, pumps, and sensors have been performed in adults and children (206–218). Evidence suggests AID systems reduce A1C levels and improve TIR (219–231). They may also lower the risk of exercise-related hypoglycemia (231) and may have psychosocial benefits (232–236). The use of AID systems depends on the preference of the person with diabetes and the selection of individuals (and/or caregivers) who are capable of safely and effectively using the devices.

The data from real-world studies on AID systems have substantiated the results observed in RCTs and have confirmed the clinical benefits of AID systems in people with type 1 diabetes. Benefits include improvement in A1C levels, TIR, and other glucometrics as well as psychosocial benefits (237–242).

Finally, real-world data showed that AID systems provide the same glycemic benefits to Medicare and Medicaid beneficiaries with type 1 and type 2 diabetes, emphasizing that access to this technology should be made available regardless of A1C levels and should be based on the individual's needs (243).

Automated Insulin Delivery Systems in Pregnancy

The use of AID systems in diabetes and pregnancy presents particular challenges, as none of the current FDA-approved systems have glucose goals that are pregnancy specific or algorithms designed to achieve pregnancy-specific glucose goals. Initiating or continuing AID systems during pregnancy needs to be assessed carefully. Selected individuals with type 1 diabetes should be evaluated as potential candidates for AID systems in the setting of expert guidance. Moreover, if the decision is made to use these systems in selected pregnant individuals, then using assistive techniques, such as the combination of sensor-augmented pump mode and hybrid closed-loop mode at different time points in pregnancy or throughout the day, should be considered and applied as needed to achieve intended goals (244). See Section 15, "Diabetes and Pregnancy," for more details.

Insulin Pumps in People With Type 2 and Other Types of Diabetes

Traditional insulin pumps can be considered for the treatment of people with type 2 diabetes who are on MDI as well as those who have other types of diabetes resulting in insulin deficiency, for instance, those who have had a pancreatectomy and/or individuals with cystic fibrosis (245–249). Similar to data on insulin pump use in people with type 1 diabetes, reductions in A1C levels have been reported in some studies (247,250). More recently, real-world reports have shown reduction of A1C levels and reduction of total daily insulin dose in individuals with type 2 diabetes initiating insulin pump therapy (251). Use of insulin pumps in insulin-requiring people with any type of diabetes may improve user satisfaction and simplify therapy (180,245).

For people with diabetes judged to be clinically insulin deficient who are treated with an intensive insulin therapy, the presence or absence of measurable C-peptide levels does not correlate with response to therapy (180). A low C-peptide value should not be required for insulin pump coverage in individuals with type 2 diabetes.

The use of insulin pumps and AID systems in type 2 diabetes is still limited; however, real-world studies have shown benefits of these technologies in these individuals (243,252).

Alternative insulin delivery options in people with type 2 diabetes may include disposable patch-like devices, which provide either a CSII of rapid-acting insulin (basal) with bolus insulin in 2-unit increments at the press of a button or bolus insulin only delivered in 2-unit increments used in conjunction with basal insulin injections (246,248,253,254). Use of an insulin pump as a means of insulin delivery is an individual choice for people with diabetes and should be considered an option in those who are capable of safely using the device.

Do-It-Yourself Closed-Loop Systems

Recommendation

7.31 Individuals with diabetes may be using systems not approved by the FDA, such as do-it-yourself closed-loop systems and others; health care professionals cannot prescribe these systems but should assist in diabetes management to ensure the safety of people with diabetes. **E**

Some people with type 1 diabetes have been using do-it-yourself systems that combine an insulin pump and an rtCGM with a controller and an algorithm designed to automate insulin delivery (255–259). Data are emerging on the safety and effectiveness of specific systems (260,261). However, these systems are not approved by the FDA, although efforts are underway to obtain regulatory approval for some of them. The information on how to set up and manage these systems is freely available on the internet, and there are internet groups where people inform each other as to how to set up and use them. Although health care professionals cannot prescribe these systems, it is crucial to keep people with diabetes safe if they are using these methods for AID. Part of this entails ensuring people have a backup plan in case of pump failure. Additionally, in most do-it-yourself systems, insulin doses are adjusted based on the pump settings

for basal rates, carbohydrate ratios, correction doses, and insulin activity. Therefore, these settings can be evaluated and modified based on the individual's insulin requirements.

Digital Health Technology

Recommendation

7.32 Systems that combine technology and online coaching can be beneficial in managing prediabetes and diabetes for some individuals. **B**

Increasingly, people are turning to the internet for advice, coaching, connection, and health care. Diabetes, partly because it is both common and numeric, lends itself to the development of apps and online programs. Recommendations for developing and implementing a digital diabetes clinic have been published (262). The FDA approves and monitors clinically validated, digital, and usually online health technologies intended to treat a medical or psychological condition; these are known as digital therapeutics or "digiceuticals" (fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications) (263). Other applications, such as those that assist in displaying or storing data, encourage a healthy lifestyle or provide limited clinical data support. Therefore, it is possible to find apps that have been fully reviewed and approved by the FDA and others designed and promoted by people with relatively little skill or knowledge in the clinical treatment of diabetes. There are insufficient data to provide recommendations for specific apps for diabetes management, education, and support in the absence of RCTs and validation of apps unless they are FDA cleared.

An area of particular importance is that of online privacy and security. Established cloud-based data aggregator programs, such as Tidepool, Glooko, and others, have been developed with appropriate data security features and are compliant with the U.S. Health Insurance Portability and Accountability Act of 1996. These programs can help monitor people with diabetes and provide access to their health care teams (264). Consumers should read the policy regarding data privacy and sharing before entering data into an application and learn how they can control the way their data will be used (some programs offer the ability to share more or less information, such as being part of a registry or data repository or not).

Many online programs offer lifestyle counseling to achieve weight loss and increased physical activity (265). Many include a health coach and can create small groups of similar participants on social networks. Some programs aim to treat prediabetes and prevent progression to diabetes, often following the model of the Diabetes Prevention Program (266,267). Others assist in improving diabetes outcomes by remotely monitoring clinical data (for instance, wireless monitoring of glucose levels, weight, or blood pressure) and providing feedback and coaching (268–273). There are text messaging approaches that tie into a variety of different types of lifestyle and treatment programs, which vary in terms of their effectiveness (274,275). There are limited RCT data for many of these interventions, and long-term follow-up is lacking. However, for an individual with diabetes, opting into one of these programs can be helpful in providing support and, for many, is an attractive option.

Inpatient Care

Recommendations

7.33 In people with diabetes using personal CGM, the use of CGM should be continued when clinically appropriate during hospitalization, with confirmatory point-of-care glucose measurements for insulin dosing and hypoglycemia assessment and treatment under an institutional protocol. **B**

7.34 People with diabetes who are competent to safely use diabetes devices such as insulin pumps and CGM systems should be supported to continue using them in an inpatient setting or during outpatient procedures, whenever possible, and when proper supervision is available. **E**

Individuals who are comfortable using their diabetes devices, such as insulin pumps and CGM, should be allowed to use them in an inpatient setting if they are well enough to take care of the devices and have brought the necessary supplies (275–279). People with diabetes who are familiar with treating their own glucose levels can often adjust insulin doses more knowledgeably than inpatient staff who do not personally know the individual or their management style. However, this should occur based on the hospital's policies for diabetes management and use of diabetes technology, and there should be supervision to ensure that the individual is achieving and maintaining glycemic goals during acute illness in a hospitalized setting where factors, such as infection, certain medications, immobility, changes in nutrition, and others, can impact insulin sensitivity and the insulin response (280–282).

With the advent of the coronavirus disease 2019 pandemic, the FDA exercised enforcement discretion by allowing CGM device use temporarily in the hospital for patient monitoring (283). This approach has been used to reduce the use of personal protective equipment and more closely monitor patients so that health care personnel do not have to go into a patient room solely to measure a glucose level (284–286). Studies have been published assessing the effectiveness of this approach, which may ultimately lead to the approved use of CGM for monitoring hospitalized individuals (278,287–296). When used in the setting of a clinical trial or when clinical circumstances (such as during a shortage of personal protective equipment) require it, CGM can be used to manage hospitalized individuals in conjunction with BGM. Point-of-care BGM remains the approved method for glucose monitoring in hospitals, especially for dosing insulin and treating hypoglycemia. Similarly, data are emerging on the inpatient use of AID systems and their challenges (278,297,298). For more information, see Section 16, "Diabetes Care in the Hospital."

The Future

The pace of development in diabetes technology is extremely rapid. New approaches and tools are available each year. It is difficult for research to keep up with these advances because newer versions of the devices and digital solutions are already on the market by the time a study is completed. The most important component in all of these systems is the person with diabetes. Technology selection must be appropriate for the individual. Simply having a device or application does not change outcomes unless the human being engages with it to create positive health benefits. This underscores the need for the health care

team to assist people with diabetes in device and program selection and to support their use through ongoing education and training. Expectations must be tempered by reality—we do not yet have technology that completely eliminates the self-care tasks necessary for managing diabetes, but the tools described in this section can make it easier to manage.

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Continuous glucose monitors and virtual care in high-risk, racial and ethnic minority populations: Toward promoting health equity

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Continuous glucose monitors (CGMs) have become an important tool to aid self-management of blood glucose for many patients with diabetes in the U.S., and the benefits of CGM use are well-documented. However, disparities in CGM use exist, with lower use in certain marginalized racial and ethnic groups. CGM may be an important and underutilized tool to help reduce inequities. Evidence supporting the use of CGMs as a part of virtual care is discussed, with an emphasis on designing virtual diabetes care programs to promote health equity. Recommendations for clinical practice and research are presented. In clinical practice, CGM should be an option for all people with diabetes who qualify based on clinical practice guidelines, regardless of race, ethnicity, or other individual characteristics. Future research should characterize the use of, benefit from, and preferences for CGM among individuals from racial and ethnic groups to guide interventions at the health system, clinic, provider, and patient levels to promote equitable, evidence-based, and guideline-directed CGM use in marginalized racial and ethnic groups with diabetes.

KEYWORDS

diabetes, continuous glucose monitor (CGM), disparities, virtual care, race & ethnicity

1 Introduction

Approximately 37 million people in the U.S. had diabetes in the year 2021 (1). Decades of research have documented health disparities in diabetes, with individuals from marginalized racial and ethnic groups experiencing excess risk of diabetes incidence, prevalence, complications, and mortality (2). Improving diabetes management and outcomes in populations of health inequity is a priority for research and public health organizations (3–5). Recent studies demonstrate that, while rates of diabetes-related complications are decreasing in the U.S., rates continue to rise in Black and Hispanic persons with diabetes (6, 7). Lowering blood glucose is directly associated with lower rates of diabetes complications

(8), making self-monitoring of blood glucose a key component of diabetes management (9). Continuous glucose monitoring (CGM) has emerged as an important tool to support self-monitoring of blood glucose and may be an important tool to help reduce inequities.

