

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	ARTIFICIAL LUMBAR INTERVERTEBRAL DISC
Policy Number	7.01.63
Category	Technology Assessment
Effective Date	03/18/04
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, an initial primary lumbar total disc arthroplasty has been medically proven to be effective and therefore is considered **medically appropriate** when **ALL** the following criteria are met:
- A. Use of an FDA approved implant in accordance with FDA requirements;
 - B. Presence of chronic, unremitting, discogenic axial lower back pain and associated disability secondary to single-level degenerative lumbar disc disease (DDD) for at least one year;
 - C. Age 18-60 years old;
 - D. Significant level of pain on a daily basis defined as either of the following:
 1. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as greater than or equal to 7;
 2. Severe, disabling, crippling, or incapacitating pain;
 - E. Clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing or essential job functions); and
 - F. Absence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse);
 - G. Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes **ALL** of the following:
 1. Regularly scheduled appointments;
 2. Follow-up evaluation;
 3. Less than clinically meaningful improvement with **BOTH** of the following for at least 6 consecutive months unless contraindicated:
 - a. Prescription strength analgesics, steroids, and/or NSAIDs; and
 - b. Provider directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician.
 - H. Moderate to severe single-level disc degeneration at L4-L5 or L5-S1 has been confirmed on recent (within 6 months) plain X-rays and advanced diagnostic imaging studies (i.e., CT, MRI);
 - I. Absence of significant facet arthropathy at the operative level.
- II. Based upon our criteria and assessment of peer-reviewed literature, lumbar artificial total disc arthroplasty is considered **not medically necessary** for **ANY** of the following:
- A. The revision of a failed lumbar artificial total disc arthroplasty;
 - B. The planned procedure includes the combined use of a prosthesis and spinal fusion (hybrid);
 - C. Lumbar partial disc prosthetics;
 - D. Simultaneous multi-level implantation;
 - E. The implant will be inserted outside of the spinal motion segments approved by the FDA;

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 2 of 7

- F. The patient has osteopenia or osteoporosis (T-score less than -1.0);
- G. Above or below or in combination with a spinal fusion or other stabilizing type of surgical procedure;
- H. A lumbar disc prosthesis not approved by the FDA or for an FDA approved indication;
- I. Degenerative disc disease about L4-L5;
- J. Presence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol abuse);
- K. Age less than 18 years or greater than 60 years;
- L. As an adjunct to the treatment of primary central or far-lateral disc herniation;
- M. There is any evidence on imaging studies of ANY of the following:
 - 1. Lytic or degenerative spondylolisthesis of Grade 2 or greater;
 - 2. Lumbar spinal stenosis;
 - 3. Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis;
 - 4. Scoliosis;
 - 5. Spinal fracture;
 - 6. Infection;
 - 7. Multi-level degenerative disc disease (2 or more levels) on a preoperative MRI and plain X-rays;
 - 8. Significant facet arthropathy at the operative level;
 - 9. Presence of tumor or active infection at the site of implantation; or
 - 10. Lumbar nerve root compression or bony spinal stenosis.
- N. Allergy or sensitivity to implant materials;
- O. Isolated radicular compression syndromes especially due to lumbar disc herniation;
- P. Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width; or
- Q. Clinically compromised vertebral bodies at the affected level due to current or past trauma.

Refer to Corporate Medical Policy #7.01.80 Artificial Cervical Intervertebral Disc.

Refer to Corporate Medical Policy # 7.01.90 Lumbar Fusion for Adults.

POLICY GUIDELINES

- I. **URGENT/EMERGENT CONDITIONS:** All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment in lieu of conservative pain management treatment.
- II. **Documentation of Nicotine Free Status:**
 - A. Patient is a non-tobacco user, or
 - B. If patient is a documented tobacco user, then patient must have abstained from tobacco use for at least six weeks prior to the planned spinal fusion surgery as evidenced by lab results (cotinine level) documenting nicotine-free status. Note: In order to complete the prior authorization process for spinal fusion surgery, planning should allow for enough time to submit lab results performed after the 6-week tobacco abstinence period.

DESCRIPTION

Replacement of the intervertebral disc or the disc nucleus with an artificial device is proposed as an alternative to interbody fusion to treat symptomatic degenerative disc disease. Interbody fusion, with or without posterior instrumentation, has been the most common surgical treatment for anterior column instability caused by degenerative disc disease. The procedure is believed to do relatively well in stabilizing the anterior column and relieving pain by eliminating motion. However, it is not physiologic and it alters the stress distribution on the adjacent segments. The issue of whether this stress alteration leads to symptomatic degeneration is still debated. It is proposed that a more functional device, an artificial disc, would restore not only the anatomy but also normal mechanical function. Many designs have been proposed over the past 40 years, both total disc and disc nucleus (partial disc replacement or PDA) devices. A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate and consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 3 of 7

of the annulus is left intact. This device consists of a hydrogel core that can absorb fluid and expand when implanted. Partial disc replacement is also referred to as a nucleus arthroplasty.

