HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: ARTIFICIAL DISC REPLACEMENT

DATE: 08/09/2012

HERC COVERAGE GUIDANCE

Artificial disc replacement should be a covered service only when all of the following criteria are met:

Lumbar artificial disc replacement

1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
2) Patients must be 60 years or under;
3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
   - Failure of at least six months of conservative treatment
   - Skeletally mature patient
   - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
   - Skeletally mature patient
   - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

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RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Oregon Health Authority

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2008). *HTA report: Artificial discs replacement (ADR).* Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/adr_final091908.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Lumbar Disease

Low back pain is a major health problem throughout the world and is the leading cause of pain and disability in adults in the United States. Chronic low back pain with degenerative disc disease is typically managed conservatively for at least six months before surgery is considered. Surgery for lumbar degenerative disc disease is only indicated when nonoperative conservative treatments fail to relieve symptoms attributed to degenerative disc disease. As there is currently no definitive way to determine a discogenic source of pain, there is no agreed upon, evidence-based surgical standard for treatment of degenerative disc disease, but fusion, discectomy, intradiscal electrocoagulation therapy (IDET), various dynamic fusion devices, and disc arthroplasty have been in use for this condition. The goal of lumbar fusion is to remove the disc and fuse the vertebrae, thereby limiting the motion at the painful segment.

Spinal fusion is thought by some to promote the degeneration of the vertebrae above or below the fusion site (adjacent segment disease); however, many uncertainties remain regarding the extent to which this occurs. Lumbar artificial disc replacement is a potential alternative to spinal fusion in patients with disabling mechanical low back pain, and is intended to preserve motion at the involved spinal level and therefore decrease stresses on adjacent segment structures and the risk of adjacent segment disease.

Cervical Disease

Cervical radiculopathy and myelopathy are neurologic conditions characterized by dysfunction of the spinal nerve roots or spinal cord, often as a result of degenerative

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disc disease or spondylosis. The average annual age-adjusted incidence of cervical radiculopathy has been reported as 83 per 100,000, and the prevalence as high as 350 per 100,000 people. While the overall prevalence of cervical spondylotic myelopathy is unknown, it is the most prevalent spinal cord dysfunction in people 55 years or older. It is not uncommon for both conditions to be present. It is estimated that nearly one fourth of surgical patients being treated for cervical degenerative disc disease have a combination of radiculopathy and myelopathy.

Surgery for cervical degenerative disc disease is only indicated when nonoperative conservative treatments fail to relieve signs of neurological compression or prevent progression of nerve damage. For cervical degenerative disc disease resulting in radiculopathy or myelopathy, the current surgical standard is anterior cervical discectomy and spinal fusion. The goal of this procedure is nerve decompression and restoration of spinal alignment and stability.

Spinal fusion is thought by some to promote the degeneration of the vertebrae above or below the fusion site (adjacent segment disease); however, many uncertainties remain regarding the extent to which this occurs.

Cervical artificial disc replacement offers a possible surgical alternative to spinal fusion for patients with radiculopathy and/or myelopathy secondary to degenerative disc disease, and is intended to preserve motion at the involved spinal level and therefore decrease stresses on adjacent segment structures and the risk of adjacent segment disease.

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Evidence Review

Efficacy/Effectiveness – Lumbar Disease

There is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement with a broad range of treatment options. There are no direct comparisons of lumbar artificial disc replacement with continued conservative nonoperative care. As of the date of this report, there are no direct comparison studies to assess the efficacy/effectiveness of lumbar artificial disc replacement compared with other forms of surgical intervention such as discectomy without fusion, other than spinal fusion.

With respect to the comparison of lumbar artificial disc replacement and fusion, there is moderate evidence that the efficacy/effectiveness of lumbar artificial disc replacement as measured by the composite measure of overall clinical success[1] is comparable with anterior lumbar interbody fusion or circumferential fusion up to two years following surgery. Efficacy of lumbar artificial disc replacement was also demonstrated to be comparable to anterior lumbar interbody fusion or circumferential fusion using the

[1] Defined as a ≥25% improvement in Oswestry Disability Index (ODI) at 24 months, no device failure requiring revision, reoperation or removal, and no neurological deterioration (additional components of the definition varied slightly between the two trials comprising the evidence base.

following individual outcomes: Oswestry Disability Index improvement, pain improvement, neurological success, SF-36 improvement, and patient satisfaction. This evidence is based on two moderate quality randomized controlled trials conducted as FDA Investigational Device Exemption non-inferiority trials. Overall clinical success was achieved in 56% of patients receiving lumbar artificial disc replacement and 48% receiving lumbar fusion. Though the results suggest that 24 month outcomes for lumbar artificial disc replacement are similar to lumbar fusion, it should be noted that a non-inferiority trial requires that the reference treatment have an established efficacy or that it is in widespread use. For the lumbar spine, the efficacy of the comparator treatment, lumbar fusion, for degenerative disc disease remains uncertain, especially when it is compared with nonoperative care.

Efficacy/Effectiveness – Cervical Disease

There is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement with a broad range of treatment options. There are no direct comparisons of cervical artificial disc replacement with continued conservative nonoperative care. As of the date of this report, there are no direct comparison studies to assess the efficacy/effectiveness of cervical artificial disc replacement compared with other forms of surgical intervention such as discectomy without fusion, other than spinal fusion.

