Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Gene expression profile testing of cancer tissue
Meeting date: March 16, 2018
Final adoption: May 18, 2018

Meeting materials are available on the HTA website.

Number and coverage topic:

20180316A - Gene expression profile testing of cancer tissue

HTCC coverage determination:

Gene expression profile testing is a **covered benefit with conditions** for breast or prostate cancer.

Gene expression profile testing is **not a covered benefit** for multiple myeloma or colon cancer.

HTCC reimbursement determination:

Limitations of coverage:

Gene expression profile (GEP) testing of breast and prostate cancer tissue is a covered benefit at a rate of one test per twelve (12) months per index cancer and when test results will impact treatment decisions.

Additional conditions for breast cancer tests:

Oncotype DX, EndoPredict, Prosigna, and MammaPrint tests are covered for Stage 1 or 2 disease when:

- Estrogen receptor positive and Human Epidermal growth factor Receptor 2 (HER2-NEU) negative, AND
- Lymph node negative or 1-3 lymph node(s) positive.

Additional conditions by test:

- *Mammostrat* and *Breast Cancer Index (BCI)* are covered only for women with stage 1 or 2 cancer deciding about hormone therapy.
- Prostate cancer tests *Oncotype DX* and *Prolaris* are covered only for low risk or favorable intermediate risk disease.
- Prostate cancer test *Decipher* is covered for men deciding between active surveillance and adjuvant radiotherapy after radical prostatectomy.

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

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.

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.