Well-conducted, large randomized controlled trials and prospective studies demonstrate that CGM improves A1C, reduces diabetes-related hospitalizations and emergency room visits, reduces the frequency of dysglycemia, reduces diabetes distress, and improves quality of life in people with diabetes on intensive insulin regimens (10–16). In addition to improving health and well-being, CGMs offer a simplified, automated approach to blood glucose monitoring that removes many hassles of daily diabetes self-management.

Recent reviews have summarized that CGM use is lower in Black/African American and Latinx American populations, relative to the White American population (17, 18). These same marginalized groups engage in lower rates of self-monitoring of blood glucose (19) and face challenges in traditional health care due to limited access to and quality of care, racism and bias in care, and social determinants. CGMs may be an important and underutilized tool to help reduce inequities.

In this paper, we summarize disparities in CGM use, barriers to equitable CGM use, and opportunities for using CGM in diverse populations as a part of virtual diabetes care to help reduce inequities. Additionally, we identify knowledge gaps and provide recommendations for research and clinical practice to promote equitable and guideline-directed diabetes care that leverages CGM, particularly as a part of virtual care.

2 Clinical practice guidelines and indications for CGM use

Several clinical practice guidelines developed by diabetes-focused professional organizations provide recommendations for CGM use for people with diabetes (20–22). The American Diabetes Association's (ADA) Standards of Medical Care in Diabetes recommends that CGM should be offered to adults and youth with diabetes on multiple daily injections or continuous subcutaneous insulin; they additionally recommend that CGM can be used by adults with diabetes on basal insulin (20). In consensus, the American Association of Clinical Endocrinology's (AACE) Clinical Practice Guidelines state that CGM is recommended for all persons with diabetes treated with intensive insulin therapy, and CGM may be recommended for individuals with type 2 diabetes (T2D) who are treated with less intensive insulin therapy (21). Uniquely, AACE's guidelines recommend CGM for individuals with problematic hypoglycemia. Although some recommendations vary across guidelines, CGM is consistently recommended for individuals with diabetes who are treated with intensive insulin regimens, with stipulation that treatment using CGM should be individualized and be offered to those who are willing and capable.

Practice guidelines are clear that CGM use is beneficial for people with T1D across the lifespan (23), and CGM adoption is increasingly common for many people with T1D (24). Practice guidelines are not definitive regarding CGM use in people with T2D. A few clinical trials in people with T2D on intensive insulin regimens have demonstrated that CGM improves hemoglobin A1C and reduces hypoglycemia (12, 14), but little is known about benefits of CGM in individuals on noninsulin or less intensive insulin regimens (25). However, The ADA's Standards of Care state that routine glucose monitoring may be helpful for adults with T2D who are not on insulin to elucidate the impact of diet, activity, and medication on glucose levels (20).

3 Disparities in CGM use

Despite clinical practice guidelines endorsing CGM use and strong evidence demonstrating the benefit of CGM, rates of CGM adoption remain low, particularly in marginalized groups. Recent reviews summarizing disparities in diabetes technology use conclude that rates of CGM use vary by race and ethnicity, with lower use in historically marginalized racial and ethnic populations (17, 18). To expand upon these reviews, characteristics of the extant studies examining CGM use by race and ethnicity are reported in Table 1. Only one new study has been published since the most recent review in this area (2022) (17). Kanbaour et al., 2023 conducted a retrospective clinic-based cohort study of 1,258 adults with T1D who received care between 2013-2020 (28). The authors report that, relative to non-Black adults, Black adults were less likely to use CGM at baseline and were less likely to initiate CGM over the study period. This study aligns with prior studies in this area, which demonstrate that CGM use is lower in non-Hispanic Black and Hispanic individuals with T1D across all age ranges, relative to non-Hispanic Whites (26, 27, 29, 30). As explained by Agarwal et al., 2022, these disparities persist after adjusting for socioeconomic status, education level, insurance, health literacy, numeracy, diabetes clinical outcomes and management factors, and care setting (17). Therefore, lower use in people with T1D from these marginalized racial and ethnic groups occurs independently of objective clinical decision-making factors.

3.1 Barriers to equitable CGM use

Factors that have the potential to cause disparities in CGM use among people with T1D and T2D have been proposed (17, 18), including provider, health system/structural, and insurance barriers that cause people with diabetes from marginalized racial and ethnic groups to have less access to CGMs.

Healthcare providers hold an important responsibility to educate patients about their treatment options and engage with patients in shared decision-making. Bias, both implicit and explicit, may contribute to providers' perceptions of patients' interest, willingness, capacity, and financial ability to obtain and effectively use CGM devices. Provider implicit bias has been documented across a variety of provider and patient populations (31). Of relevance to CGM use, a few studies document provider implicit bias to recommend diabetes technology based on insurance (32, 33) and race or ethnicity (33). Relatedly, a recent clinic-based retrospective study demonstrated that, relative to non-Black adults, Black adults with T1D were less likely to discuss CGMs with their providers and be prescribed a CGM than non-Black adults (see Table 1) (28). It is plausible that providers may eliminate CGM as an option for members of marginalized groups based on biases, stereotypes, and generalizations regarding factors such as health literacy, socioeconomic status, and social contexts affecting their ability to take on new treatment regimens; however, this is an area requiring

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TABLE 1 Characteristics of studies examining CGM use by race and ethnicity.

Authors	Study Design	Study Participants & Setting	Analysis	Adjustment for Covariates	Results
Agarwal et al., 2021 (26)	Cross-sectional	300 young adults (18-28 years) with T1D recruited from six T1D Exchange clinic sites (the Young Adult Racial Disparities in T1D Study)	% CGM use by race and ethnicity; statistical differences between groups determined by χ^2 test; % CGM use by race and ethnicity with adjustment based on multivariate logistic regression	Demographic factors, socioeconomic status, insurance status, health literacy, clinic attendance, care site, and diabetes-management factors	CGM use was lower among Black (28%) and Hispanic (37%) than among White (71%) young adults (*ps* <.001); there were no differences between Black and Hispanic young adults. After adjustment for covariates, percentage differences between groups attenuated; CGM use was lower among Black (31%) than among White (53%) and Hispanic (58%) young adults[±].
Foster et al., 2019 (27)	Retrospective study	22,697 adults and children (1-93 years) enrolled in the T1D Exchange clinic registry from 2016-2018	% CGM use stratified by race and ethnicity, age category, and income level	No adjustment Results are stratified by age and income	CGM use was lower among Black than among White adults across all age ranges and income levels.
Kanbour et al., 2023 (28)	Retrospective clinic-based cohort	1,258 adults (≥18 years) with T1D who received care at a comprehensive diabetes center clinic from 2013-2020	% CGM use by race and ethnicity; statistical differences between groups determined by χ^2 test; Multivariate logistic regression with race (Black vs. non-Black) and covariates as IVs and CGM discussions and prescribing by a physician as DVs in separate analyses	Demographic factors, employment status, neighborhood status, insurance type, number of diabetes visits, other diabetes technology use, tobacco use, substance use, anxiety/depression, diabetes-related clinical values	Black adults were less likely than non-Black adults to use CGM at baseline (7.9% vs. 30.3%), initiate CGM over the study period (43.6% vs. 72.1%), discuss CGMs with their provider (79.6% vs. 91.7%), and be prescribed a CGM (50.0% vs. 68.4%; all *ps* <.001). In multivariate logistic regression analysis, Black adults were less likely to discuss CGMs with their provider (OR = 0.51; 95% CI 0.29, 0.90) and be prescribed a CGM (OR = 0.61; 95% CI 0.41, 0.93) than non-Black adults[±].
Lai et al., 2021 (29)	Retrospective chart review	1,509 children (<17 years) with T1D who received care at an urban children's hospital from 2015-2018	Multivariate logistic regression with race and ethnicity and covariates as IVs and CGM initiation as DV	Insurance type, age of diagnosis, and sex	CGM initiation was more frequent among White than among Black (OR=2.2, 95% CI=1.6-3) or Hispanic children (OR = 2.0, 95% CI 1.3-3) [±].
Fantasia et al., 2021 (30)	Retrospective chart review	227 adults (≥18 years) with T1D seen in an Endocrinology clinic in a safety-net hospital from 2016-2017	% technology use by race and ethnicity; Multivariate logistic regression with race and ethnicity and covariates as the IVs and CGM use as the DV	Age, language, insurance, and annual income	Technology use was lower in Black adults (OR = 0.25, 95% CI = 0.11-0.56) and "Other" race or ethnicity adults (OR = 0.30, 95% CI = 0.11-0.78) than among White adults[±].

CGM, continuous glucose monitor; DV, dependent variable; IV, independent variable; T1D, type 1 diabetes; [±], adjusted analysis.

further study. Critically, these perceived barriers to using CGM are the same reasons why CGM is important to use in marginalized populations with diabetes who may benefit from automated and simplified daily diabetes routines.

People with diabetes may not be aware that CGM is an option or that insurance may cover the cost of the device. This may be especially the case among marginalized populations with limited healthcare access and suboptimal quality of care (34–38). Social determinants of health are systemic, structural barriers caused by the conditions in which people are born, grow, work, live, and age (39). Social determinants of health include socioeconomic status, neighborhood and physical environment, food environment, health care access/affordability/quality, and social contexts (40). In the U.S., these social determinants adversely affect marginalized populations and are directly associated with worse diabetes-related outcomes (40). In the setting of structural barriers to optimal diabetes management, it is even more imperative that the most effective treatment tools, including CGM, be made available.

The high cost of CGM and restrictive insurance policies are a barrier to CGM use. Based on data from the T1D Exchange, the most common barriers to CGM initiation and use are the cost of CGM and insurance coverage (41, 42). Insurance policies impose restrictions on who is eligible for CGM and require rigorous documentation from providers to demonstrate medical necessity (43, 44), requiring patients to have high-quality and consistent care by knowledgeable providers to facilitate CGM insurance coverage. Additionally, some insurance policies require patients to obtain CGMs through durable medical equipment suppliers (43), rather than through pharmacies in local communities. There is evidence demonstrating that obtaining CGM as a pharmacy benefit is faster than through durable medical equipment companies, thus reducing time-to-initiation of CGM (45). As added challenges, insurance policies for CGM coverage vary by

insurance provider and evolve in response to advances in diabetes technology and most recently the COVID-19 pandemic. In response to the pandemic, the Centers for Medicare and Medicaid (CMS) updated policies to reduce barriers to CGM access by eliminating requirements for in-person visits, lab tests, and documented finger sticks (46). However, it is unclear whether these changes will persist, and challenges remain (47). Some private insurance does not cover CGM for T2D (48). Emerging evidence indicates that access to CGM varies by region within the US due, in part, to insurance coverage (49). Illustratively, Southeast states (e.g., Texas, Arkansas, Mississippi) have the lowest CGM use through Medicaid in the US (49). Variable and limited use of CGM in Medicaid beneficiaries may be due to variability in policies by state (43). As of 2022, Medicaid in 40 states covers CGM in some capacity, with variability in coverage based on diabetes-specific documentation (e.g., documentation of hypoglycemic episodes, hypoglycemia unawareness, and insulin pump use), prescriber qualifications (e.g., some states limit to endocrinologists only), need for preauthorization, coverage for people with type 2 diabetes, coverage for children, and locale of prescription fill (durable medical equipment supplier versus pharmacy). In July 2021, the requirement of documenting 4 blood glucose measurements *via* fingerstick per day was eliminated to increase access to CGM, particularly in the context of the COVID-19 pandemic. Medicaid policies by state are discussed comprehensively in a report from the Center for Healthcare Strategies (43). Critically, Medicaid enrollees are least likely to use a CGM, with particularly low rates of use among Black Americans and Hispanic individuals (50), highlighting the potential impact of insurance policies on CGM use disparities.

