

# HEALTH EVIDENCE REVIEW COMMISSION (HERC)

## COVERAGE GUIDANCE: ARTIFICIAL DISC REPLACEMENT

**Initial HERC approval 8/09/2012**  
**Reaffirmed 11/13/2014**

*This coverage guidance was created under HERC's 2012 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.*

*As a part of the normal evidence review process, the Health Technology Assessment Subcommittee reviewed new evidence in September, 2014 (see Appendix A) and found five new systematic reviews and two new guidelines from trusted sources. They determined that, although the new evidence is conflicting, updating this guidance was not necessary since the recommendations were based primarily on FDA indications. However, the guidance's recommendation language has been altered to be consistent with that of more recent guidances.*

### HERC Coverage Guidance

Artificial disc replacement is recommended for coverage 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.

## **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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## **EVIDENCE SOURCES**

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](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 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.

## **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<sup>1</sup> 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 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.

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<sup>1</sup> Defined as a  $\geq 25\%$  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).

## **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).

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.

## **Overall summary**

There are no direct comparisons of either lumbar or cervical artificial disc replacement with continued conservative non-operative 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.]<sup>2</sup>

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

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis or osteopenia<sup>3</sup>
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3mm and/or > 11° of rotational difference to either adjacent level<sup>4</sup>
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene and titanium)<sup>5</sup>
- 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)<sup>6</sup>
- 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)<sup>7</sup>
- Patients with SCDD at more than one level<sup>8</sup>

### **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<sup>9</sup>-S1. Degenerative disc disease is defined as

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<sup>2</sup> 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®.

<sup>3</sup> Defined as T-score < 2.5, only for Prodisc-C®

<sup>4</sup> Only for Prodisc-C®

<sup>5</sup> Stainless steel for PRESTIGE®

<sup>6</sup> Only for Prodisc-C®

<sup>7</sup> Only for Prodisc-C®

<sup>8</sup> Only for Prodisc-C®

<sup>9</sup> L3 for Prodisc-L®

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<sup>10</sup> of spondylolisthesis at the involved level. Patients receiving the 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<sup>11</sup>
- Bony lumbar stenosis
- Allergy or sensitivity to implant materials<sup>12</sup>
- 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<sup>13</sup>
- Clinically compromised vertebral bodies at affected level due to current or past trauma<sup>14</sup>
- Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1<sup>15</sup>

### **Procedure**

Artificial disc replacement

### **Diagnoses**

Degenerative disc disease

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<sup>10</sup> Grade 1 for Prodisc-L®

<sup>11</sup> Defined as T-score < 1.0 for Prodisc-L®

<sup>12</sup> Specified as cobalt, chromium, molybdenum, polyethylene and titanium for Prodisc-L®

<sup>13</sup> For Prodisc-L® only

<sup>14</sup> For Prodisc-L® only

<sup>15</sup> For Prodisc-L® only

## APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
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
<b>CD-9 Volume 3 (Procedure Codes)</b>	
84.6	Replacement of spinal disc
<b>CPT Codes</b>	
22856	Total disc arthroplasty (artificial disc) anterior approach, including discectomy with end plate preparation (includes osteophylectomy 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 osteophylectomy for nerve root or spinal cord 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 osteophylectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical
<b>HCPCS Level II Codes</b>	
None	

Note: Inclusion on this list does not guarantee coverage

## APPENDIX A

### Scanning results

Five reviews were identified in the core sources that were published after the date of the WA HTA, as well as two guidelines. Summary results and/or conclusions are presented below.

**Blue Cross Blue Shield Association (2014). Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine. Technology Evaluation Center Assessment Program.**

[http://www.bcbs.com/blueresources/tec/vols/28/28\\_13.pdf](http://www.bcbs.com/blueresources/tec/vols/28/28_13.pdf)

#### Main results

“Artificial intervertebral disc arthroplasty (AIDA) for the treatment of patients with cervical degenerative disc disease does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.”

- Has regulatory approval
- Evidence is insufficient to support conclusions about the comparative effect of AIDA on health outcomes
- While studies show non-inferiority to fusion (6 RCTs), however, the design of the trials allows some margin of inferiority
- Similar clinical outcomes at 2 years, continued to 4-5 years but with high drop out in the longer studies, resulting in a lack of certainty about long term outcomes
- Have not been evaluated outside the investigational setting

**Blue Cross Blue Shield Association (2014). Artificial Lumbar Disc Arthroplasty. Technology Evaluation Center Assessment Program.**

[http://www.bcbs.com/blueresources/tec/vols/28/28\\_07.pdf](http://www.bcbs.com/blueresources/tec/vols/28/28_07.pdf)

#### Main results

“The use of an artificial disc in lumbar spine arthroplasty for chronic symptomatic degenerative disc disease unresponsive to conservative management does not meet the TEC criteria.”

- Has regulatory approval
- This evidence is insufficient to demonstrate a relative clinical benefit of ProDisc versus fusion (1 RCT), particularly because the effectiveness of the comparator— fusion— versus nonsurgical treatments is not well defined. Thus, the randomized trial of ProDisc is suspect as a valid non-inferiority trial and does not prove superiority.
- The evidence is insufficient to determine whether use of ProDisc in lumbar spine arthroplasty improves the net health outcome of patients with symptomatic DDD.

