



Washington State
Health Care Authority

Health Technology Assessment Updates

Josh Morse, HTA Program Director

WA – Health Care Authority

March 16, 2018



Today's agenda

1. Gene expression profile testing of cancer tissue
2. Consideration of changes to committee bylaws



Meeting reminders

- Meeting is being recorded
- A transcript of proceedings will be made available on HTA website: www.hca.wa.gov/hta/meetings-and-materials
- When participating in discussions:
 - ❖ State your name; and
 - ❖ Use the microphone
- To provide public comment during today's meeting:
 - ❖ Sign-up at the table outside this meeting room



HTA program background

- The Health Technology Assessment (HTA) program is administered under the Washington State Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
 - ❖ Safety
 - ❖ Efficacy/ Effectiveness
 - ❖ Cost-effectiveness



HTA program background

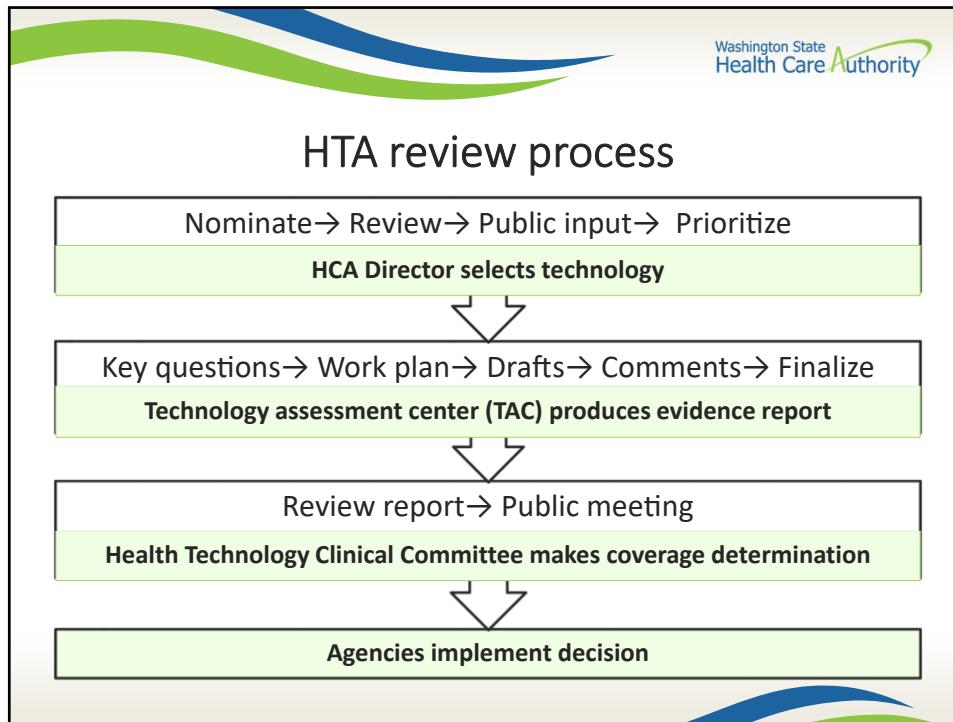
- Multiple state agencies participate to identify topics and implement policy decisions:
 - ❖ **Health Care Authority**
 - _ Uniform Medical Plan
 - _ Medicaid
 - ❖ **Labor and Industries**
 - ❖ **Department of Corrections**
- Agencies implement determinations of the HTA program within their existing statutory framework.



HTA program purpose

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners who determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.





To participate...

- Visit the HTA Web site:
www.hca.wa.gov/about-hca/health-technology-assessment
- Sign up to receive HTA program notifications via email
- Provide comment on:
 - Proposed topics
 - Key questions
 - Draft & final reports
 - Draft decisions
- Attend HTCC public meetings/ present comments directly to the clinical committee.
- Nominate health technologies for review.



