

Corporate Medical Policy

Artificial Intervertebral Disc

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Description of Procedure or Service

During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to spinal fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed, and to maintain the normal biomechanics of the adjacent vertebrae.

Lumbar

Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in which fusion is indicated. Patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for the artificial disc.

Use of a motion-preserving artificial disc increases the potential for a variety of types of implant failure. These include device failure (device fracture, dislocation, or wear), bone-implant interface failure (subsidence, dislocation-migration, vertebral body fracture), and host response to the implant (osteolysis, heterotopic ossification, and pseudotumor formation).

While a number of artificial intervertebral discs in the lumbar spine have been used internationally, only three devices (activL®, Charité® and ProDisc®-L) have received approval from the U.S. Food and Drug Administration (FDA). Because the long-term safety and effectiveness of these devices were not known, approval was contingent on completion of post-marketing studies. The activL® (Aesculap Implant Systems), The Charité® (DePuy) and ProDisc®-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level; activL® and Charité® are approved for use in levels L4–S1, and the ProDisc®-L is approved for use in levels L3–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. 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 U.S. The Maverick™ artificial disc (Medtronic) is not marketed in the U.S. due to patent infringement litigation. The metal-on-metal FlexiCore® artificial disc (Stryker Spine) has completed the investigational device exemption trial as part of the FDA approval process and is currently being used under continued access. Kineflex-L™ (Spinal Motion) is a 3-piece modular metal-on-metal implant. An FDA advisory committee meeting on the Kineflex-L™ was scheduled for July 2013, but was cancelled without explanation.

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Cervical

Cervical degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord result in myelopathy, which is manifested by subtle changes in gait or balance, weakness in the arms or legs, and numbness of the arms or hands, in severe cases. The prevalence of DDD secondary to cervical spondylosis increases with age. An estimated 60% of individuals older than 40 years have radiographic evidence of cervical DDD. By age 65, some 95% of men and 70% of women have at least one degenerative change evident at radiographic examination. It is estimated that approximately 5 million adults in the United States are disabled to an extent by spine-related disorders, although only a small fraction of those are clear candidates for spinal surgery.

Anterior cervical discectomy and fusion (ACDF) is currently considered the definitive surgical treatment for symptomatic DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurological symptoms may be expected in more than 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and emplacement of either autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In artificial intervertebral disc arthroplasty (AIDA), an artificial disc device is secured in the prepared intervertebral space rather than in bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomical disc space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. The potential to reduce the risk of adjacent-level degenerative disc disease (DDD) above or below a fusion site has been the major rationale driving device development and use.

The Prestige® ST Cervical Disc (Medtronic) received FDA premarket application (PMA) approval as a Class III device on July 16, 2007. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy. The device is implanted via an open anterior approach.

The Prestige® LP artificial cervical disc was approved by FDA in 2014. The Prestige® LP differs from the original Prestige cervical disc in terms of material and fixation. The LP implant is composed of a proprietary titanium-ceramic composite and has 2 rails that press-fit into holes created during the surgical procedure. In 2016, the Prestige® LP was approved by FDA for 2 adjacent levels. A post-approval study will follow the investigational device exemption (IDE) patients who received the Prestige® LP at 2 contiguous levels for 10 years. Medtronic will also submit to FDA adverse events, device failures, and complaint analysis for 10 years. This includes subsequent surgeries, heterotopic ossification, device malfunction, and other serious device-related complications.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in December 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C is conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial, 7-year follow-up on 99 continued access subjects, and a 5-year enhanced surveillance study to more fully characterize adverse events when the device is used under general conditions of use. The post-approval study reports are to be delivered to the FDA annually.

The Bryan® Cervical Disc (Medtronic Sofamor Danek) consists of 2 titanium-alloy shells encasing a polyurethane nucleus and has been available outside of the United States since 2002. The Bryan Cervical Disc was approved by the FDA in May 2009 for treatment using an anterior approach of

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single-level cervical DDD. As a condition for approval of this device, the FDA required the manufacturer to extend its follow-up of enrolled subjects to 10 years after surgery. The study will involve the investigational and control patients from the pivotal investigational device exemption (IDE) study arm, as well as the patients who received the device as part of the continued access study arm. In addition the manufacturer must perform a 5-year enhanced surveillance study of the BRYAN® Cervical Disc to more fully characterize adverse events when the device is used in a broader patient population.