4 CGM use in virtual diabetes care

The COVID-19 pandemic precipitated an abrupt shift toward virtual care for ambulatory health services. In the post-pandemic era, there continues to be a role for telehealth and health technology, which improve care in some instances and circumvent barriers such as limited access, transportation, or time to attend medical visits (51, 52). Clinical practice guidelines for diabetes recommend visits with a provider every 3-6 months to measure hemoglobin A1C, conduct a physical exam, measure vitals, and review the treatment plan (53). It has been proposed that telehealth can reduce the frequency of in-person visits for some patients with diabetes (54). However, telehealth limits the physician's ability to conduct physical exams and measure clinical values. To augment telehealth, there has been interest in the use of technology for remote patient monitoring.

In diabetes virtual care, CGM devices allow for remote monitoring of blood glucose. Blood glucose values can automatically be collected, uploaded, and accessible to providers, allowing for real-time monitoring between visits and providing a wealth of data to guide treatment decision-making. Moreover, time spent interpreting CGM data is billable through insurance, promoting the sustainability of provider review of blood glucose records (44). For people with diabetes, CGM as a part of diabetes virtual care has the potential to empower patients to leverage their blood glucose data to guide daily decisions about diabetes self-management behaviors between visits.

Evidence suggests that it is feasible and acceptable to implement CGM remotely *via* telehealth without the need for in-office visits. A qualitative study among parents of youth with T1D demonstrated that telehealth CGM initiation was well-accepted (55). Another study in a small sample (n=34) of predominantly White (85%) adults with T1D and T2D using insulin demonstrated that the telehealth CGM initiation, delivered by a diabetes educator, was feasible and improved A1C and diabetes distress (56). Additionally, a study among adults with T2D found that a virtual diabetes clinic that incorporated a mobile application, telehealth visits with an endocrinologist, and CGM use improved A1C and reduced hyperglycemia and diabetes distress (57, 58). These findings suggest that virtual models of diabetes care leveraging CGM can work, although larger trials should be conducted in more representative samples. It is the case, however, that in practice CGM initiation is frequently done *via* self-initiation with online video instruction and education provided by the device manufacturers.

5 Disparities in smartphone ownership and internet access: Potential impact on CGM use

Although CGMs can operate without a smartphone or internet access (i.e., by using a reader to obtain glucose data from the CGM sensor), CGM use is optimal when people can view their glucose data on their smartphones and share their blood glucose data with their providers using an internet connection. Therefore, the use of continuous glucose monitors relies, in great part, on access to and proficiency with using smartphones and the internet. Rates of smartphone ownership and internet access in the US are increasing, but unique trends that vary by race and ethnicity and location warrant attention (see Table 2). Within the last decade, rates of smartphone ownership increased from 56% in 2013 (59) to 81% in 2019 (60). In 2019, rates of smartphone use were generally similar across race and ethnicity groups, but use appeared lower among rural relative to urban and suburban locations. In contrast, broadband internet access has remained relatively stable over time, with only slight increases between 2013 (61) and 2019 (60). Notably, internet access at home appears lower in Black or African American and Hispanic individuals relative to White individuals and lower in rural relative to urban and suburban locations. There has been a stark increase over time in "Smartphone Only" internet use. Between 2013 (61) and 2019 (60), rates of accessing the internet at home with only a smartphone increased from 8% to 17% among US adults, with higher rates in Black or African American and Hispanic individuals relative to White individuals and higher rates in rural and urban relative to suburban locations. In sum, rates of smartphone use are on the rise. Although members of racial and ethnic minoritized groups continue to have limited broadband internet access, they are emergingly accessing smartphones and relying on their smartphones for internet access from home.

Trends in smartphone ownership and internet access should be considered as efforts are taken to promote equitable CGM use and diabetes technology use. Health care team members should discuss smartphone and internet access with patients when collaboratively

TABLE 2 Smartphone ownership and internet access patterns in the U.S. by race and ethnicity and by location, 2013-2019.

	Smartphone Ownership†		Broadband Internet Access at Home†		"Smartphone Only" Internet Use†	
	2013	2019	2013	2019	2013	2019
US Adults, %	56	81	70	73	8	17
Race/Ethnicity						
White, %	53	82	74	79	8	12
Black or African American, %	64	80	62	66	10	23
Hispanic, %	60	79	53	61	16	25
Location						
Urban, %	59	83	70	75	9	17
Suburban, %	59	83	73	79	7	13
Rural, %	40	71	62	63	9	20

†Data obtained from the Pew Research Center (60-62).

evaluating the option of using CGM. Researchers using CGM in their studies should confirm smartphone ownership and internet access for their participants and, in cases where access is limited, provide connected devices to circumvent selective recruitment based on access. Health systems and policymakers should attend to these trends and disparities in the use of and access to devices and the internet, particularly as technology and telehealth continue to become an important part of healthcare delivery.

6 Equitable virtual care in diabetes

It is a common assumption that virtual care models have the potential to address barriers faced by marginalized populations. For instance, virtual care has the capacity to improve access to health care providers and clinics, eliminate transportation barriers, and allow appointments to be conducted where people live and work, thus reducing conflicts due to work schedules and personal/family responsibilities. Yet, it has been documented that virtual care can increase healthcare disparities (62–64). Commonly discussed is the "digital divide," a term that describes disparities in access to digital devices and internet connection (65). Even among those with access to devices, there are further disparities in digital literacy (i.e., knowledge and skills to use technology effectively) (66–68) that may contribute to disparities in technology use outcomes. Moreover, accessing and using CGM technology may be limited by language barriers and device compatibility, as some CGM applications are available in English only and are compatible with a limited range of smartphone devices and operating systems (69).

To prevent disparities in access to, use of, and outcomes of virtual care, telehealth and health technology should be intentionally designed to promote equity. Weiss et al. report that the impact of health technology on health disparities depends on a particular community's context and pathways through which they use and access the technology (70). Additionally, African American individuals expressed that past abuses by the U.S. medical system affect their views on new and innovative medical care (71). Shaw et al. provide recommendations to improve health equity in virtual care in the context of COVID-19 (64). Key recommendations were to engage marginalized community members in the planning and evaluation of virtual care programs, simplify complex interfaces and workflows, and leverage supportive intermediaries to help patients engage with virtual care. These recommendations are applicable to integrating CGM use in a virtual care environment with marginalized groups.

7 Recommendations for research and clinical practice

In order to design virtual care models using CGM that are effective and meaningful for people with diabetes from marginalized racial and ethnic groups, we must first characterize rates of CGM use, benefits of CGM use, and patient preferences around CGMs and diabetes virtual care, within each race and ethnic group. Research funding should be directed specifically to supporting research in marginalized populations. Consistent with these needs, research recommendations are summarized in Table 3 and described below.

First, research is needed to examine the rates of CGM use within marginalized groups with T1D and T2D, including Black/African American, Native American, Latinx American, and Asian American groups. Although studies of disparities in CGM use provide a signal of low use in some groups with T1D, no study has reported rates of use in Native American and Asian American groups with T1D, and no study has reported rates of use in people with T2D by race and ethnicity.

Second, research is needed to characterize the effect of CGM use on diabetes-related clinical, behavioral, and psychosocial outcomes within marginalized populations, including Black or African American, Native American, Latinx American, and Asian American groups. It is well-established that CGM improves clinical and behavioral outcomes on the aggregate, but, to our knowledge, no study has reported the benefits of CGM in each racial and ethnic group. This represents a critical gap in our understanding of the potential benefit of CGM in diverse communities with diabetes.

Third, there is a need to conduct qualitative research to understand diverse patient perspectives on CGM use and diabetes virtual care. Soliciting patient perspectives will elucidate the preferences, barriers, and needs of diverse communities related to

TABLE 3 Research and clinical recommendations for CGM use in marginalized populations as a component of diabetes virtual care.

Domain	Specific Recommendations
Research Recommendations	1. Characterize the rates of CGM use within marginalized groups with T1D and T2D, including Black or African American, Native American, Latinx American, and Asian American groups. 2. Characterize the effect of CGM use on diabetes-related clinical, behavioral, and psychosocial outcomes within marginalized groups, including Black or African American, Native American, Latinx American, and Asian American groups. 3. Conduct qualitative research to understand diverse patient perspectives of CGM use and diabetes virtual care. 4. Design, evaluate, and implement culturally relevant and meaningful interventions for CGM use as a component of virtual care, based on the formative research, above, and in alignment with clinical practice guidelines
Clinical Recommendations	1. Develop population-based approaches to: a) systematically provide education about the option of CGM to all people with diabetes to support shared decision-making related to imitating CGM, and b) systematically identify patients who may qualify for CGM based on clinical practice guidelines, regardless of race, ethnicity, or other individual characteristic. 2. Deliver evidence-based and meaningful education and support programs for CGM initiation and maintenance that are tailored to the needs, preferences, and challenges of that individual and their community. 3. Design diabetes virtual care models to promote equity by involving marginalized community members in the planning and evaluation of virtual care to ensure the programs align with the community's needs and preferences. 4. Incorporate CGM into diabetes virtual care to augment remote monitoring of blood glucose for providers and patients to leverage as a part of shared-decision-making, treatment planning, and daily diabetes management.

CGM, continuous glucose monitoring, T1D, type 1 diabetes, T2D, type 2 diabetes.

the use of diabetes technology and telehealth, which will guide the development of interventions and clinical operations at the health system, provider, and patient levels to promote equitable, guideline-directed care using CGMs. Illustratively, in a qualitative analysis of Black and Latinx individuals who dropped out of a diabetes telehealth study, themes emerged around disinterest, inconvenience, and lack of perceived benefit (72). In the broader diabetes literature, qualitative studies document patient preferences and perspectives. A study among African American adults with diabetes identified that shared decision-making was affected by providers' bias, discrimination, and cultural discordance as well as patients' mistrust of White physicians and internalized racism (73). A study among predominantly Mexican American people with diabetes reported that the telephone-based intervention approach may be impersonal and may impede the establishment of a trusting bond (74). Additionally, providers' cultural and linguistic competence is essential to develop a trusting patient-provider relationship for Hispanic adults with diabetes (75). Another qualitative study reported that African American and Latino individuals share concerns about confidentiality and the physical absence of the provider in telemedicine (71). This collection of findings provides insights, but future qualitative research should directly examine preferences related to CGM use and diabetes virtual care.