Thank you

More Information: www.hca.wa.gov/hta

Email: shtap@hca.wa.gov

Health Technology Clinical Committee

Date: January 19, 2018

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the [HTA website](#)

Draft HTCC Minutes

Members present: John Bramhall, MD, PhD, Gregory Brown, MD, PhD; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Amy Lawson Yuen, MD, PhD; Brent Wisse, MD

HTCC Formal Action

1. **Call to order:** Dr. Brown, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented an overview of the development and purpose of the HTA program. He also provided information regarding the 2018 committee calendar.
3. **July 14, 2018 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve July 14, 2017 minutes as written, seconded. Committee voted to accept the minutes.

Action: Eight committee members approved the July 14, 2017 meeting minutes.

4. **Genomic microarray testing and whole exome sequencing**

Clinical expert: The chair introduced Amy Lawson Yuen, MD, PhD, Genomic Institute, MultiCare Health System, Tacoma, WA.

Agency utilization and outcomes: Shana Johnson, MD, Associate Medical Director, Health Care Authority, presented the state agency perspective on *Genomic microarray testing*. The full presentation is published with the [January 19, meeting materials](#).

Scheduled and open public comments: The chair called for public comments. Comments were provided by:

- Jessie Conta, Genetic Counselor, Seattle Children's Hospital
- Julie Simon, Genetic Counselor, Genetic Support Foundation
- Deb Doyle, State Genetics Coordinator, Washington State Department of Health

Public presentation materials provided are published with the [January 19, meeting materials](#).

DRAFT

Vendor report / HTCC question and answer:

Nedra Whitehead, MS, PhD, RTI-UNC, presented the evidence review for *Genomic microarray and whole exome sequencing*. The full presentation is published with the [January 19, meeting materials](#).

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 *Genomic microarray testing* is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of *Genomic microarray testing* compared to no genetic testing. 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 cover *Genomic microarray testing* with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Genomic microarray testing	0	9	0

Discussion

The committee reviewed and discussed the available studies of use of *Genomic microarray testing*. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select use of *Genomic microarray testing* was equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, *Genomic microarray testing*.

Limitations N/A**Action**

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have a NCD for the use of *Genomic microarray testing*.

The committee discussed clinical guidelines identified for *Genomic microarray testing* from the following organizations:

- International Standard Cytogenomic Array (ISCA) Consortium (2010).
- National Institute for Health and Care Excellence (NICE) (2011).
- American College of Medical Genetics and Genomics (ACMG) (2013).
- Clinical Report from the American Academy of Pediatrics (AAP), Committee on Genetics (2014).
- American Academy of Neurology (AAN) (2015).

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on the use of *Genomic microarray testing* for public comment, followed by consideration for final approval at the next public meeting.

5. Continuous glucose monitoring

Clinical expert: The chair introduced Brent E. Wisse, MD, Associate Professor, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington, Harborview Medical Center, Seattle, WA

Agency utilization and outcomes: Daniel Lesser, MD, MHA, Chief Medical Officer, Health Care Authority, presented the state agency perspective for *Continuous glucose monitoring*. The full presentation is published with the [January 19, meeting materials](#).

Scheduled and open public comments: The chair called for public comments.

- Tomas Walker, Dexcom, Senior U.S. Medical Director
- Catherine Pihoker, MD
- Amy Bronstone, Dexcom Health Services Researcher
- Zoe Alfaro, citizen
- Richard Hellmund, Abbott Diabetes Care
- Irl Hirsch, MD, University of Washington, School of Medicine
- Edward Lacava, MD, EvergreenHealth
- Jennifer Cruz, patient
- Polly Shrek, patient
- Laura Keller, American Diabetes Association

Vendor report/ HTCC question and answer: Andrea Skelly, MPH, PhD, Aggregate Analytics, presented the evidence review of *Continuous glucose monitoring -RR*. The full presentation is published with the [January 19, meeting materials](#).

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 *Continuous glucose monitoring* is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of Continuous glucose monitoring compared to self-monitoring with conventional meters and other study methods (i.e. sham CGM). 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 cover *Continuous glucose monitoring* with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Continuous glucose monitoring	0	9	0

Discussion

The committee reviewed and discussed the available studies of *Continuous glucose monitoring*. Details of study design, inclusion criteria, outcomes, technology used and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select use of *Continuous glucose monitoring* was equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, *Continuous glucose monitoring*.

