

Health Technology Clinical Committee

Date: January 19, 2018

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted: March 16, 2018

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

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](#).

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.