

<b>Place name of Medical Policy:</b> Artificial Disc Replacement			
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<b>Specialty:</b>	Orthopedic Surgery	<b>Reviewed Date:</b>	07/06/17
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**POLICY**

- The only indication for artificial disc replacement is one level disease with no evidence of degenerative changes at any other levels.
- The use of the artificial disc is still considered experimental both for the lumbar and the cervical regions. The use for cervical replacement is currently not a consideration. Please review the criteria and studies noted below to support this statement.
- Although currently FDA approved, the disc prosthesis is generally not covered by non-workers' compensation health plans.
- There is evidence that multilevel replacements have a low success rate in the lumbar area.
- There is insufficient evidence to draw extensive/effectiveness conclusions comparing artificial disc replacement with other recommended treatment options, including fusion. It should be remembered that the artificial disc was designed to maintain motion in the spine. At the same time it should be noted that the amount of motion between vertebrae is minimal and not of functional use. Most of spinal motion is in fact motion at the hips.

**ALL THE FOLLOWING CRITERIA MUST BE MET PRIOR TO ANY SURGICAL CONSIDERATION:**

1. Unremitting back pain and disability for at least 6 months
2. Post completion of multidisciplinary pain program
3. Failed standard medical and surgical management
4. Skeletally mature patient
5. Single level disc degeneration confirmed by complex imaging studies
6. Age 60 or less
7. No consideration for usage for anyone over 60 years of age
8. Consistent with FDA approved indications
9. No osteoporosis/ spondylosis
10. No infection
11. No sensitivity to implant material

## **SUPPORTING DOCUMENTATION**

ODG Low Back (updated 06/27/17) - Online Version

Disc replacement

See Disc prosthesis.

ODG Low Back (updated 06/27/17) - Online Version

Disc prosthesis

Not recommended. While using artificial disc replacement (ADR) to treat degenerative disc disease has gained substantial attention, it is not possible to draw any positive conclusions concerning its effect on improving patient outcomes.

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

The studies quoted below have failed to demonstrate superiority of disc replacement over lumbar fusion, which is also not a recommended treatment in ODG for degenerative disc disease. The anatomic implications of total disc replacement are different from total hip or total knee replacements, and the perceived corollary between total disc replacement and total hip or knee replacement is not justified. Furthermore, longevity of this new procedure is unknown, especially with a relatively young average age in workers' comp patients, and the consequences of failure of an implant in close proximity to caudal equina and vital organs (e.g., aorta, vena cava and iliac arteries) are of concern. Plus, adjacent segment disease seems to be a natural aging process, and despite early intentions, ADR has not proven any benefit in altering that progression compared to fusion. See separate document with all studies focusing on Disc prosthesis. (Cinotti-Spine, 1996) (Klara-Spine, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-Spine, 2004) (Gamradt-Spine, 2005) (Gibson-Cochrane, 2005) See also the Neck Chapter.

Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials. (deKleuver, 2003) At the current time radiculopathy is an exclusion criterion for the FDA studies on lumbar disc replacement. (McAfee-Spine, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-Spine, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study, better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) On the other hand, this case series reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007) Recent research: A high-quality meta-analysis/health technology assessment concluded that there is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement (ADR) with a broad range of recommended treatment options, including conservative nonoperative care, since, other than spinal fusion, there are currently no direct comparison studies. With respect to the comparison of lumbar artificial disc replacement (L-ADR) and fusion, overall clinical success was achieved in 56% of patients receiving L-ADR and 48% receiving lumbar fusion. Though the results suggest that 24-month outcomes for L-ADR are similar to lumbar fusion, it should be noted that 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. Given what is known about lumbar fusion as a comparator and having evidence that only compares L-ADR with lumbar fusion limits the ability to fully answer the efficacy/effectiveness question. (Zigler, 2007) (Blumenthal, 2005) (Dettori, 2008) Although there is fair evidence that artificial disc replacement is similarly effective compared to fusion for single level degenerative disc disease, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) The ECRI health technology assessment concluded that the safety data on lumbar ADR are inadequate to draw conclusions about long-term safety. (ECRIa, 2009) This RCT compared disc prosthesis with multidisciplinary rehabilitation for 12-15 days, and found differences in favor of surgery, but the difference between groups was smaller than the difference that the study was designed to detect. In concluding, given the association of surgery with potentially serious complications, and the considerable improvement in the rehabilitation group, they recommended considering a multidisciplinary rehabilitation first. (Hellum, 2011) A just-released Cochrane systematic review concludes that the lumbar artificial disc is still not ready for routine clinical use because the long-term risks and benefits of this treatment have not been documented adequately. (Jacobs, 2012) A Back Letter article entitled "Future Still Uncertain for the Lumbar Artificial Disc" reports that patients, physicians, and healthcare