Limitations N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD on continuous glucose monitoring systems.

The committee discussed clinical guidelines identified for *Continuous glucose monitoring* from the following organizations:

- American Diabetes Association (ADA) Standards of Medical Care in Diabetes, (2017).
- Joslin Diabetes Center and Joslin Clinic Clinical guideline for adults with diabetes (2015, revised 2017).
- Endocrine Society Clinical Practice Guideline Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, (2016).
- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan, (2015).
- Endocrine Society Clinical Practice Guideline Diabetes and Pregnancy, (2013).
- Endocrine Society Clinical Practice Guideline Continuous Glucose Monitoring, (2011).
- NICE National Clinical Guideline Centre, Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system), (2016).
- NICE National Clinical Guideline Centre Type 1 diabetes in adults: diagnosis and management, (2015).
- National Collaborating Centre for Women and Children's Health Diabetes (Type 1 and Type 2) in children and young people: diagnosis and management, (2015).

- National Collaborating Centre for Women and Children's Health Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period, (2015).
- Wright et al, A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People under 18 Years, (2017).
- Choudhary et al, Evidence-Informed Clinical Practice Recommendations for Treatment of Type 1 Diabetes Complicated by Problematic Hypoglycemia (2015).
- Working Group of the Clinical Practice Guidelines on Diabetes Mellitus Type I: Clinical practice guidelines for diabetes type 1, (2012).

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on the use of *Continuous glucose monitoring* for public comment, followed by consideration for final approval at the next public meeting.

6. Meeting adjourned.

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Genomic microarray testing*

Meeting date: January 19, 2018

Final adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:

20180119A - Genomic microarray testing

HTCC coverage determination:

Genomic microarray testing is a covered benefit with conditions.

HTCC reimbursement determination:

Limitations of coverage

Genomic microarray for diagnosing genetic abnormalities in children with any one of the following:

- Significant dysmorphic features or congenital anomalies,
- Global developmental delay or clinical diagnosis of intellectual disability,
- Clinical diagnosis of autism spectrum disorder.

AND

- Targeted genetic testing, if indicated, is negative,
- Clinical presentation is not specific to a well-delineated genetic syndrome,
- The results of testing could impact the clinical management.

Non-covered indicators: N/A

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

* Originally titled ***Genomic microarray testing and whole exome sequencing***. This policy applies only to genomic or chromosomal microarray testing.

DRAFT

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 Genomic microarray testing is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of Genomic microarray testing compared to no genetic testing. 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 cover Genomic microarray testing with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Genomic microarray testing	0	9	0

Discussion

The committee reviewed and discussed the available studies of use of Genomic microarray testing. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select use of Genomic microarray testing was equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, Genomic microarray testing.

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have a NCD for the use of Genomic microarray testing.

The committee discussed clinical guidelines identified for Genomic microarray testing from the following organizations:

- International Standard Cytogenomic Array (ISCA) Consortium (2010).
- National Institute for Health and Care Excellence (NICE) (2011).
- American College of Medical Genetics and Genomics (ACMG) (2013).
- Clinical Report from the American Academy of Pediatrics (AAP) Committee on Genetics (2014).
- American Academy of Neurology (AAN) (2015).

The committee's determination is consistent with these guidelines.

DRAFT

The committee chair directed HTA staff to prepare a findings and decision document on use of Genomic microarray testing for public comment, 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.

DRAFT

Genomic microarray testing

Draft findings and decision Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Genomic microarray testing.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	February 26, 2016	
Public comments	February 26, to March 10, 2016	14
Selected technologies published	April 18, 2016	
Public comments	April 19, to May 18, 2016	30
Draft key questions published	August 16, 2017	
Public comments	August 16 to 29, 2017	14
Final key questions published	September 14, 2017	
Draft report published	November 9, 2017	
Public comments	November 9 to December 8, 2017	30
Final report published	December 29, 2017	
Public meeting	January 19, 2018	
Draft findings & decision published	January 5, 2018	
Public comments	January 7 to 20, 2018	14
	Total	102

Overview

Category	Comment Period		Cited Evidence
	February 7 – 20, 2018		
Patient, relative, and citizen	0		0
Legislator and public official	0		0
Health care professional	0		0
Industry & manufacturer	0		0
Professional society & advocacy organization	0		0
Total	0		0

HTCC Coverage and Reimbursement Determination Analytic Tool

From page 7

Next Step: Proposed Findings and Decision and Public Comment

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

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

Next Step: Final Determination

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

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie), outcome Chair will lead discussion to determine next steps.