- The evidence is insufficient to determine whether use of ProDisc in lumbar spine arthroplasty is as beneficial as lumbar spinal fusion. The artificial disc was not compared with nonsurgical approaches.
- Have not been evaluated outside the investigational setting

**Hayes. (2012). Artificial Disc Replacement for Cervical Degenerative Disc Disease. Reviewed Dec 17, 2013.**

<https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=11387>

### **Authors' conclusions**

Several moderate-size randomized controlled trials (RCTs) comparing different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF) have been published. Evidence to date demonstrates that total disc replacement (TDR) is at least as effective as ACDF in improving signs and symptoms associated with degenerative disease and improving quality of life (QOL) for up to 2 years. The evidence also shows that total disc replacement (TDR) reduces the need for reoperation and reduces the incidence of dysphagia. Low-quality evidence suggests that TDR reduces the risk of new adjacent segment disease (ASD) but may have higher rates of intraoperative and perioperative complications. Reliable follow-up data for more than 3 years are lacking, which is an especially serious limitation regarding the evidence for the intended advantage of TDR (reduction in long-term ASD). Positive but sparse evidence suggests that bilevel TDR is less safe than single-level TDR, but a few studies with several limitations suggest that it is comparable to bilevel ACDF in safety and efficacy.

Hayes Rating (based on 12 RCTs): B - For single-level TDR for the treatment of cervical disc disease in patients who are candidates for ACDF and who do not have forms of degenerative disc disease, allergies, comorbidities, or concomitant treatments that are expected to interfere with successful arthroplasty.

D2 – For TDR in patients with multilevel cervical disc disease who are candidates for ACDF. This Rating is based on positive but very sparse evidence regarding the efficacy and safety of TDR for the treatment of multilevel disease.

**Hayes. (2013). Lumbar Total Disc Replacement for Degenerative Disc Disease.**

<https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=6963>

### **Authors' conclusions**

The available evidence suggests that, compared with spinal fusion, lumbar total disc replacement (LTDR) for degenerative disc disease (DDD) using the ProDisc or Charité may lead to improved outcomes lasting  $\geq 5$  years after surgery. However, the longer-term clinical outcome of LTDR is still unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the

disc may occur and that, in some cases, revision surgery may be needed. Long-term follow-up results from randomized controlled studies are available from only 2 randomized trials, and it is, therefore, not known if the benefits of LTDR are maintained. Furthermore, patient selection criteria still need to be refined.

Hayes Rating (based on 9 RCTs): C For LTDR using the ProDisc or InMotion (formerly Charité) in patients with DDD who would otherwise undergo lumbar spinal fusion. This Rating is based on the evidence suggesting that these discs may lead to improved outcomes compared with spinal fusion, the concern about potential degeneration of adjacent discs and wear of the disc itself, and the potential need for revision surgery.

D 2 – For LTDR using the Maverick, FlexiCore, or Kineflex discs in patients with DDD who would otherwise undergo lumbar spinal fusion. This Rating is based on the paucity of evidence for these types of artificial discs.

**Jacobs W, Van der Gaag NA, Tuschel A, de Kleuver M, Peul W, Verbout AJ, Oner FC. (2012). Total disc replacement for chronic back pain in the presence of disc degeneration. Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD008326. DOI:10.1002/14651858.CD008326.pub2.**

### **Authors' conclusions**

Based on 7 RCTs.

“Although statistically significant, the differences between disc replacement and conventional fusion surgery for degenerative disc disease were not beyond the generally accepted clinical important differences with respect to short-term pain relief, disability and Quality of Life. Moreover, these analyses only represent a highly selected population. The primary goal of prevention of adjacent level disease and facet joint degeneration by using total disc replacement, as noted by the manufacturers and distributors, was not properly assessed and not a research question at all. Unfortunately, evidence from observational studies could not be used because of the high risk of bias, while these could have improved external validity assessment of complications in less selected patient groups. Non-randomised studies should however be very clear about patient selection and should incorporate independent, blinded outcome assessment, which was not the case in the excluded studies. Therefore, because we believe that harm and complications may occur after years, we believe that the spine surgery community should be prudent about adopting this technology on a large scale, despite the fact that total disc replacement seems to be effective in treating low-back pain in selected patients, and in the short term is at least equivalent to fusion surgery.”

**NICE. (2009). Prosthetic intervertebral disc replacement in the lumbar spine.**  
<http://www.nice.org.uk/guidance/ipg306/resources/guidance-prosthetic-intervertebral-disc-replacement-in-the-lumbar-spine-pdf>

### **Authors' conclusions**

“Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

**NICE. (2010). Prosthetic intervertebral disc replacement in the cervical spine.**  
<http://www.nice.org.uk/guidance/ipg341/resources/guidance-prosthetic-intervertebral-disc-replacement-in-the-cervical-spine-pdf>

### **Authors' conclusions**

“Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.”

## **Summary**

The recently published evidence is conflicting, with two sources supporting the current coverage guidance recommendations for cervical artificial disc and one contradicting them. Similarly, one source supports the current coverage guidance recommendations for lumbar artificial disc and two sources contradict them.

Since the recommendations for this coverage guidance relied primarily on FDA indications rather than the evidence source, updating this guidance document may not be required.