Finally, preliminary evidence demonstrates that CGM can be initiated *via* telehealth (56) and that diabetes virtual care that incorporates CGM is feasible and improves outcomes (57, 58). However, there is a need to design, evaluate, and implement culturally relevant and meaningful interventions for CGM use as a component of virtual care, based on the formative research, above, and in alignment with clinical practice guidelines.

In clinical practice, increasing CGM access and use in diverse populations will require widespread changes for health systems, clinics, and providers. Fundamentally, CGM should be offered to all patients who may qualify based on clinical practice guidelines, regardless of race, ethnicity, or other individual characteristics. Implicit bias and discrimination in health care may impact providers' prescribing practices for diabetes technology (32, 33), even among qualified and well-meaning providers. Interventions to reduce bias in care increase provider awareness but do not result in sustained behavior change (76). To circumvent provider bias in CGM prescription, population-based approaches can be developed to systematically provide education about the option of CGM to all people with diabetes and identify the population of patients who may qualify for CGM based on clinical practice guidelines. For instance, patient registries can be developed from the electronic medical record to identify patient populations (e.g., diagnosed with T1D or T2D and on intensive insulin regimens). Members of the health care team can engage with every patient with diabetes to provide education on the option of CGM and its benefits/limitations to empower patients with knowledge to effectively engage with providers in shared decision-making.

For patients who will initiate CGM, the healthcare team should deliver evidence-based, meaningful education and support programs for CGM initiation and maintenance that are tailored to the needs, preferences, and challenges of that individual. Members of the healthcare team who engage patients in these conversations should be culturally aware and knowledgeable about CGM. Social determinants of health should be assessed and incorporated into interventions, as they influence many facets of diabetes treatment and decision-making.

Marginalized populations face barriers to obtaining high-quality care. The shift to virtual care in the wake of the COVID-19 pandemic presented an opportunity to address these barriers through telehealth and technology. Diabetes virtual care should be designed to promote equity by involving marginalized community members in planning and evaluation to ensure the programs align with the community's needs and preferences. Virtual care should consider device access and digital literacy and should engender a trusting relationship in the absence of in-person interaction. CGM devices can be incorporated into diabetes virtual care to augment remote monitoring of blood glucose for providers and patients to leverage as a part of shared decision-making and diabetes management.

8 Conclusions

Disparities in access to and use of CGM in historically marginalized racial and ethnic populations contribute to widening of, rather than reduction in, long-standing disparities in diabetes outcomes in the U.S. It is well-established that CGM use improves the health and well-being of many patients with diabetes (11, 15, 16). However, there is a need to increase access to CGM and to characterize the use and potential benefit of CGM use in diverse populations.

The causes of disparities in CGM use are complex and multifactorial, and strategies to address these disparities will require widespread changes, including policy changes, with multilevel interventions at the health system, provider, and patient levels. Yet, CGMs may be particularly beneficial for marginalized populations with diabetes, who stand to benefit the most from improved blood sugar management and simplified, automated approaches to daily diabetes management. CGMs may be an important and underutilized tool to help reduce inequities in diabetes care and outcomes, particularly when used in virtual diabetes care.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding author.

Author contributions

EV contributed to the conceptualization, literature review, synthesis of literature, and draft writing. FH-B, PE, AM, PG, and SF contributed to the conceptualization, article identification, and review of drafts. SF and FH-B additionally contributed to the identification and refinement of recommendations. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Health Equity and Diabetes Technology:
A Study of Access to Continuous Glucose Monitors by Payer and Race
Executive Summary

Background

Approximately 122 million Americans live with diabetes or prediabetes. One and a half million Americans are newly diagnosed with diabetes each year, and in the past 20 years, the number of adults diagnosed with diabetes has more than doubled. Diabetes increases adult risk of premature death by 60 percent. These figures, especially the risk of diabetes-related complications and morbidity, are even more pronounced among medically underserved communities, low-income communities, and people of color. Today, 38 million Americans live in poverty, and 76 percent of Americans living in poverty are people of color. Diabetes prevalence is inversely related to household income level, with the poorest communities seeing the highest rates of the condition. For example, according to the NIH, those who earn less than $30,000 per year are three times as likely to have diabetes than those who make more than $80,000 per year.

For all people living with diabetes, continuous glucose monitors (CGM) provide significant, potentially life-changing benefits for diabetes management and in turn for avoidance or delay of serious co-morbidities, hospitalizations and even death. A CGM provides much greater detail to patients and their health care providers than traditional blood glucose meters do regarding an individual's blood glucose levels, offering opportunities to analyze patient data more granularly than was previously possible and providing additional information to aid in achieving glycemic targets. CGMs also provide biofeedback in real time, allowing individuals with diabetes to modify their diet and insulin dose as needed in consultation with their health care provider. As a result, individuals with Type 1 and Type 2 diabetes who use a CGM are shown to have less hypoglycemia, and they experience a reduction in their average blood glucose (A1C).

According to the American Diabetes Association's (ADA) Standards of Care:

> CGM is essential for creating the ambulatory glucose profile (AGP) and providing data on time in range, percentage of time spent above and below range, and variability. Access to CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management. This allows for close tracking of glucose levels with adjustments of insulin dosing

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> and lifestyle modifications and removes the burden of frequent [self-monitoring of blood glucose]. Interruption of access to CGM is associated with a worsening of outcomes; therefore, it is important for individuals on CGM to have consistent access to the devices.

Access to CGM technology is extremely important given its clear benefits, especially for those communities experiencing an outsized impact of diabetes. Prior studies have shown that access to health insurance is the strongest single predictor of whether adults with diabetes are likely to receive high quality diabetes care. Compared with insured adults with diabetes, the uninsured have 60 percent fewer office visits with a physician, are prescribed 52 percent fewer medications, and have 168 percent more emergency department visits. Not surprisingly, as the data show, access to health insurance is also a strong predictor of whether people with diabetes have access to and use a CGM as well.

Study Questions

The research is robust when it comes to the relationship between health insurance coverage and high-quality diabetes care. The same is true about the interaction among income, race, and incidence of diabetes. The ADA commissioned new data from Health Management Associates to determine whether access to CGMs is a health disparity issue by asking two questions:

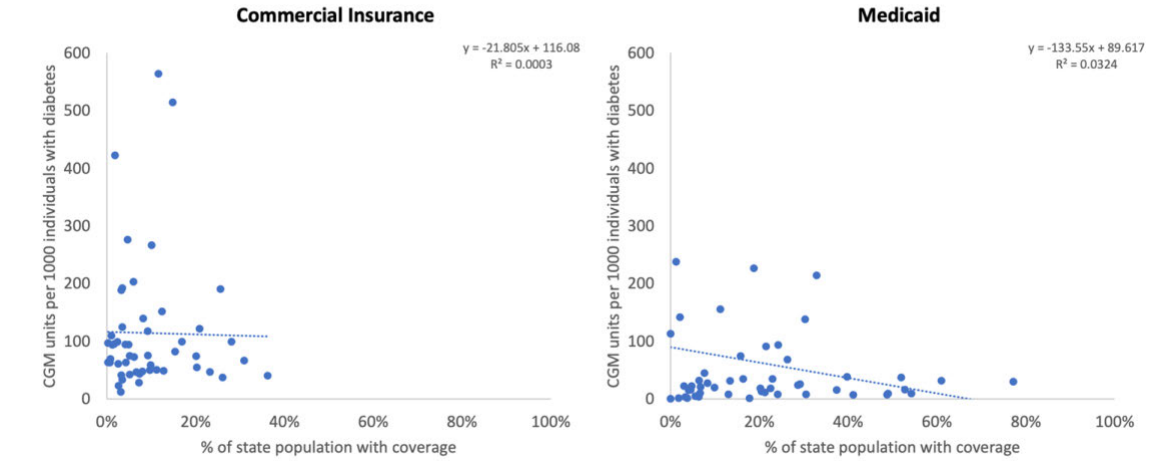
1. Which types of health insurance coverage make a person with diabetes more or less likely to access a CGM?
2. Is a person with diabetes more or less likely to be prescribed a CGM based on their age, race or where they live?

Major Findings

In this study, we find that poorer, older, Black and Brown Americans have less access to CGMs than their counterparts. In particular, three troubling trends emerge from the new data:

- ***Individuals with Medicaid are the least likely to use a CGM, especially people of color with Medicaid***. Individuals enrolled in Medicaid who take insulin are two to five times less likely to use a CGM than those who have a commercial health insurance plan. This coverage gap is less pronounced when only white individuals with Medicaid coverage are considered. States with higher rates of white Americans enrolled in Medicaid have a higher CGM use than states with higher rates of Black Americans, where Medicaid coverage of CGMs is abysmally low. Hispanic individuals are also less likely to get a CGM if they are covered by Medicaid than a commercial health insurance plan.

Age 19-44 Black Population with Diabetes



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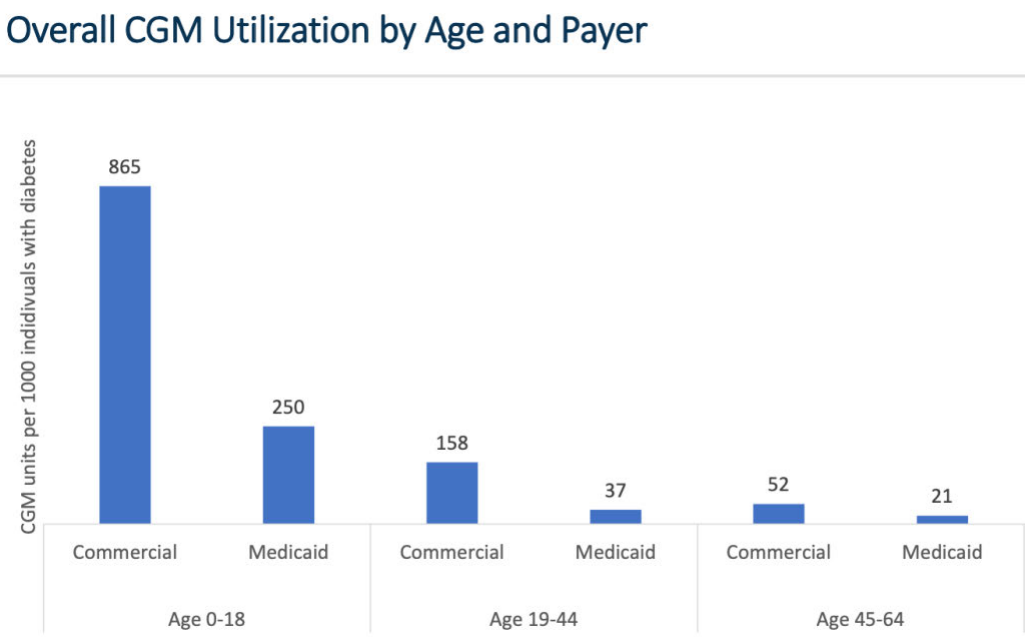
- ***Young people are more likely to get CGMs than older Americans are***. Insulin-dependent children younger than 18 who have diabetes are significantly more likely to use a CGM than pre-Medicare age individuals between the ages of 45 and 64. This gap is reduced when only individuals with commercial insurance plans are considered, highlighting Medicaid's barriers to CGM access across populations.