There is moderate evidence for the cervical spine that cervical artificial disc replacement is superior to anterior cervical discectomy with fusion with respect to overall clinical success (77% versus 68%) and neurological success (92% versus 86%), and is comparable with anterior cervical discectomy with fusion with respect to Neck Disability Index, and pain up to two years following surgery. The evidence is based on two moderate quality randomized controlled FDA Investigational Device Exemption non-inferiority trials. There is evidence that segmental motion is maintained or improved up to three years in the lumbar artificial disc replacement patients and up to four years in cervical artificial disc replacement patients compared with preoperative motion. It is unclear the true extent to which preserving segmental motion by using artificial disc replacement instead of fusion influences rates of adjacent segment disease. Whether adjacent segment disease is a continuation of a disease process necessitating fusion or a result of fusion continues to be disputed. Furthermore, there continues to be debate on whether the presence of adjacent segment disease is clinically important given that patients with marked radiographic adjacent segment disease often have no symptoms.

Safety – Lumbar and Cervical Disease

There is insufficient evidence to draw extensive safety conclusions comparing artificial disc replacement with a broad range of treatment options. There are no direct comparisons of either lumbar or cervical artificial disc replacement with continued conservative nonoperative care. As of the date of this report, there are no direct comparison studies to assess the safety of either lumbar or cervical artificial disc replacement compared with other forms of surgical intervention such as discectomy without fusion (other than spinal fusion).

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There is moderate evidence that lumbar artificial disc replacement is as safe as lumbar anterior or circumferential fusion, and that cervical artificial disc replacement is safer than anterior cervical discectomy and fusion as measured by the risk of device failure or device/surgical procedure related adverse events or complications up to two years following surgery. There is insufficient data at this time to determine the longer term safety of both lumbar artificial disc replacement and cervical artificial disc replacement.

Special or subpopulations – Lumbar and Cervical Disease

There is insufficient evidence to draw conclusions regarding the safety and efficacy of lumbar artificial disc replacement in the few special populations studied (elderly, smokers, athletes). No studies or sub-analyses were found on the use of cervical artificial disc replacement in special or subpopulations.

Economic implications – Lumbar and Cervical Disease

There are inadequate data from partial economic studies reflecting short time horizons for lumbar artificial disc replacement and no economic studies for cervical artificial disc replacement to truly assess the potential cost-effectiveness of artificial disc replacement technology. One report and one previously done HTA suggest that the type of fusion may influence complication rates and therefore costs.

Additional Implications – Lumbar and Cervical Disease

The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the longer term safety and efficacy of L-ADR or C-ADR compared with fusion. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term.

Findings contained in this report primarily reflect use of ADR at a single level and it may not be appropriate to extrapolate the results to patients with ADR at multiple levels or for indications other than those evaluated during the FDA trials.

[Evidence Source]

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Overall Summary

There are no direct comparisons of either lumbar or cervical artificial disc replacement with continued conservative nonoperative care or other forms of surgical intervention such as discectomy without fusion. While lumbar artificial disc replacement appears to be non-inferior to lumbar fusion, the effectiveness of lumbar fusion for degenerative disc disease compared to non-operative care remains uncertain. Cervical artificial disc replacement appears to be comparable or superior to anterior cervical discectomy with fusion in effectiveness, and superior in safety. Long-term (greater than two year) safety and outcomes for artificial disc replacement are unknown.

FDA Indications – Cervical Discs (Prestige®, Prodisc-C®)

The Artificial Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single level discectomy [for intractable radiculopathy and/or myelopathy. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.] [2]

FDA Contraindications – Cervical Discs (Prestige®, Prodisc-C®)

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis or osteopenia[3]
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3mm and/or > 11° of rotational difference to either adjacent level[4]
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene and titanium)[5]
- Severe spondylosis characterized by bridging osteophytes or a loss of disc height > 50% or an absence of motion (<20), as this may lead to limited range of motion and may encourage bone formation (e.g., heterotopic ossification, fusion)[6]
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)[7]
- Patients with SCDD at more than one level[8]

FDA Indications – Lumbar Discs (Charite'®, Prodisc-L®)

The Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L4[9]-SI. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These degenerative disc disease patients should have no more than 3mm[10] of spondylolisthesis at the involved level. Patients receiving the

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[2] For intractable symptomatic cervical disc disease, defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height for Prodisc-C®.

[3] Defined as T-score < 2.5, only for Prodisc-C®

[4] Only for Prodisc-C®

[5] Stainless steel for PRESTIGE®

[6] Only for Prodisc-C®

[7] Only for Prodisc-C®

[8] Only for Prodisc-C®

[9] L3 for Prodisc-L®

[10] Grade 1 for Prodisc-L®

Artificial Disc should have failed at least six months of conservative treatment prior to implantation.

FDA Contraindications – Lumbar Discs (Charite'®, Prodisc-L®)

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis or osteopenia[11]
- Bony lumbar stenosis
- Allergy or sensitivity to implant materials[12]
- Isolated radicular compression syndromes, especially due to disc herniation
- Pars defect
- Involved vertebral endplate dimensionally smaller than 34.5 mm in the medial-lateral and/or 27 mm in the anterior-posterior directions[13]
- Clinically compromised vertebral bodies at affected level due to current or past trauma[14]
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1[15]

PROCEDURE

Artificial disc replacement

DIAGNOSES

Degenerative disc disease

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
722.0	Displacement of cervical intervertebral disc without myelopathy
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.5	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.7	Intervertebral disc disorder with myelopathy
722.9	Other and unspecified disc disorder
ICD-9 Volume 3 (Procedure Codes)	
84.6	Replacement Of Spinal Disc
CPT Codes	
22856	Total disc arthroplasty (artificial disc) anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22857	Total disc arthroplasty (artificial disc) anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord

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[11] Defined as T-score < 1.0 for Prodisc-L®
[12] Specified as cobalt, chromium, molybdenum, polyethylene and titanium for Prodisc-L®
[13] For Prodisc-L® only
[14] For Prodisc-L® only
[15] For Prodisc-L® only

	decompression and microdissection), single interspace, lumbar
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0092T	Total disc arthroplasty (artificial disc) anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical
HCPCS Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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