RATIONALE

While a number of artificial intervertebral discs in the lumbar spine have been used internationally, only three devices (activL®, Charité®, ProDisc®-L) have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of postmarketing studies. The activL® (Aesculap Implant Systems), Charité® (DePuy), and ProDisc®-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at 1 level; activL® and Charité® are approved for use in levels L4-S1; and ProDisc®-L is approved for use in levels L3-S1. The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. Production under the name Charité® was stopped in 2010. The INMOTION® is not currently marketed in the United States.

The US FDA Investigational Device Exemptions multicenter trial comparing single level discectomy and implantation of the Charité disc with interbody fusion with BAK cage and bone graft reported a success rate, using a composite measure of success, of 63% compared to 53% for BAK fusion for patients followed for up to 24 months, but did not show statistically significant superiority in most outcome measures. In 2008, Guyer and colleagues reported five-year follow-up of a subset of the patient cohort who had participated in the IDE trial of the Charité artificial disc. Of the initial 14 sites, 6 declined participation in the five-year continuation study, and an additional 8 patients were excluded from analysis, leaving 233 patients from the original randomized study. There were 133 cases included in the 5-year assessment (57% from the 8 sites). Based on a denominator of 375 patients originally enrolled in the IDE trial, this report represents 30% of the study population. Complications are emerging with longer-term follow-up. Shim, et al. (2007) reported that clinical outcomes of both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients regardless of the device used.

The FDA granted marketing approval for ProDisc in August 2006. The device is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L3-S1. Patients should have no more than grade 1 spondylolisthesis at the involved level and should have failed at least six months of conservative treatment prior to implantation. FDA approval of the ProDisc-L was based on a randomized controlled trial with 24 months follow-up comparing disc replacement with spinal fusion. Both treatment groups improved on all outcome measures; by study definitions of improvement on Oswestry Disability Index and range of motion, 64% of ProDisc subjects and 45% of the fusion group achieved overall success (53% and 41% respectively by the FDA's definitions). JE Zigler, et. al. (2012) reported five-year follow-up data of this pivotal trial. Out of an original 236 patients randomized, 186 (79%) were included in the follow-up of clinical outcomes (134 ProDisc and 52 controls) and 70% (123 ProDisc and 43 controls) were included for radiographic outcomes. Results showed non-inferiority but not superiority of artificial disc replacement, with 53.7% of the ProDisc patients and 50% of the fusion patients achieving overall success at five years.

A 2015 Medical Technology assessment evaluated seven randomized controlled trials (RCTs), one nonrandomized trial, and six uncontrolled studies with long-term (seven to 17 years) results published between 2002 through July 2015. A total of 2882 patients who underwent one or two level disc replacement treatment were included. The findings suggest that 1-level lumbar disc replacement (LDR) is comparable in efficacy and safety to fusion for the treatment of symptomatic degenerative disc disease in selected patients who have failed conservative treatment.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 4 of 7

CPT Codes

Code	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace, lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, lumbar
0163T	Total disc lumbar arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar
0164T	Removal of total disc lumbar arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar
0165T	Revision including replacement of total disc lumbar arthroplasty (artificial disc) , anterior approach, each additional interspace, lumbar

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HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
Multiple diagnosis codes	

REFERENCES

Aghayev E, et al. Five-year results of lumbar disc prostheses in the SWISS spine registry. Eur Spine J 2014 Oct;23(10):2114-26.

*Berg S, et al. Disc height and motion patterns in the lumbar spine in patients operated with total disc replacement or fusion for discogenic back pain. Results of a randomized controlled trial. Spine J 2011 Nov;11(11):991-8.

BlueCross BlueShield Association. Artificial intervertebral disc: lumbar spine. Medical Policy Reference Manual Policy #7.01.87. 2019 April 08.

*BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment Program. Artificial vertebral disc replacement. 2007 Jun;22(2);1-24.

BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment Program. Artificial Lumbar Disc Arthroplasty. 2014 Jan;28(7).

*Chou R, et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical practice Guideline. Spine 2009 May 1;34(10):1094-109.

*Chou R, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009 May 1;34(10):1066-77.

*David T. Long-term results of one-level lumbar arthroplasty: minimum 10-year follow-up of the CHARITE artificial disc in 106 patients. Spine 2007 Mar 15;32(6):661-6.