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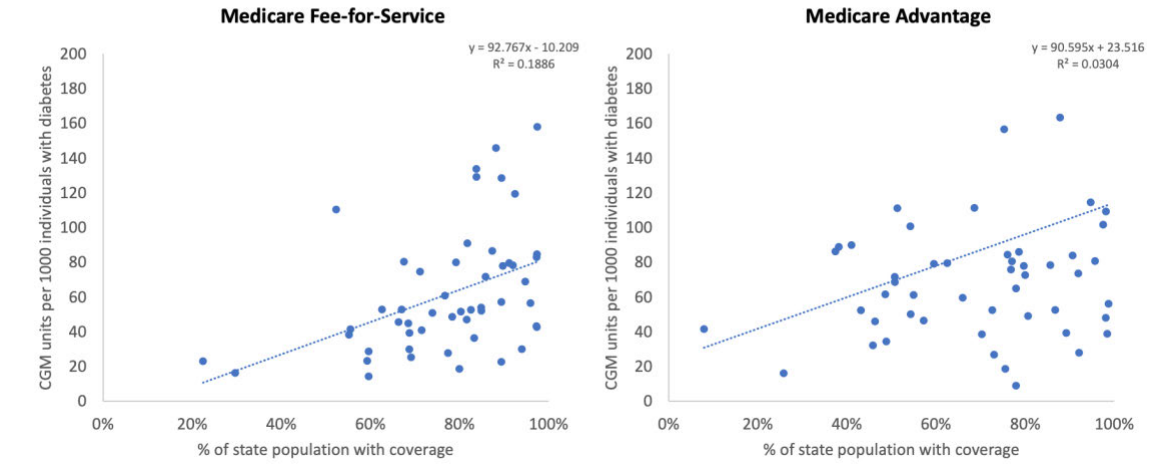
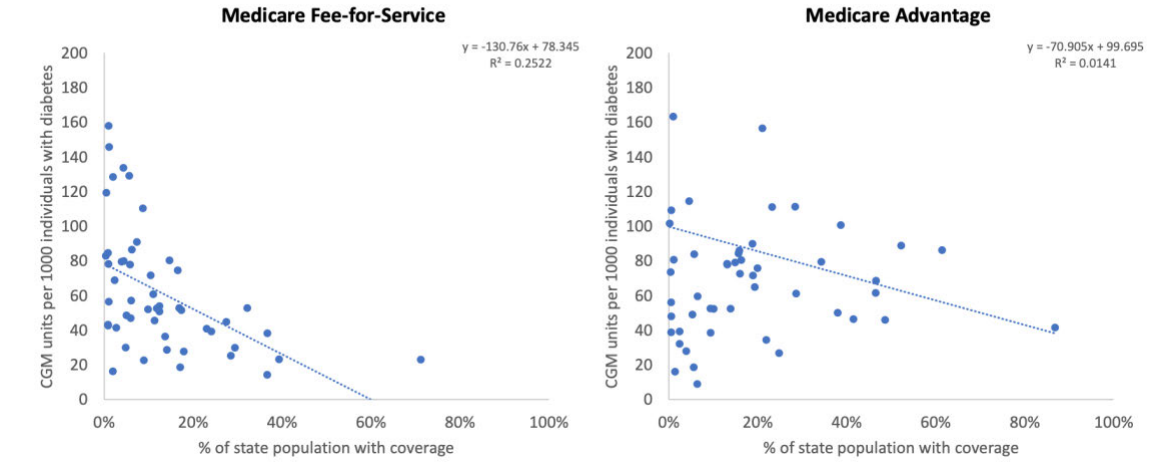
- ***Black Americans are at the most pronounced disadvantage when it comes to CGM access***. Regardless of their age or what kind of health insurance coverage they have, states with higher rates of Black individuals who have diabetes have a lower rate of CGM access and utilization. The discrepancy is particularly stark among the Medicare population. States with a higher rate of white individuals on Medicare or Medicare Advantage have a significantly higher CGM utilization rate than states with a greater Black Medicare population.

White Medicare Population with Diabetes



Black Medicare Population with Diabetes



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Study Methodology

This study pulled 2019 and 2020 data from a wide variety of sources, ensuring as comprehensive a picture as possible of CGM access across types of health insurance, age, and geography. These sources include:

1. Insurance claims for CGM units with corresponding information on patient age, type of insurance coverage (Medicare fee-for-service, Medicare Advantage, commercial and Medicaid) and zip code.
2. The 2019 American Community Survey with information on the under-65 population, their state of residence, age, race, and type of coverage (commercial and Medicaid).
3. The 2019 Medicare Beneficiary Summary File with information on the 2019 Medicare population and their state of residence, race and whether they participated in traditional Medicare or Medicare Advantage; and
4. The National Health Interview Survey with information on diabetes diagnoses and prevalence by age, race, and type of coverage (commercial, Medicaid and Medicare).

Using this data, this study developed an estimated number of individuals with diabetes, calculated the age, coverage, and state of CGM utilization per 1000 individuals with diabetes, and compared state-level coverage rates by race with state-level CGM utilization to determine whether access to CGM technology is limited in communities of color relative to areas with a higher population of white Americans.

Conclusion

CGMs have transformed the diabetes management landscape, giving individuals with diabetes a vital tool to manage their blood glucose, quickly adjust behavior and avoid preventable complications. However, for many who stand to benefit most from these breakthroughs, access remains financially out of reach. While important progress has been made to expand access to medical technology for Medicare beneficiaries with diabetes—such as the recent, permanent removal by the Centers for Medicare and Medicaid Services of Medicare's four-times-a-day testing requirement that has long been a barrier to qualify for a CGM—far more action is necessary to increase access among currently underserved populations. Federal policymakers should take further action to reduce the burden of Medicare's CGM coverage requirements that limit access for low-income and minority people with diabetes.

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For low-income people with diabetes who rely on Medicaid, the diabetes management technology they need may not be covered adequately, or at all. Because Medicaid coverage is often determined on a state-by-state basis, there are wide discrepancies in diabetes technology access from one state to another. Given both the short- and long-term health benefits of using a CGM and insulin pump for those with poor glycemic control, federal and state government officials can and should take steps to drive improved and more uniform coverage policies for diabetes technology and supplies within Medicaid as a vital health equity measure. For example, states can promote CGM use by making them available through as many channels as possible, including both mail-order and local pharmacies, to increase access for the diverse populations that can benefit from CGMs.

As with prescription drugs, device manufacturers typically pay rebates to middlemen like PBMs to carry their products, and the rebates similarly have a market-distorting impact that inherently reduces access to lower-priced, more cost-effective devices. We note that individuals who access CGMs across insurance coverage types often pay more for their devices as a result of rebates negotiated by pharmacy benefit managers. Opportunities to expand PBM rebate reform in the diabetes technology and supplies categories are meaningful, in much the same way they offer the promise of less burdensome costs in the prescription drug market. Diabetes device focused PBM rebate reform can bring needed pricing transparency, reduce costs at the counter and improve patient access to this vital technology.

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Washington State Health Care Authority

Submit competed petition to: shtap@hca.wa.gov; **or**
Atten: Health Technology Assessment
PO Box 42712, Olympia, Washington 98504-2712; **or**
FAX (360) 586-8827

Petition for technology review or re-review

Your name:	Nicole Treanor
Mailing address:	[redacted]
E-mail address:	[redacted]
Telephone number:	[redacted]

Note: Not all questions will apply to all technologies. For assistance email the HTA program at the address above, or phone (360) 725-5126 (TTY 711).

Technology topic Continuous Glucose Monitoring (CGM)

If this topic has been reviewed by the health technology assessment program in the past, skip to question 7, below. See technologies HTCC has previously reviewed.

1. Background information

- Does this technology have FDA approval? ☐ Yes ☐ No
- When was this technology approved?
- For what indications has FDA approved this technology?
- Why do you believe this technology merits consideration for assessment?
- Proposed research questions.

Click here to enter text.

2. Potential patient harm(s) or safety concerns

- What is the potential for patient harm, related to use of this technology?
- What are the likelihood and severity of the potential harms or adverse outcomes that may result from recommended use of this technology?
- Are there significant potential harms associated with this technology compared to alternatives?

Click here to enter text.

3. Therapeutic efficacy, effectiveness or diagnostic accuracy

- What is the potential effectiveness of this technology on the indicated clinical condition? (e.g., prevent/reduce mortality; increase quality of life)
- How are indicated conditions diagnosed? Is there a consensus on diagnosis?

- For diagnostic technologies: Is this technology compared to a "gold standard" technology?
- What is the diagnostic accuracy or utility?
- What published, peer-reviewed literature documents the efficacy of this technology or the science that underlies it? Please enclose publications or bibliography.

Click here to enter text.

4. Estimated total cost per year

- What are the direct health care costs of this technology (annual or lifetime)?
- What is the potential cost-effectiveness of this new technology compared with other alternatives?
- Which private insurers reimburse for use of this technology? Please provide contact information and phone numbers.

Click here to enter text.

5. Secondary considerations

- **Number of persons affected** - What are the numbers of people affected by this technology in the State of Washington?
- **Severity of condition(s)** - What is the severity of the condition treated by this technology? Does it result in premature death; short or long term disability? How would this technology increase the quality of care for the State of Washington?
- **Policy-related urgency -** Is there a particular urgency related to this technology? Is it new and rapidly diffusing? How long has this technology been in use? Is there a standard of care? Is this technology or proposed use(s) controversial?
- **Potential or observed variation** - What is the observed or potential for under, or overuse of this technology? Are there any variations in use or outcomes by region or other characteristics?
- **Special populations and ethical concerns** - Is use limited to small populations; what characteristics are present (e.g., race, ethnicity, religion, rare condition, socioeconomic status) that may impact policy decision?

Click here to enter text.

6. References

- List other organizations that have completed technology assessments on this topic (please provide date of technology assessments and links).
- Cite any Center for Medicare and Medicaid Services (CMS) national coverage decision on this topic and the date issued.
- Provide list of key references used in preparing this petition.

- Have any relevant medical organizations (e.g., American Medical Association) expressed an opinion on this technology? If so, please provide verification documents and contact names, numbers and links.
- Bibliography or reference list of requestor attached: ☐ Yes ☐ No

Click here to enter text.

7. For re-review petitions only

Re-review of a technology requires new evidence that could change a previous decision. What new evidence should be considered? Please provide specific publication information and/ or references.