Health Technology Clinical Committee

DRAFT Findings and Decision

Topic: Continuous glucose monitoring- re-review

Meeting date: January 19, 2018

Final adoption:

Meeting materials are available on the HTA website.

Number and coverage topic:

20180119B - Continuous glucose monitoring

HTCC coverage determination:

Continuous glucose monitoring is a **covered benefit with conditions**.

This determination does not pertain to 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
- Inability to recognize, or communicate about, symptoms of hypoglycemia.

Continuous glucose monitoring is covered for pregnant women with:

- Type 1 diabetes,
- Type 2 diabetes and on insulin prior to pregnancy,
- 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,
- Gestational diabetes whose blood glucose is not well controlled (HbA1C above target or experiencing episodes of hyperglycemia or hypoglycemia) during pregnancy and require insulin.

Non-covered indicators: N/A

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

DRAFT

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 Continuous glucose monitoring (CGM) is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of Continuous glucose monitoring compared to self-monitoring with conventional meters and other study methods (i.e. sham CGM). 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 cover Continuous glucose monitoring with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Continuous glucose monitoring	0	9	0

Discussion

The committee reviewed and discussed the available studies of Continuous glucose monitoring. Details of study design, inclusion criteria, outcomes, technology used and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select use of Continuous glucose monitoring was equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, Continuous glucose monitoring.

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD on CGM systems.

The committee discussed clinical guidelines identified for Continuous glucose monitoring from the following organizations:

- American Diabetes Association (ADA) Standards of Medical Care in Diabetes, (2017).
- Joslin Diabetes Center and Joslin Clinic Clinical guideline for adults with diabetes (2015, revised 2017).
- Endocrine Society Clinical Practice Guideline Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, (2016).
- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan, (2015).

DRAFT

- Endocrine Society Clinical Practice Guideline Diabetes and pregnancy, (2013).
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- Choudhary et al, Evidence-Informed Clinical Practice Recommendations for Treatment of Type 1 Diabetes Complicated by Problematic Hypoglycemia (2015).
- Working Group of the Clinical Practice Guidelines on Diabetes Mellitus Type I: Clinical practice guidelines for diabetes type 1, (2012).The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of Continuous glucose monitoring for public comment; followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

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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.

DRAFT

Continuous glucose monitoring – re-review

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Continuous glucose monitoring – re-review.

Timeline

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Technology recommendations published	February 26, 2016	
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Overview

Category	Comment Period		Cited Evidence
	January 31 to 14, 2018	3	
Patient, relative, and citizen	1	0	
Legislator and public official	0	0	
Health care professional	1	0	
Industry & manufacturer	1	1	
Professional society & advocacy organization	0	0	
Total	3	1	

Comments

Respondents	Cited Evidence
<input type="checkbox"/> 1. Fran Boyles, MD Swedish Medical Hospital	No
<input type="checkbox"/> 2. Rene Taylor, MS, RD, BC-ADM, CDE Dexcom	Yes
<input type="checkbox"/> 3. Debbie Stixrud Patient	No

From: Broyles, Frances <Frances.Broyles@swedish.org>
Sent: Thursday, February 8, 2018 6:35 PM
To: HCA ST Health Tech Assessment Prog
Subject: 670 G

Importance: High

I am writing regarding coverage for Apple Health patients and those covered by the PEBB program. It is imperative, that coverage for the 670 G closed loop pump system, (THIS IS NOT AN ARTIFICIAL PANCREAS) but an insulin pump tied to a continuous glucose monitoring device that regulates insulin delivery, be approved. This is a life saving device for patients with Type 1 and Type 2 Diabetes with hypoglycemic unawareness, as well as difficult to control hyperglycemia. It will lower hospitalizations, ER visits and complications. I would be happy to give you my direct experience with this system.