In more recent years, continued FDA approval requires completion of 2 postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10-year enhanced surveillance of adverse event data. Continued approval is contingent on submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, or other serious device-related complications, and analysis of all explanted discs. The following have received FDA approval:

- The PCM [porous-coated motion] Cervical Disc® (NuVasive) received FDA approval in 2012 (P100012). The PCM® is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert that fits between the endplates.
- Secure®-C (Globus Medical) was approved in 2012 (P100003). The Secure®-C is a 3 piece semi-constrained device with 2 metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is 3 piece semiconstrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert. The Mobi-C® is approved for 1 (P110002) or 2 level (P110009) disc replacement.

A number of other devices are under study in FDA Investigational Device Exemption (IDE) trials in the United States.

Cervical Disc Prostheses Under Investigation in the U.S.

Prosthesis Manufacturer	Implant Composition	Articulation Design	Bearing Surface	Bearing Constraint	Fixation	FDA Status
Kineflex C® Cervical Artificial Disc Implant (Spinal Motion)	Cobalt-chromium-molybdenum	Three piece, metal core	MoM	Unconstrained	Primary-central keel Secondary – endplate ingrowth	FDA IDE clinical trial complete
Freedom® Cervical Disc (AxioMed)						FDA IDE trial Recruiting
M6-C (Spinal Kinetics)	Titanium endplates and polymer core	7-piece, with endplates and a nucleus, fibrous annulus, and sheath				FDA IDE trial recruiting complete

IDE: investigational device exemption; MoM: metal-on-metal; MoP: metal-on-polyethylene

Updates to the regulatory status of these devices can be viewed at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> using the FDA product code “MJO”.

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*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for cervical artificial intervertebral disc when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Artificial Intervertebral Disc is covered

Cervical artificial intervertebral disc implantation may be considered **medically necessary** when ALL of the following criteria are met:

1. The device is approved by FDA, AND
2. The patient is skeletally mature, AND
3. The patient has intractable cervical radicular pain or myelopathy
 - a. which has failed at least 6 weeks of conservative nonoperative treatment, including active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources AND physical therapy; OR
 - b. if the patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment, AND
4. Disc degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography, AND
5. Cervical degenerative disc disease is from C3 – C7, AND
6. The patient is free from contraindication to cervical artificial intervertebral disc implantation.

Simultaneous cervical artificial intervertebral disc implantation at a second contiguous level may be considered medically necessary if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (ie, Mobi-C, Prestige LP).

Subsequent cervical artificial intervertebral disc implantation at an adjacent level may be considered medically necessary when all of the following are met:

1. Criteria 1 to 6 above are met; AND
2. The device is FDA-approved for 2 levels; AND
3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; AND
4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

When Artificial Intervertebral Disc is not covered

Artificial intervertebral discs of the lumbar spine are considered **investigational**.

Cervical artificial intervertebral disc implantation is considered **investigational** for all other indications, including the following:

- Disc implantation at more than 2 levels

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- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Translational instability
- Anatomical deformity (eg, ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)
- Malignancy

BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

Lumbar

The evidence for the lumbar artificial intervertebral disc in individuals who have lumbar degenerative disc disease includes randomized controlled trials (RCTs) with 5-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment related morbidity. The Charité disc has been withdrawn from the U.S. market, and its successor, the INMOTION, is not marketed in the United States. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. Superiority of ProDisc-L with circumferential fusion was achieved at 2 but not 5 years in this unblinded trial. At this time, the potential benefits of the artificial disc (e.g., faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. In addition, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Some randomized trials have concluded that this technology is noninferior to fusion, but outcomes that would make noninferiority sufficient to demonstrate the clinical benefit of the artificial lumbar disc have not been established. The evidence is insufficient to determine the effects of the technology on health outcomes.