Continous Glucose Monitoring
Diabetes Technology: Standards of Care in Diabetes—2024
Diabetes Care 2024;47(Suppl. 1):S126–S144 | https://doi.org/10.2337/dc24-S007

Gavin JR, Bailey CJ. Real-World Studies Support Use of Continuous Glucose Monitoring in Type 1 and Type 2 Diabetes Independently of Treatment Regimen. Diabetes Technol Ther. 2021 Sep;23(S3):S19-S27. doi: 10.1089/dia.2021.0211. PMID: 34165343.

Continuous Glucose Monitoring Impact and Implications of Real-World Evidence: Past, Present, and Future
James R. Gavin III and Clifford J. Bailey
Diabetes Technology & Therapeutics 2023 25:S3, S-5-S-13

Vrany EA, Hill-Briggs F, Ephraim PL, Myers AK, Garnica P, Fitzpatrick SL. Continuous glucose monitors and virtual care in high-risk, racial and ethnic minority populations: Toward promoting health equity. Front Endocrinol (Lausanne). 2023 Jan 25;14:1083145. doi: 10.3389/fendo.2023.1083145. PMID: 36761197; PMCID: PMC9905720.

Ferreira ROM, Trevisan T, Pasqualotto E, Chavez MP, Marques BF, Lamounier RN, van de Sande-Lee S. Continuous Glucose Monitoring Systems in Noninsulin-Treated People with Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Diabetes Technol Ther. 2024 Feb 13. doi: 10.1089/dia.2023.0390. Epub ahead of print. PMID: 38090767.

DIABETES TECHNOLOGY & THERAPEUTICS Volume 25, Number 10, 2023 ª Mary Ann Liebert, Inc. DOI: 10.1089/dia.2023.0268

Martens T, Beck RW, Bailey R, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA. 2021;325(22):2262–2272.
doi:10.1001/jama.2021.7444

Evolving Use of Continuous Glucose Monitoring Beyond Intensive Insulin Treatment
Eugene E. Wright and Savitha Subramanian
Diabetes Technology & Therapeutics 2021 23:S3, S-12-S-18

Continuous Glucose Monitoring Systems in Noninsulin-Treated People with Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials
Rafael Oliva Morgado Ferreira, Talita Trevisan, Eric Pasqualotto, Matheus Pedrotti Chavez, Beatriz Friedrichsen Marques, Rodrigo Nunes Lamounier, and Simone van de Sande-Lee

Diabetes Technology & Therapeutics 2024 26:4, 252-262

Safety and Efficacy of Femoroacetabular Impingement Syndrome Procedures: Assessing Signals for Update

Provided by:

Aggregate Analytics, Inc.

Prepared by:

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Erika D. Brodt, BS
Joseph R. Dettori, PhD

December 8, 2023

Table of Contents

Previous Coverage Decision

Femoroacetabular impingement (FAI) syndrome was first reviewed by the HTA program in 2011.

- In 2014, a review of FAI medical literature was conducted to determine if newly available published evidence could change the original coverage determination. The technology was not selected for rereview.
- In 2018, a second update literature review was conducted. The technology was not selected for rereview.
- In 2019, the HCA director selected FAI for rereview based on newly available published evidence that could change the original coverage determination.
- A rereview of femoroacetabular impingement syndrome was completed in 2019. The Committee's Coverage Decision for the 2019 report is summarized below.

Health Technology Background

Femoroacetabular impingement (FAI) results from abnormal morphology of the acetabulum and femoral head/neck resulting in abnormal contact between the proximal femur and acetabulum during the end range of hip motion, particularly flexion and internal rotation. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over coverage of the femoral head). Proponents for operative intervention believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.

Hip surgery is an invasive procedure to correct FAI using either an open surgery or arthroscopic approach. The surgeon resects abnormal outgrowths of bone, removes damaged cartilage, and reshapes the femoral neck to ensure that there is sufficient clearance between the rim of the joint socket and the neck of the femur. Labral debridement and labral repair are surgical treatment options for treating damaged labral tissue when addressing FAI. After corrective surgery, avoidance of weight bearing for several weeks to months and rehabilitation is required. Surgery to correct FAI includes arthroscopy, open dislocation of the hip, and arthroscopy combined with a mini-open approach.

Health Technology Clinical Committee's Findings and Coverage Decision

Topic: Hip Surgery for Femoroacetabular Impingement Syndrome (FAI)
Meeting Date: November 22, 2019
Final Adoption: January 17, 2020

HTCC Coverage Determination

Hip Surgery for Femoroacetabular Impingement Syndrome (FAI) is **not** a covered benefit.

Committee Findings

The committee reviewed and discussed the available studies for use of hip surgery for FAI. The discussion focused on studies available since the original review in 2011. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points. A majority of committee members found the evidence sufficient to determine that use of hip surgery for FAI was less safe or unproven for safety and less cost-effective or unproven for cost-effectiveness. The committee prospective on the efficacy of hip surgery for FAI was evenly divided between unproven and more effective in some cases.

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for surgical treatment of FAI.

No new evidence-based clinical guidelines were identified for this review. The original review included a guideline from the National Institutes for Health and Clinical Excellence (NICE) for arthroscopic and open hip surgery. This guideline had not been updated since the original review (2011). The committee discussed two identified expert consensus documents (not formal guidelines) for FAI from the following organizations:

- The Warwick Agreement
- Lynch systematic review, 2019

There are no current or new guidelines for the HTCC to compare for consistency with their determination.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments and state agency utilization information. The committee decided that the current evidence on hip surgery for femoroacetabular impingement syndrome (FAI) is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of FAI. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover hip surgery for FAI.

1. Purpose of Report

A prior update report was completed in October 2019. The purpose of this update is to determine whether or not there is sufficient evidence published subsequent to the last signal assessment to trigger a re-review of this technology. The key questions from the 2019 report are listed below.

Key question 1
What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with no surgery for FAI?

Key question 2
What is the evidence of the safety of hip surgery for FAI compared with no surgery?

Key question 3
What is the evidence that hip surgery for FAI compared with no surgery has differential efficacy or safety issues in sub populations?

Key question 4
What evidence of cost implications and cost-effectiveness of hip surgery compared with no surgery exists for FAI?

2. Methods

2.1 Literature Searches

We conducted an electronic literature search for the period January 1, 2018 through October 11, 2023 using identical search terms used for the last report for key questions 1 through 4. This search included three main databases: PubMed/Medline, Cochrane Library, and EMBASE. Appendix A reports the search methodology for this topic.

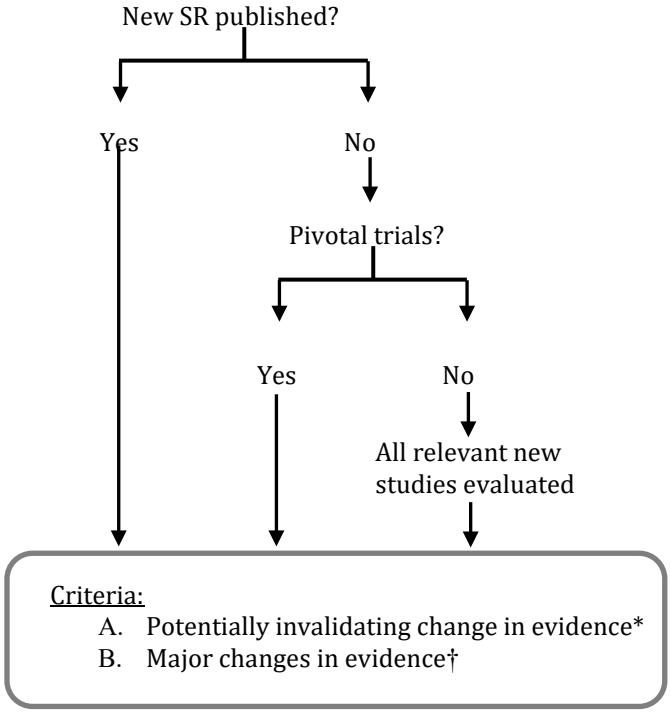
2.2 Study selection

We used the same inclusion and exclusion criteria as the 2019 HTA.

2.3 Compilation of Findings and Conclusions

For this assessment we constructed a summary table that included the key questions 1-4, the 2019 conclusions, new sources of evidence, new findings, and new conclusions based on available signals. To assess whether the conclusions might need updating, we used an algorithm based on a modification of the Ottawa method, Figure 1.

Figure 1. Algorithm of the modified Ottawa Method of Identifying Signals for SR Update



*A-1. Opposing findings: Pivotal trial or SR including at least one new trial that characterized the treatment in terms opposite to those used earlier

A-2. Substantial harm: Pivotal trial or SR whose results called into question the use of the treatment based on evidence of harm or that did not proscribe use entirely but did potentially affect clinical decision making

A-3. Superior new treatment: Pivotal trial or SR whose results identified another treatment as significantly superior to the one evaluated in the original review, based on efficacy or harm.

†B-1. Important changes in effectiveness short of "opposing findings"

B-2. Clinically important expansion of treatment

B-3. Clinically important caveat

B-4. Opposing findings from discordant meta-analysis or nonpivotal trial

3. Results

3.1 Search

From 195 citations returned from the updated search, 179 were excluded at title/abstract review. Of the 16 reviewed at full text, 12 systematic reviews and metaanalyses[1-11] and 2 RCTs[12,13] that addressed in part or in full key questions 1 through 4, were retained (Figure 2). The results of all the systematic reviews were summarized (Appendix B). Two newer metaanalyses[7,11] included the two new randomized trials. However, one of these systematic reviews included duplicate data for a primary outcome in the pooled analysis.[11] Therefore, one systematic review addressing the efficacy of treatment with the most up-to-date RCTs informed the assessment for KQ1.[7] One meta-analysis addressed KQ2,[7] and one addressed KQ4.[14] No new studies were found addressing KQ3. A full list of excluded studies and the reasons for exclusions can be found in Appendix C.

3.2 Identifying signals for re-review

Table 1 shows the original key questions, the conclusions of the original report, the new sources of evidence, the new findings, and the recommendations of Aggregate Analytics, Inc. (AAI) regarding the need for update. Appendix B summarizes the results for the included systematic reviews.

