Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Cell-free DNA prenatal screening for chromosomal aneuploidies
Meeting date: January 17, 2020
Final adoption: Pending

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20200117A – Cell-free DNA prenatal screening for chromosomal aneuploidies (cfDNA)

HTCC coverage determination:

Cell-free DNA prenatal screening for chromosomal aneuploidies is **a covered benefit**.

HTCC reimbursement determination:

Limitations of coverage: N/A

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 cfDNA is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of cfDNA. 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 cell-free DNA prenatal screening for chromosomal aneuploidies.

	Not covered	Covered under certain conditions	Covered unconditionally
Cell-free DNA prenatal screening for chromosomal aneuploidies	0	2	8

Discussion

The committee reviewed and discussed the available studies for use of cfDNA prenatal screening for chromosomal aneuploidies. Details of the screening test accuracy, outcomes and other factors including the affected volume of confirmatory testing were discussed in detail. A majority of committee members found the evidence sufficient to determine that use of cfDNA prenatal screening for chromosomal aneuploidies is safer, more effective or more cost-effective than comparators.

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 NCD for cfDNA prenatal screening for chromosomal aneuploidies. The committee discussed clinical guidelines identified for cfDNA from the following organizations:

- Human Genetics Society of Australia, Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- NHS Fetal Anomaly Screening Programme
- Society of Obstetricians and Gynaecologists of Canada, Canadian College of Medical Geneticists
- American College of Medical Genetics and Genomics (ACMG)
- American College of Obstetricians and Gynecologists, Society for Maternal–Fetal Medicine
- Society for Maternal–Fetal Medicine
- Austrian Society of Obstetrics and Gynecology, Austrian Society of Ultrasound in Medicine, Austrian Society of Pre- and Perinatal Medicine, Austrian Society of Human Genetics, German Society of Ultrasound in Medicine, Fetal Medicine Foundation Germany, Swiss Society of Ultrasound in Medicine

- Chromosome Abnormality Screening Committee on behalf of the Board of the International Society for Prenatal Diagnosis
- European Society of Human Genetics, American Society of Human Genetics
- International Society of Ultrasound in Obstetrics and Gynecology (ISUOG)
- Israeli Society of Medical Genetics NIPT Committee
- National Society of Genetic Counselors
- Polish Gynecological Society, Polish Human Genetics Society

The committee's determination is consistent with the identified guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of cfDNA 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.