

**Health Technology Clinical Committee
Findings and Decision**

Topic: Genomic microarray testing*

Meeting date: January 19, 2018

Final adoption: March 16, 2018

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

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.

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 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.