Figure 2. Flow chart showing results of literature search

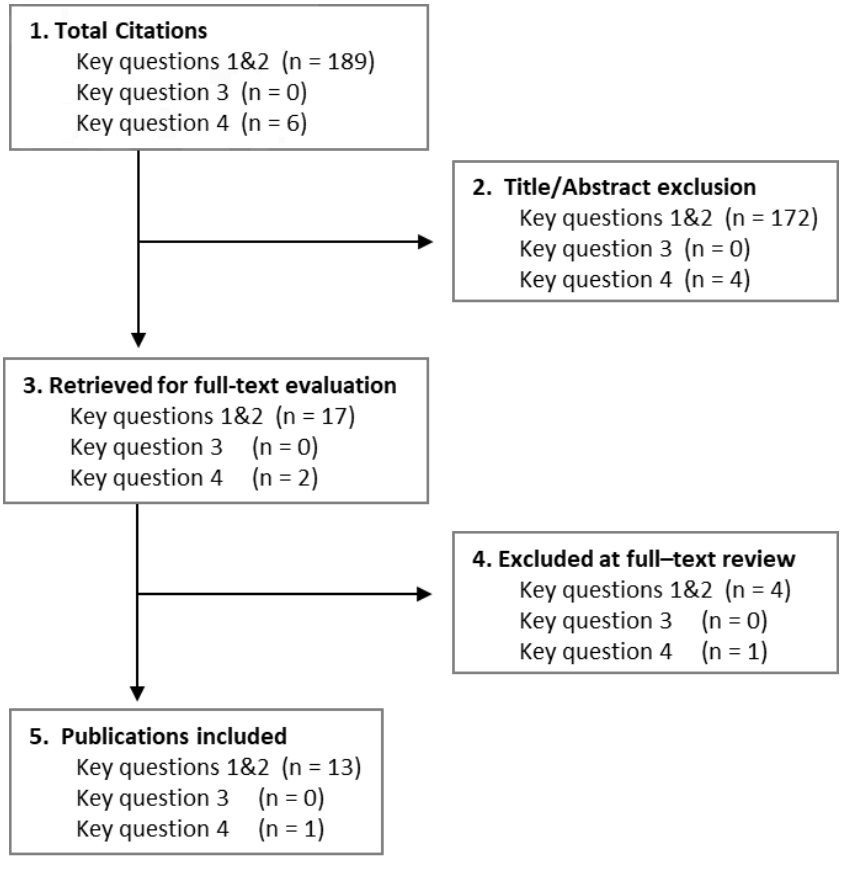


Table 1. Summary Table of Key Questions 1-4

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from AAI
Key Question 1: What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative treatment for FAI/FAIS? Including consideration of short-term (≤5 years) intermediate-term (>5 years to <10 years) and long-term (≥10 years) outcomes?			
• Improvement favoring arthroscopy versus physical therapy was seen for function based on the iHOT-33 in 3 RCTs and the HOS-Sport subscale in 2 RCTs at 6 to 8 months. However, only the difference on the HOS-Sport subscale is likely clinically significant. (SOE: low) • No clear difference between groups was seen for functional outcomes at any other timepoint measured: i-HOT-33 at 12 months (2 trials) and 24 months (1 trial), and no difference the HOS-ADL and HOS-Sport subscales at 12 and 24 months in one RCT. (SOE: low for the i-HOT-33 at 12 months; insufficient for the i-HOT-33 at 24 months and the HOS-ADL and -Sport subscales at both timepoints). • One RCT reported that more arthroscopy patients compared with physical therapy patients achieved clinically important improvements in function according to the HOS-ADL subscale in the short term (8 months). • Greater improvement in pain based on the Copenhagen hip and groin outcome score (HAGOS) was reported by patients who received arthroscopy versus PT at 8 months in one RCT. Though the difference may be clinically important, the confidence interval is wide. This same trial found that fewer arthroscopy patients reported pain on hip motion, but there were no differences between groups on other assessments; clinical relevance of differences is unclear (SOE: low). • Across two RCTs, two patients (1.0%) in the arthroscopy groups compared with no patient who received PT required conversion THA over 12 and 24 months; sample size and follow-up likely impacted the ability to adequately capture this event (SOE: insufficient).	**Systematic Review:** • One SR (Lamo-Espinosa)[7] containing two new RCTs (Hunter, Martin)[12,13]	<u>Efficacy</u> • One new SR reported improvement favoring arthroscopy versus physical therapy based on the iHOT-33 (4 RCTs, pooled MD 10.65 on a 0-100 scale, 95% CI 6.54 to 14.76), and the HOS-ADL (3 RCTs, pooled MD 8.09 on a 0-100 scale, 95% CI 3.11 to 13.07) at one-year follow-up. The difference for the iHOT-33 exceeds the MCID of 6.1 and is likely clinically important. The difference in the HOS-ADL approached the MCID and may be clinically important. • There are no new data with respect to conversion to total hip arthroplasty or longer-term outcome.	This section of the report contains new data in the form of 2 RCTs. Pooled results suggest that hip surgery for FAI may be more efficacious with respect to functional outcomes than physical therapy in the short-term (B-1 criteria for trigger) There continues to be no evidence for intermediate- or long-term outcomes.

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from AAI
Key Question 2: What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?			
Safety • The risk of reoperation (other than conversion to THA) occurred in 4% (arthroscopy and open dislocation) and 9% of the patients (mini-open). • There was only one reported head-neck fracture (0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion. • Heterotopic ossification occurred in 2% to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation. • Neurological complications (nerve palsy, paresthesia, and neuropraxia) were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure. Most were transient in nature.	**Systematic Review:** Lamo-Espinosa[7]	Safety • One systematic review (Lamo-Espinosa) found a higher pooled risk of osteoarthritis in patients receiving hip arthroscopy compared with physical therapy in the short term (2 trials, 17.5% [7/490] vs. 2.6% [1/39], odds ratio 6.8, 95% CI 0.9 to 52.9). Following surgery for FAI, the pooled risks for the following outcomes in the short term were: additional surgery in 2 trials, 10% (9/89); infection in 3 trials, 1.7% (5/299); numbness (transient) in 2 trials, 26.7% (50/187); nerve injury in 1 trial, 1.8% (2/112). • There are no intermediate or long-term safety data available.	This section of the report remains valid and does not need updating.
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from AAI**
Key Question 3. What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety issues in subpopulations?			
Differential efficacy, effectiveness or safety • We found no studies comparing the differential efficacy, effectiveness or safety of surgery versus nonsurgical care in FAI patients. • Outcomes following FAI surgery were consistently worse in patients with greater preoperative osteoarthritis compared with those with less osteoarthritis. • There was no reported difference in outcomes in patients with varying degrees of chondral damage assessed during surgery.	**Systematic Review:** No new sources of evidence	• We found no new studies comparing the differential efficacy, effectiveness or safety of surgery versus nonsurgical care in FAI patients.	This section of the report remains valid and does not need updating.

• No data from other subpopulations were found.			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from AAI**
Key Question 4. What is the cost-effectiveness of hip surgery for FAI/FAIS compared with non-operative treatments in the short and long term?			
Cost-effectiveness There were no cost-effectiveness, cost utility or costing studies found on FAI surgery.	**Systematic Review:** Go[14]	In the majority of the studies, hip arthroscopy had a higher initial cost but provided greater gain in QALYs than did a nonoperative treatment. In certain cases, hip arthroscopy can be cost-effective given a long enough duration of benefit and appropriate patient selection. However, there is further need for literature to analyze willingness-to-pay thresholds.	This section of the report remains valid and does not need updating.

AAI = Aggregate Analytics, Inc.; AVN = avascular necrosis; CER = comparative effectiveness review; CI = confidence interval; FAI(S) = femoroacetabular impingement (syndrome); HAGOS = Copenhagen hip and groin outcome score; HOS-ADL = Hip Outcome Score Activities of Daily living subscale; HOS-Sport = Hip Outcome Score Sport subscale; iHot-33 = International Hip Outcome Tool; MCID = minimal clinically important difference; MD = mean difference; QALY = Quality-adjusted life years; RCT = randomized controlled trial; SOE = strength of evidence; SR = systematic review; THA = total hip arthroplasty.

Conclusions of the 2023 Signals for Update Assessment - FAI

Efficacy

- There are several new systematic reviews on FAI since the publication of the HTA in 2019. The majority do not include new studies. However, the latest SR published in 2023 included two new RCTs in their pooled analysis. Their results suggest that functional outcomes after one-year are better in those receiving hip surgery for FAI compared with physical therapy. These differences may be clinically meaningful. (Criteria B-1)

Safety

- One systematic review found a marked increase in the risk of osteoarthritis in patients receiving hip arthroscopy compared with physical therapy in 2 trials (OR 6.8, 95% CI 0.9 to 52.9).
- The risk of reoperation in those receiving arthroscopy was 10%.

Differential Efficacy and Safety

- We identified no new studies comparing the differential efficacy, effectiveness or safety of surgery versus nonsurgical care in FAI patients.

Cost Effectiveness

- One systematic review concluded that hip arthroscopy had a higher initial cost but provided greater gain in QALYs than did a nonoperative treatment. In certain cases, hip arthroscopy can be cost-effective given a long enough duration of benefit and appropriate patient selection. However, there is further need for literature to analyze willingness-to-pay thresholds.

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APPENDIX A. SEARCH STRATEGIES

Below is the search strategy for PubMed. Parallel strategies were used to search other electronic databases listed below. Keyword searches were conducted in the other listed resources. In addition, hand-searching of included studies was performed.

Appendix Table B1: PubMed Search strategy for Key Questions 1, 2, and 3

	Search Strategy (LIMITS)	Search Dates	No. of hits
1.	FEMOROACETABULAR IMPINGEMENT* OR FEMOROACETABULAR IMPINGEMENT* OR "Femoroacetabular Impingement"[Mesh] OR ((HIP OR ACETABUL* OR FEMUR OR FEMORAL) AND IMPINGEMENT*) OR “femoral osteochondroplasty” OR “femoral osteoplasty”	01/01/2018 to 10/11/2023	
2.	"Reoperation"[Mesh] OR "Femur Head Necrosis"[Mesh] OR "Arthroplasty, Replacement, Hip"[Mesh] OR REOPERATION REATTACHMENT OR AVN OR AVASCULAR NECROSIS OR TOTAL HIP OR TOTAL JOINT OR ARTHROPLASTY OR INFECTION* OR DEATH OR COMPLICATION* OR ADVERSE EVENT OR "Intraoperative Complications"[Mesh] OR SCIATIC* OR NERVE OR NEURO* OR FRACTURE* OR INTRAABDOM* OR CARDIAC ARREST OR THROMBO* OR EMBOL* OR INSTABILITY	01/01/2018 to 10/11/2023	
3.	#1 AND #2 AND (SYSTEMATIC REVIEW OR RANDOMIZED CONTROLLED TRIAL) LIMIT ENGLISH	01/01/2018 to 10/11/2023	189

Appendix Table B2: PubMed Search strategy for Key Question 4

	Search Strategy (LIMITS)	Search Dates	No. of hits
1.	FEMOROACETABULAR IMPINGEMENT* OR FEMOROACETABULAR IMPINGEMENT* OR "Femoroacetabular Impingement"[Mesh] OR ((HIP OR ACETABUL* OR FEMUR OR FEMORAL) AND IMPINGMENT*) OR “femoral osteochondroplasty” OR “femoral osteoplasty”	01/01/2018 to 10/11/2023	
2.	COST OR "Cost-Benefit Analysis"[Mesh])	01/01/2018 to 10/11/2023	
3.	#1 AND #2 (LIMIT ENGLISH)	01/01/2018 to 10/11/2023	6