Cervical

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met non-inferiority criteria as measured by the Neck Disability Index (NDI) and overall success composite outcome. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At 4 to 5 years, the trial results are consistent with continued non-inferiority of AIDA for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige and ProDisc-C pivotal trials continues to show lower secondary surgery rates, although this is not a consistent finding in other reports. Longer term results for other discs are expected, given the U.S. Food and Drug Administration (FDA) requirement for 7-year post-approval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to more fully characterize adverse events in a broader patient population. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs, but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of ACDF. There have been no safety signals with discs that have been approved by the FDA for single-level AIDA. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2- and 4-year follow-ups,

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the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for NDI scores, NDI success rates, reoperation rates, and overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level AIDA for clinical outcomes and lower cumulative reoperation rates. Adjacent segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared to 2-level ACDF patients. FDA approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at 2 years. The increase in overall success rates at 2 years has been maintained for those patients who have reached the 5- and 7-year follow-ups. Based on this evidence, it can be concluded that 2-level AIDA with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome. □

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0095T, 0098T, 0163T, 0164T, 0165T, 0375T, 22856, 22857, 22858, 22861, 22862, 22864, 22865.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Specialty Matched Consultant Advisory Panel - 6/2004

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Specialty Matched Consultant Advisory Panel – 11/2010

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 10/4/2011

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Specialty Matched Consultant Advisory Panel – 11/2011

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 9/2012

Zigler JE. Five-year results of the ProDisc-L multicenter, prospective, randomized, controlled trial comparing ProDisc-L with circumferential spinal fusion for single-level disabling degenerative disk disease. *Semin Spine Surg* 2012; 24(1):25-31

Specialty Matched Consultant Advisory Panel – 10/2012

Zigler JE, Delamarter R, Murrey D et al. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study. *Spine (Phila Pa 1976)* 2013; 38(3):203-9.

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 9/8/2016

Specialty Matched Consultant Advisory Panel – 10/2016

Policy Implementation/Update Information

- 7/29/04 New policy implemented. Artificial Intervertebral Disc is considered investigational. Reviewed by Specialty Matched Consultant Advisory Panel 6/22/04. Notification given 7/29/04. Effective date 10/14/04.
- 1/20/05 Removed the statement from the Description of Service or Procedure section that indicated; "No artificial intervertebral disc has received FDA approval as of May 2004." Added information related to the approval by FDA of the Charite disc in October of 2004. Rationale added to Policy Guidelines section. References added.
- 6/2/05 References added. Policy number added to Key Words section.
- 6/16/05 Date added to reference.
- 7/7/05 Added new CPT codes: 0090T, 0091T, 0092T, 0093T, 0094T, 0095T, 0096T, 0097T, 0098T
- 1/19/06 Added new 2005 CPT code 0091T to "Billing/Coding" section.
- 6/5/06 Specialty Matched Consultant Advisory Panel review 5/3/2006. No changes to policy statement. Updated date of literature search in "Policy Guidelines" section. References added.

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- 1/3/07 Added the following new 2007 CPT codes: 0163T, 0164T, 0165T, 22857, 22862, and 22865 from "Billing/Coding section. Removed deleted CPT codes, 0091T, 0094T, and 0097T.
- 6/30/08 Specialty Matched Consultant Advisory Panel review 5/29/08. No changes to policy statement. References added.
- 1/5/09 Added CPT codes 22856, 22861, and 22864 to the "Billing/Coding" section. Removed deleted CPT codes 0090T, 0093T, and 0096T. (btw).
- 6/22/10 Policy Number(s) removed. (amw)
- 12/21/10 Reviewed by Medical Director 8/14/2010. Description extensively revised. No change to policy statement. Rationale updated in "Guidelines" section. Specialty Matched Consultant Advisory Panel review 11/29/2010. References added.(btw)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/30/2011 Updated "Description" section. Updated "Policy Guidelines" section. No change to policy intent. References added. (btw)
- 11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Revised Description section. Updated Policy Guidelines section. No change to policy intent. References added. (btw)
- 12/31/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. Description section updated. No change to policy intent. Reference added. (btw)
- 4/1/14 Description and Policy Guidelines sections updated. No change to policy intent. Senior Medical Director review 2/27/2014. References added. (btw)
- 11/11/14 Specialty Matched Consultant Advisory Panel review 10/28/2014. No change to policy intent. (sk)
- 12/30/14 Added new codes 0375T and 22858 for effective date 1/1/2015. Deleted code 0092T effective 12/31/2014. (sk)
- 4/28/15 Reference added. (sk)
- 12/30/15 Specialty Matched Consultant Advisory Panel review 10/28/2015. Reference added. Policy statement changed to "BCBSNC will provide coverage for cervical artificial intervertebral disc when it is determined to be medically necessary because the medical criteria and guidelines shown below are met". (sk)
- 5/31/16 Reference added. Policy Guidelines updated. Information on activL® device added to Description section. (sk)
- 10/25/16 Reference added. Additional covered indications added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment

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and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.