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 5 of 7

- *Delamarter R, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. J Bone Joint Surg Am 2011 Apr 20;93(8):705-15.
- Ding F, et al. Total disc replacement versus fusion for lumbar degenerative disc disease: a systematic review of overlapping meta-analyses. Eur Spine J 2017 March;26(3):806-815.
- *Di Silvestre M, et al. Two-level lumbar disc replacement. Eur Spine J 2009 Jun;18 Suppl 1:64-70.
- Formica M, et al. Lumbar total disc arthroplasty: outdated surgery or here to stay procedure? A systematic review of the current literature. J Orthop Traumatol 2017 July 6. [Epub ahead of print].
- Furnes H, et al. Total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain and degenerative discs: 8-year follow-up of a randomized controlled multicenter trial. Spine J 2017 Oct; 17(10):1480-1488.
- Garcia R Jr, et al. Lumbar total disc replacement for discogenic low back pain: two-year outcomes of the activL multicenter randomized controlled IDE clinical trial. Spine 2015 Dec;40(24):1873-1881.
- *Gornet MF, et al. Lumbar Disc Arthroplasty with MAVERICK Disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial. Spine 2011 Dec 1;36(25):E1600-11.
- *Guyer RD, et al. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: Five-year follow-up. Spine J 2009 May 9(5):374-86.
- Guyer RD, et al. Comparison of 2 lumbar total disc replacements: results of a prospective, randomized, controlled, multicenter Food and Drug Administration trial with 24-month follow-up. Spine 2014 May 20;39(12):925-31.
- Guyer RD, et al. Five-year follow-up of a prospective, randomized trial comparing two lumbar total disc replacements. Spine 2016 Jan;41(1):3-8.
- *Hannibal M, et al. ProDisc-L total disc replacement: a comparison of 1-level versus 2-level arthroplasty patients with a minimum 2-year follow-up. Spine 2007 Oct 1;32(21):2322-6.
- *Harrop JS, et al. Lumbar adjacent segment degeneration and disease after arthrodesis and total disc arthroplasty. Spine 2008 Jul 1;33(15):1701-7.
- Hoff EK, et al. ALIF and total disc replacement versus 2-level circumferential fusion with TLIF: a prospective, randomized, clinical and radiological trial. Eur Spine J 2016 May;25(5):1558-1566.
- Johnsen LG, et al. Cost-effectiveness of total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back pain: a Norwegian multicenter RCT. Spine 2014 Jan;39(1):23-32.
- *Katsimihis M, et al. prospective clinical and radiographic results of CHARITE III artificial total disc arthroplasty at 2- to 7-year follow-up: a Canadian experience. Can J Surg 2010 Dec;53(6):408-15.
- Lackey A, et al. A systematic review and meta-analysis of outcomes in hybrid constructs for multi-level lumbar degenerative disc disease. J Clin Neurosci 2016 Dec;34:23-29.
- Lu SB, et al. An 11-year minimum follow-up of the Charite III lumbar disc replacement for the treatment of symptomatic degenerative disc disease. Eur Spine J 2015 Sept;24(9):2056-2064.
- Lu S, et al. Prospective clinical and radiologic results of Activ L total disc replacement at 1- to 3-year follow-up. J Spinal Disord Tech 2015 Nov;28(9):E544-550.
- Lu S, et al. Long-term clinical results following Charite III lumbar total disc replacement. Spine J 2017 Sept 1. [Epub ahead of print].
- Mattei TA, et al. Clinical outcomes of total disc replacement versus anterior lumbar interbody fusion for surgical treatment of lumbar degenerative disc disease. Global Spine J 2017 Aug;7(5):452-459.

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 6 of 7

*National Institute for Health and Clinical Excellence (NICE). Prosthetic intervertebral disc replacement in the lumbar spine (IPG306). Issue date Jul 2009 [<https://www.nice.org.uk/guidance/ipg306>] accessed 6/5/2019.

North American Spine Society (NASS). Coverage policy recommendations. Lumbar artificial disc replacement. 2019 Feb [<https://www.spine.org/coverage>] accessed 6/5/19.

*Park CK, et al. Degenerative changes of discs and facet joints in lumbar total disc replacement using ProDisc II: minimum two-year follow-up. Spine 2008 Jul 15;33(16):1755-61.

Rao MJ, et al. Artificial total disc replacement versus fusion for lumbar degenerative disc disease: a meta-analysis of randomized controlled trials. Arch Orthop Trauma Surg 2014 Feb;134(2):149-58.

*Shim CS, et al. Charité versus ProDisc: a comparative study of a minimum 3-year follow-up. Spine 2007 Apr 20;32(9):1012-8.

*Siepe CJ, et al. Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. Spine J 2014 Aug 1;14(8):1417-31.

*Van den Eerenbeemt KD, et al. Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. Eur Spine J 2010 Aug;19(8):1262-80.

Wuertinger C, et al. Motion preservation following total lumbar disc replacement at the lumbosacral junction: a prospective long-term clinical and radiographic investigation. Spine J 2017 June 30. [Epub ahead of print].

*Yajun W, et al. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease. Eur Spine J 2010 Aug;19(8):1250-61.

*Zigler JE, et al. Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. J Neurosurg Spine 2012 Dec;17(6):504-11.

Zigler J, et al. ISASS policy statement- lumbar artificial disc. Int J Spine Surg 2015 March 12;9:7.

*Zweig T, et al. Influence of preoperative nucleus pulposus status and radiculopathy on outcomes in non-segmental total disc replacement: results from a nationwide registry. BMC Musculoskelet Dis 2011 Dec 2;12:275

*Key Article

KEY WORDS

ActivL[®], Bryan, Charité, Disc, ProDisc-L

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for lumbar artificial disc replacement. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=313&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>

Medical Policy: ARTIFICIAL LUMBAR INTERVERTEBRAL DISC

Policy Number: 7.01.63

Page: 7 of 7