systems were wise to resist the massive wave of publicity in favor of the artificial disc for the treatment of chronic back pain. (Wiesel, 2012) According to this study, there should be a tempering of enthusiasm for dynamic alternatives to fusion/stabilization, such as disc replacement, because the clinical benefits of the purported mechanical rationale for their development seem questionable, at least after a mean of 13 years. (Mannion, 2014)

**Safety and complications:** There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion. The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the long-term safety and efficacy of L-ADR compared with fusion. This is an important matter, particularly in workers' comp patients who may be younger. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term. (Dettori, 2008) Revision procedures have included posterior stabilization or anterior revision or conversion to arthrodesis. Risk of great vessel and retroperitoneal injury is greater than with primary procedures. (Patel, 2008) We do not know the long-term failure rate or impact of particular wear on these devices, and the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus these devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007)

**Indications:** Indications for L-ADR include, among other factors, primary back pain and/or leg pain in the absence of nerve root compression with single level disease. This group of patients is different than those undergoing cervical ADR and results from one group should not be inferred to the other. Cervical ADR is performed in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could affect upper extremities, lower extremities, bowel, and bladder function). The problem of identifying those likely to respond to treatment is of concern for L-ADR in that the surgical procedure is designed to treat degenerative disc disease that is thought to be the origin of the patient's pain, but certainty around the diagnosis as the cause of low back symptoms varies. Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis, facet mediated pain and osteoporosis. In fact, the proportion of patients who have an indication for L-ADR make up only approximately 5% of those who might undergo lumbar fusion. (Dettori, 2008)

**Current US treatment coverage recommendations:** Variations exist in coverage policies for ADR for CMS and selected bell-weather payers. Medicare: The Centers for Medicare and Medicaid Services (CMS) will not cover lumbar ADR for patients older than 60 years of age and decisions regarding coverage of patients younger than 60 years of age are at the discretion of local CMS contractors. (Medicare, 2007) Aetna considers prosthetic intervertebral discs medically necessary for degenerative disc disease at one level. (Aetna, 2007) Blue Cross/Blue Shield: Coverage is not recommended. (Blue Cross/Blue Shield, 2007) Cigna covers the lumbar intervertebral disc prosthesis. (Cigna, 2007) Harvard Pilgrim does not cover artificial disc replacement for DDD as an alternative to spinal fusion. (Harvard Pilgrim, 2006) Washington State Department of Labor and Industries: Initially concluded that data insufficient to draw conclusions, L-ADR should be considered experimental only. (Washington LNI, 2004) Then in March of 2009, based on the 2008 Washington Technology Assessment (Dettori, 2008), Washington LNI released an official Coverage Determination stating that Lumbar ADR would be covered under these conditions: (1) Post-completion of a multi-disciplinary pain program; (2) Age 60 or less; (3) Consistent with FDA approved indications (i.e., failure of 6-months non-operative treatment, skeletally mature patient, single disc only, no infection, no sensitivity to implant materials, no osteoporosis or spondylosis). (Washington, 2009) Health Net considers both artificial lumbar and cervical disc replacements investigational and therefore not medically necessary. (Health Net, 2012) Artificial disc acceptance has been poor. According to the latest AHRQ data, the volume of lumbar disc prosthesis procedures (ICD 84.65) declined by 28% in the latest year, to 1,026 in 2011 from 1,424 in 2010 (the procedure peaked in 2005 at 3,165), while average costs increased, from \$61,812 to \$87,302. (HCUP, 2014)

## **REFERENCE(S)**

ODG Low Back (updated 06/27/17) - Online Version