Fran Broyles, M.D.

Swedish System Medical Director

Diabetes, Endocrinology and Nutrition
1124 Madison Suite 400
Seattle, WA 98122
Office: 206.215.2440



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To: WA State Health Care Authority and Health Technology Clinical Committee
RE: Concerns with the Draft CGM Guidelines and its Verbiage

Dated: 02/13/2018

I was asked by my Diabetic Educator to write last Fri in response to the newly drafted guidelines. I have lived with Type 1 Diabetes for 53 years and have experienced challenges living in WA State and receiving the necessary technology and equipment/supplies for controlling a disease that impacts every area of my health and quality of life while on the Medicaid Program. I am encouraged by the work already done for the draft I have read – in fact, excited as some of the hurdles I have faced appear to have been addressed. I could easily outline my stories – at my age there are many ... having led support groups I can share concerns and stories as this isn't just about an academic viewpoint but people's lives are in the balance here. Life and death for many of us! It touches work, family, personal, health both physical and emotionally. But I am confident in your listening to public comment I hope there are others who have done so.

My purpose is the importance of HOW your coverage criteria is worded and will appear in your final draft. Your coverage criteria does not appear to include the 670G sensor augmented pump. And states "This determination does not pertain to closed loop or artificial pancreas". I want to add my voice to so many of us who need this technology to please add this to the coverage criteria.

A CURE would be the most cost effective perhaps. None of the complications and ongoing treatment and oversight would be necessary. But we aren't there yet – I have been on pump and CGM therapy for a while now and control is still a time-consuming daily battle. The pump and cgm I wear was just a stepping stone for the 670G type system – the goal is control and prevention of life threatening lows and highs that cause infection and so many other complications of Diabetes.

The new system that is called the 670G sensor augmented pump has the ability to not only gather the data but to ADJUST requirements of insulin or stop it if necessary. The older systems do not have these capabilities. Now that the FDA has approved this new system the battle for a brittle diabetic has hope and a light at the end of the tunnel. The GUESSWORK by providers and the diabetic striving to prevent severe hypoglycemic events in timing and amounts continue to be a battle with the current pump and cgm technology that are listed in your criteria. The 670G (or systems like it) is a brand new level of care. Can you imagine for the sake of cost only allowing someone a crank phone on the wall - totally obsolete but it is a device that CAN communicate – the newer technology replaces and resolves problems of what the original couldn't do. Staying with the old you may limp along but it doesn't solve the problems we are striving to resolve. If you begin the process with medical necessity through appeal ...

My experience when the Heath Authority doesn't clearly state in their policy that these systems are covered become a nightmare of being tossed from the Contracted Insurance Provider to the Health Authority. Sometimes months of appeals and review boards or outside review boards and I have continued up the ladder to the legislature, senators and even to the governors' office – when the State cut budget to exclude Durable Medical Equipment and yet by law required all commercial insurances to carry it. Proven Medical Necessity was not the criteria that the final decision was made on. It was decided by an outside review board outside of the state - based on typical coverage from that particular Insurance Groups policy's own formulary and policy.

Bottom line, my hope is that Washington State will stand out as an example and a leader to the other states around the country. The many facets of Health Care politically is an area that the populace still hold their breath wondering how things are going to play out. The Diabetic Community is a large one according to the states statistics. I believe with well thought out policies and careful implementing of policy and verbiage and being willing to invest in updated technology even in this arena you will reap the rewards of actually lower expenses in the crisis of Health Care and support the wellness of so many of us who have waited all our lives for this kind of help in managing our disease.

Respectfully, Debbie Stixrud, [REDACTED], [REDACTED]



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San Diego, CA 92121
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February 12, 2018

Washington State Health Care Authority
Health Technology Clinical Committee (HTCC)
Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501

Dear members of the HTCC:

I appreciate the diligence HTCC applies to developing coverage decisions and the opportunity to provide comments on the *Draft Findings and Decision for Continuous Glucose Monitoring (CGM) - Update*.

With this letter, I would like to provide comments on two aspects of the *Draft Findings and Decision for CGM - Update* followed by more specific remarks.

