Washington State Health Care Authority

Health Technology Clinical Committee

Date: **March 16, 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

HTCC Minutes

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

Clinical experts: Nancy E. Davidson, 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. **January 19, 2018 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve January 19, 2018 minutes as written, seconded. Committee voted to accept the minutes.

   Action: Eight committee members approved the January 19, 2018 meeting minutes.

4. **Genomic microarray testing and whole exome sequencing - Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision. No changes were made to the draft.

   Action: Eight committee members voted to approve the Genomic microarray testing and whole exome sequencing draft findings and decision**.**

5. **Continuous Glucose Monitoring - Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. Changes were suggested for clarification. Under limitations of coverage, first paragraph– an "or" was placed after each of the bullet points. Under the first paragraph, third bullet point: "Unable" replaced "Inability".

   Three comments were received on the draft decision. The committee reviewed and discussed the comments. No additional changes were made to the draft.

Action: Eight committee members voted to approve the Continuous glucose monitoring findings and decision.

6. Genomic expression profile testing of cancer tissue

Clinical expert: The chair introduced Nancy E. Davidson, MD, Senior Vice President and Director, Clinical Research Division, Fred Hutchinson Cancer Research Center; President and Executive Director, Seattle Cancer Care Alliance; Head, Department of Medicine, Division of Medical Oncology, University of Washington School of Medicine.

Agency utilization and outcomes: Emily Transue, MD, MHA, Associate Medical Director, Health Care Authority, presented the state agency perspective on for *Genomic expression profile testing of cancer tissue*. The full presentation is published with the March 16 meeting materials.

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

- Devki Saraiya , MS, CGC, Myriad Genetic Laboratories
- Karen Heller, MS, CGC, Myriad Genetic Laboratories

Public presentation materials provided are published with the March 16, meeting materials.

Vendor report / HTCC question and answer:

Valerie J. King, MD, MPH, OHSU/Center for Evidence-based Policy presented the evidence review for *Genomic expression profile testing of cancer tissue.* The full presentation is published with the March 16 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 gene expression profile testing of cancer tissue is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of gene expression profile testing of cancer tissue 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 with conditions gene expression profile testing of breast and prostate cancer tissue.

Separately, the committee voted to not cover gene expression profile testing of cancer tissue for colon cancer and multiple myeloma.

	Not covered	Covered under certain conditions	Covered unconditionally
Breast Cancer	1	7	0
Prostate Cancer	1	7	0
Colon Cancer	7	1	0
Multiple Myeloma	8	0	0

Discussion

The committee reviewed and discussed the available studies of Gene expression profile testing of cancer tissue. 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 gene expression profile testing of cancer tissue could impact treatment decisions.

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD on gene profile expression testing for breast, prostate, or colon cancers or multiple myeloma. The committee discussed clinical guidelines identified for gene expression profile testing of cancer tissue from the following organizations:

- American Society of Clinical Oncology (ASCO) *Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early-Stage Invasive Breast Cancer*, (2016).
- The American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology, Molecular Biomarkers in Colon Cancer, (2017).
- European Group on Tumor Markers (EGTM) Use of biomarkers in breast cancer, (2017).
- European Group on Tumor Markers (EGTM) Use of biomarkers in multiple myeloma, (2017).
- European Group on Tumor Markers (EGTM) Use of biomarkers in colon cancer, (2016).
- European Society for Medical Oncology (ESMO) Clinical Practice Guidelines Breast Cancer, (2015).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: Breast Cancer, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: Prostate Cancer, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer: Multiple Myeloma, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: Colon Cancer, (2017).

- NICE National Institute for Health and Care Excellence, Breast Cancer, (2013).

The committee chair directed HTA staff to prepare a findings and decision document on use of gene expression profile testing of cancer tissue for public comment; followed by consideration for final approval at the next public meeting.

7. **2018 Bylaws:** Chair presented suggested updates to the current HTCC bylaws. Bylaws were revised in order to:
   - Align with updates to Washington Administrative Code and Revised Code of Washington changes in 2016;
   - Improve readability; and
   - Guarantee consistency between topic areas and the new laws.

   Chair referred members to the draft bylaws and called for discussion. A suggested change under the heading of "Committee Membership and Terms, Appointment", paragraph 1: The reference to total length of committee membership, WAC 182.55.025, be presented in full written format.

   Chair called for public comments on proposed HTCC bylaws changes. No comments received.

   Chair called vote on revised bylaws.

   Action: Eight committee members voted to approve the 2018 bylaws as amended.

8. **Meeting adjourned.**

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.