Electronic Database Searches

The following databases have been searched for relevant information:

Cochrane Database of Systematic Reviews
Cochrane Registry of Clinical Trials (CENTRAL)
PubMed
ClinicalTrials.gov
AHRQ - Healthcare Cost and Utilization Project
Canadian Agency for Drugs and Technologies in Health
Google

APPENDIX B. SUMMARY OF INCLUDED STUDIES

Appendix Table B1. Summary of Included Systematic Reviews Comparing Hip Surgery Versus No Surgery for Femoroacetabular Impingement

Assessment	Evidence- base Used	Outcomes	Results Effect Estimate (95% CI)	Authors' Conclusions
Systematic Review Used to Assess Trigger				
Lamo-Espinosa et al.[1] 2022	5 RCTs (Griffin 2018, Mansell 2018, Palmer 2019, Hunter 2021, Martin)	iHot-33 (12 month f/u) HOS-ADL (6-8 month f/u) HOS-ADL (12 month f/u) Complications surgery vs no surgery	IHOT-33: MD 10.65 (6.54, 14.76) HOS ADL: MD 5.19 (0.77, 9.61) HOS-ADL: MD 8.09 (3.11, 13.07) Infection: 5/299 (1.7%) vs. 0/306 Add Surgery: 9/89 (10%) vs. 0/89 Numbness: 50/187 (26.7%) vs. 0/196 Nerve Injury: 2/112 (1.8%) vs. 0/110 Osteoarthritis: 7/40 (17.5%) vs. 1/39 (2.6%), OR 6.8 (0.9 to 52.9)	Arthroscopic surgery showed statistical superiority over the control group without exceeding the MCID in most studies; however, the results might have been influenced by secondary variables. Finally, arthroscopic surgery results in a high rate of conversion to osteoarthritis.
Other Systematic Reviews Published After the Last Report				
Zhu et al.[2] 2022	5 RCTs (Griffin 2018, Mansell 2018, Palmer 2019, Hunter 2021, Martin)	iHot-33 (12 month f/u) HOS-ADL (6-8 month f/u) EQ-5D 5L (12 month f/u) EQ-5D 3L/5L (12 month f/u)	IHOT-33: MD 9.43 (6.11, 12.76) HOS-ADL: MD 6.98 (2.13, 11.83) EQ-5D 5L: MD 2.52 (-1.15, 6.19) EQ-5D 3L/5L: MD 0.06 (9.01, 0.11)	Hip arthroscopy is statistically superior to conservative treatment in both long-term and short-term effects.
Mahmoud et al. 2022	4 RCTs (Griffin 2018, Mansell 2018, Palmer 2019, Hunter 2021)	iHot-33 (12 month f/u) EQ-5D 5L (12 month f/u) EQ-5D 3L/5L (12 month f/u)	IHOT-33: SMD 9.84 (2.31, 17.38) EQ-5D 5L: SMD 36.55 (-4.57, 17.67) EQ-5D 3L/5L: SMD .06 (-90.3, 0.14)	Apart from SF-12 and Global Rating of Change, all other scores have shown significantly better outcomes with HA in comparison to TPP at 8- and 12-month follow-up points. Hip arthroplasty offers better patient-reported outcomes than targeted physiotherapy programs for

Assessment	Evidence- base Used	Outcomes	Results Effect Estimate (95% CI)	Authors' Conclusions
				management of FAIS at 8- and 12-months follow-up.
Mok et al.[3] 2021	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u) HOS-Sport (6-8 month f/u) HOS-ADL (6-8 month f/u)	iHOT-33: MD 2.11 (1.37, 2.85) HOS-Sport: MD 7.56 (-2.96, 18.08) HOS-ADL: MD 9.22 (5.93, 12.51)	Arthroscopic hip surgery provided essential benefit compared with conservative therapy in improving activity of daily living and quality of life.
Ferreira et al. 2021	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u) EQ-5D 5L (12 month f/u)	iHOT-33: MD 11.02 (4.893, 17.21) EQ-5D 5L: MD 3.69 (-0.02, 7.40)	Hip arthroscopic surgery for FAI provides superior outcomes compared to non-operative care at 12 months, but not at 24 months.
Casartelli et al.[3] 2021	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u)	iHOT-33: MD 10.9 (4.7, 17.0)	Both hip arthroscopy and physical therapy resulted in statistically and clinically significant short-term improvements in hip pain, function, and quality of life in patients with FAIS. Hip arthroscopy was statistically superior to physical therapy in improving the outcome at follow-up even if improvement may not be detected by patients.
Bastos et al. 2021	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u)	iHOT-33: MD 5.53 (-3.11, 14.16)	There is moderate-quality evidence that surgical treatment is not superior to conservative treatment for femoroacetabular impingement syndrome in the short term, and there is low-quality evidence that it is not superior in the medium term
Schwabe et al. 2020	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u) HOS-Sport (6-8 month f/u) HOS-ADL (12 month f/u)	iHOT-33: SMD 11.3 (1.9, 20.7) HOS-Sport: SMD 6.23 (-6.76, 19.22) HOS-ADL: SMD 3.88 (-9.55, 17.32)	Superior short-term outcomes for surgery versus PT. However, PT did result in improved outcomes and did not appear to compromise the surgical

Assessment	Evidence- base Used	Outcomes	Results Effect Estimate (95% CI)	Authors' Conclusions
				outcomes of patients for whom therapy failed and who progressed to surgery.
Kim et al. 2020	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u) HOS-Sport (6-8 month f/u) HOS-ADL (6-8 month f/u)	iHOT-33: MD 8.42 (3.22, 13.63) HOS-Sport: MD 2.65 (-16.82, 22.11) HOS-ADL: MD 5.15 (-3.72, 14.01)	Patients with FAI syndrome treated with hip arthroscopy have statistically superior hip-related outcomes in the short term compared with those treated with physical therapy alone.
Gatz et al.[3] 2020	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u) HOS-Sport (6-8 month f/u) HOS-ADL (6-8 month f/u) EQ-5D 5L (12 month f/u)	iHOT-33: MD 9.67 (4.52, 14.83) HOS-Sport: MD 11.94 (5.41, 18.46) HOS-ADL: MD 10.42 (5.45, 15.39) EQ-5D 5L: MD 3.75 (0.39, 7.12)	Arthroscopic hip surgery is an effective therapeutic treatment for FAI revealing superior results than a non-surgical approach with physiotherapy.
Dwyer et al.[3] 2020	3 RCTs (Griffin 2018, Mansell 2018, Palmer 2019)	iHot-33 (12 month f/u)	iHot-33: MD 3.46 (1.20,6.86)	Patients with FAI syndrome treated with hip arthroscopy have statistically superior hip-related outcomes in the short term compared with those treated with physical therapy alone.

CI = confidence interval; EQ-5D-5L: EuroQol 5 Dimensions quality of life questionnaire; HAGOS = Copenhagen hip and groin outcome score; HOS-ADL = Hip Outcome Score Activities of Daily living subscale; HOS-Sport = Hip Outcome Score Sport subscale; iHot-33 = International Hip Outcome Tool; MCID = minimal clinically important difference; MD = mean difference; RCT = randomized controlled trial

[1]Infection, nerve injury and osteoarthritis risks were included from an imbedded cohort not randomized.

[2]This systematic review included duplicate data from Realpe 2021[15], a report based on the Griffin 2018 randomized trial.

[3]Some outcome measured were pooled from different follow-up times (6 months and 12 months).

APPENDIX C. EXCLUDED STUDIES AT FULL REVIEW

STUDY	REASON FOR EXCLUSION
KQs 1 and 2	
Griffin DR, Dickenson EJ, Achana F, et al. Arthroscopic hip surgery compared with personalised hip therapy in people over 16 years old with femoroacetabular impingement syndrome: UK FASHIoN RCT. *Health Technol Assess*. Feb 2022;26(16):1-236.	Duplicate data from Griffin 2018
Anzillotti G, Iacomella A, Grancagnolo M, et al. Conservative vs. Surgical Management for Femoro-Acetabular Impingement: A Systematic Review of Clinical Evidence. *J Clin Med*. Oct 2 2022;11(19)	Qualitative study, no pooled analysis
Ayeni OR, Karlsson J, Heels-Ansdell D, et al. Osteochondroplasty and Labral Repair for the Treatment of Young Adults With Femoroacetabular Impingement: A Randomized Controlled Trial. *Am J Sports Med*. Jan 2021;49(1):25-34.	No non-operative treatment arm (arthroscopy vs. lavage)
Realpe AX, Foster NE, Dickenson EJ, Jepson M, Griffin DR, Donovan JL. Patient experiences of receiving arthroscopic surgery or personalised hip therapy for femoroacetabular impingement in the context of the UK fashion study: a qualitative study. *Trials*. Mar 16 2021;22(1):211.	Observational cohort imbedded in an RCT
KQ 4	
Griffin DR, Dickenson EJ, Achana F, et al. Arthroscopic hip surgery compared with personalised hip therapy in people over 16 years old with femoroacetabular impingement syndrome: UK FASHIoN RCT. *Health Technol Assess*. Feb 2022;26(16):1-236.	Duplicate data from Griffin 2018

Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Femoroacetabular Impingement Syndrome – Re-review
Meeting Date: November 22, 2019
Final Adoption: January 17, 2020

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20191122B – Hip surgery for femoroacetabular impingement syndrome – re-review

HTCC coverage determination:

Hip surgery for femoroacetabular impingement syndrome is **not a covered benefit**.

HTCC reimbursement determination:

Limitations of coverage:

N/A

Non-covered indicators:

Hip surgery for femoroacetabular impingement syndrome.

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments and state agency utilization information. The committee decided that the current evidence on hip surgery for femoroacetabular impingement syndrome (FAI) is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of FAI. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover hip surgery for FAI.

	Not covered	Covered under certain conditions	Covered unconditionally
Hip surgery for femoroacetabular impingement syndrome	8	2	0

Discussion

The committee reviewed and discussed the available studies for use of hip surgery for FAI. The discussion focused on studies available since the original review in 2011. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points. A majority of committee members found the evidence sufficient to determine that use of hip surgery for FAI was less safe or unproven for safety and less cost-effective or unproven for cost-effectiveness. The committee prospective on the efficacy of hip surgery for FAI was evenly divided between unproven and more effective in some cases.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for surgical treatment of FAI.

No new evidence-based clinical guidelines were identified for this review. The original review included a guideline from the National Institutes for Health and Clinical Excellence (NICE) for arthroscopic and open hip surgery. This guideline had not been updated since the original review (2011). The committee discussed two identified expert consensus documents (not formal guidelines) for FAI from the following organizations:

- The Warwick Agreement
- Lynch systematic review, 2019

There are no current or new guidelines for the HTCC to compare for consistency with their determination.

The committee chair directed HTA staff to prepare a findings and decision document on hip surgery for FAI for public comment, to be followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.