My two main concerns are summarized as follows:

1. The *Reimbursement Determination* section of the *Draft Findings and Decision for CGM - Update* includes language that differs from the January 19th meeting discussion and AMDG recommendations¹. Specifically, an “OR” was omitted between clinical indications. This omission misrepresents the intent of the committee, AMDG recommendations, and would require individuals to meet 3 clinical indications instead of 1 or more.
2. The *Medicare National Coverage Decision* section of the *Draft Findings and Decision for CGM - Update* fails to recognize CMS Ruling 1682R which established Medicare coverage for therapeutic CGM.

HTCC reimbursement determination:

DRAFT language: *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),
- 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),
- Inability to recognize, or communicate about, symptoms of hypoglycemia.

SUGGESTED language: *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**
- Inability to recognize, or communicate about, symptoms of hypoglycemia.

Medicare National Coverage Decision:

According to the *Draft Findings and Decision for CGM - Update*, “The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD on CGM systems.”

This finding fails to acknowledge the following CMS Ruling referenced in your *Continuous Glucose Monitoring - Update Final Evidence Report (December 29th, 2017)*:

“CMS updated their policy on CGM devices in a ruling (CMS Ruling 1682R) published on January 12, 2017. This ruling separated CGM devices into therapeutic and non-therapeutic devices, and allows for therapeutic devices to be considered as durable medical equipment (DME). Therapeutic devices are those used as a replacement for fingerstick BG testing for diabetes treatment decisions (i.e. used as a primary system and not as an adjunct) and must meet five criteria used to classify DMEs. The ruling does not establish CGM broadly as medically necessary but does allow for claim-by-claim payment for devices approved for therapeutic uses.”^{2,3}

Nationally, there are two Medicare Administrator Contractors (MAC) that service all four durable medical equipment (DME) jurisdictions. CGS Administrators, LLC and Noridian Healthcare Solutions, LLC process Medicare Part A and Part B (A/B) medical claims or DME claims for Medicare Fee-For-Service beneficiaries. Both Medicare Administrator Contractors have established identical coverage determinations for therapeutic CGM.

Per the Joint DME MAC Article^{4,5}, therapeutic CGM may be covered by Medicare when the beneficiary has diabetes and meets the following criteria:

- Has been using a blood glucose meter (BGM) and performing frequent($\geq 4X/day$) testing;
- Is insulin-treated with MDI or a Medicare-covered CSII pump;
- The insulin regimen requires frequent adjustment on the basis of BGM or CGM testing results;
- Within 6 months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria are met; and
- Every 6 months following the initial prescription of CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM and treatment plan.

In conclusion, we respectfully request the HTCC correct the reimbursement determination language and include Medicare’s coverage decision on therapeutic CGM in the *Final Findings and Decision for CGM - Update*. Thank you for your consideration.

Sincerely,

[REDACTED]
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2. Washington State Health Care Authority Continuous Glucose Monitoring -Update Final Evidence Report; Pages 120, 122-123. <https://www.hca.wa.gov/assets/program/continuous-glucose-monitoring-final-rpt-20171221.pdf>
3. Centers for Medicare and Medicaid Services. Ruling No.: [CMS-1682-R], Classification of therapeutic continuous glucose monitors as “Durable medical equipment” under Medicare Part B. Available at: <https://www.cms.gov/regulations-and-guidance/guidance/rulings/cms-rulingsitems/cms1682r.html>. Accessed June 26, 2017.
4. CGS Administrators LLC. Coding and Coverage – Therapeutic Continuous Glucose Monitors (CGM). Joint DME MAC Article. <https://cgsmedicare.com/jc/pubs/news/2017/0317/cope2581.html>. Accessed February 11, 2018.
5. Noridian Healthcare Solutions, LLC. Coding and Coverage – Therapeutic Continuous Glucose Monitors (CGM). Joint DME MAC Article. <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors>. Accessed February 11, 2018.

HTCC Coverage and Reimbursement Determination Analytic Tool

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Next Step: Proposed Findings and Decision and Public Comment

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

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

Next Step: Final Determination

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

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie), outcome Chair will lead discussion to determine next steps.