

**Health Technology Clinical Committee
Final Findings and Decision**

Topic: Artificial disc replacement – Re-review

Meeting date: January 20, 2017

Final adoption: March 17, 2017

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:

20170120B – Artificial disc replacement – Re-review

HTCC coverage determination:

Lumbar artificial disc replacement is **not a covered benefit**.

Cervical artificial disc replacement is a **covered benefit with conditions**, consistent with the criteria identified in the reimbursement determination.

HTCC reimbursement determination:

Limitations of coverage:

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletally mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patients must have advanced imaging and clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy or spinal cord compression at two consecutive levels is required.

Non-covered indicators: NA

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

Final

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 concluded that the current evidence on lumbar and cervical artificial disc replacement should be considered and voted on separately. The committee also determined that current evidence is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of artificial disc for these conditions compared to current alternative strategies. 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 not cover lumbar artificial disc replacement and separately voted to cover with conditions cervical artificial disc replacement.

	Not covered	Covered under certain conditions	Covered unconditionally
Lumbar artificial disc replacement	10	0	0
Cervical artificial disc replacement	0	10	0

Discussion

The committee reviewed and discussed the available studies of lumbar artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that lumbar artificial discs replacements were unproven for safety and unproven for effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to not cover lumbar artificial disc replacement.

The committee reviewed and discussed the available studies of cervical artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that cervical artificial discs replacements were at least equivalent for safety and effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to cover with conditions, cervical artificial disc replacement.

Limitations

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletal mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patient must have advanced imaging or clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy, or spinal cord compression at two consecutive levels is required.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for lumbar artificial disc replacement.

The committee discussed clinical guidelines identified for cervical artificial disc replacement from the following organizations:

- Diagnosis and treatment of Cervical Radiculopathy from Degenerative Disorders (2010) North American Spine Society
- Cervical spine injury medical treatment guidelines (2014) State of Colorado Department of Labor and Employment, Division of Workers' Compensation
- Cervical and Thoracic spine disorders (2011) American College of Occupational and Environmental Medicine

The committee's cover with conditions determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on cervical artificial disc replacement 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 Administrator.