

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 when approved, 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Production under the name Charité® was stopped in 2010.

A number of other artificial lumbar discs are in development or available only outside of the United States:

- The INMOTION® lumbar artificial disc (DePuy Spine) is a modification of the Charité® device with a change in name under the same premarket approval. 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.

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- 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.

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, and, in severe cases, leads to weakness in the arms or legs and numbness of the arms or hands. 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) has historically been 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 80% to 100% of ACDF patients. ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and placement of a PEEK (polyetheretherketone) or titanium interbody cage plus autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate. Although there may be slight differences between autograft and allograft sources in the postoperative rate of union, clinical studies have demonstrated similar rates of postoperative fusion (90%-100%) and satisfactory outcomes using either bone source. Studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD and need for secondary surgery.

Cervical disc arthroplasty is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In cervical disc arthroplasty, an artificial disc device is secured in the prepared intervertebral space rather than an interbody cage and/or bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. The cervical disc arthroplasty was designed to 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. Disc arthroplasty and ACDF have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia. However, the chief complaint in cervical disc arthroplasty candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis or spondylolisthesis.

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. Intractable radiculopathy and/or myelopathy should be present, with at least one of the following items

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producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (e.g., magnetic resonance imaging, computed tomography, x-rays): herniated disc and/or osteophyte formation. The FDA required Medtronic (the Prestige disc manufacturer) to conduct a seven-year postapproval clinical study of the safety and function of the device and a five-year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

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 ProDisc C Vivo is currently marketed by Centinal Spine.

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 single-level cervical DDD defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography, myelography and computed tomography, and/or magnetic resonance imaging results. Patients receiving the Bryan® Cervical Disc should have failed at least six weeks of nonoperative treatment before implantation. 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 two postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to seven years. The second study provides ten-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.

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- Secure®-C (Globus Medical) was approved in 2012 (P100003). The Secure®-C is a three piece semi-constrained device with two metal (cobalt chromium molybdenum alloy) endplates and a polyethylene insert.
- The Mobi-C® (LDR Spine) received FDA approval in 2013. Mobi-C® is a three 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.
- The M6-C™ (Spinal Kinetics) received FDA approval for single level degenerative radiculopathy in 2019 (P170036). The device is comprised of ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates. The device is secured with low profile fins.

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 | FDA Status |
|-------------|------------------|---------------------------------|
| Kineflex C® | Spinal Motion | FDA IDE clinical trial complete |
| Freedom® | AxioMed | FDA IDE trial |
| Simplify | Simplify Medical | FDA IDE trial |

IDE: investigational device exemption

Updates to the regulatory status of these devices can be viewed at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> using the FDA product code “MJO”.

*****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 disc arthroplasty 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

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- 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 disc arthroplasty.

Simultaneous cervical disc arthroplasty 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 (i.e., Mobi-C, Prestige LP).

Subsequent cervical disc arthroplasty 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 disc arthroplasty is considered **investigational** for all other indications, including the following:

- Disc implantation at more than 2 levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or > 11° angular difference to that of either level adjacent to the two treated levels
- Anatomical deformity (e.g., ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Moderate or severe facet joint disease or degeneration.
- Active infection
- Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
- Malignancy

BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

Lumbar

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes randomized controlled trials (RCTs) of artificial discs vs. fusion with five-year outcomes and case series with longer term outcomes. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment related morbidity. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement compared to spinal fusion. Superiority of ProDisc-L with circumferential fusion was achieved at two but not at five years in this unblinded trial. At this time, the potential benefits of the artificial disc (e.g., faster recovery, reduced

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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. No RCTs compared activL® to spinal fusion or conservative care. RCTs were limited by a lack of blinding, insufficient followup to evaluate potential harms, and lack of comparison to the criterion standard for treatment of degenerative disc disease. 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 cervical disc arthroplasty, 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 two-year follow-up, trials of all artificial cervical discs met non-inferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on five devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At four to five years, the trial results are consistent with continued non-inferiority of cervical disc arthroplasty 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. 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 cervical disc arthroplasty. The evidence is sufficient to determine 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 cervical disc arthroplasty of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The FDA approval for the Prestige LP was based on superiority to two-level ACDF in overall success at two years. The increase in overall success rates at two years has been maintained for those patients who have reached the ten-year follow-up. At two- and four-year follow-ups, the first artificial cervical disc approved for two levels (Mobi-C) was found to be superior to ACDF for Neck Disability Index (NDI) scores, NDI success rates, reoperation rates, and overall success composite outcome. At five years, trial results were consistent with the continued superiority of two-level cervical disc arthroplasty 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 two-level ACDF patients. Based on this evidence, it can be concluded that two-level cervical disc arthroplasty with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine 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.

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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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Specialty Matched Consultant Advisory Panel – 11/2011

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Specialty Matched Consultant Advisory Panel – 10/2012

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Specialty Matched Consultant Advisory Panel – 10/2016

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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.

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- 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.
- 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)

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- 11/10/17 References added. Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
- 8/24/18 References added. (sk)
- 11/9/18 Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
- 1/1/19 Reference added. Medical Director review. In When Not Covered section, the following changes were made. “Translational instability” was changed to “Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or > 11° angular difference to that of either level adjacent to the two treated levels”. “Presence of facet arthritis” was changed to “Moderate or severe facet joint disease or degeneration”. (sk)
- 7/1/19 M6-C removed from table titled “Cervical Disc Prostheses Under Investigation in the U.S.” (sk)
- 8/27/19 References added. (sk)
- 11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)
- 8/25/20 References added. Change in terminology from 'artificial intervertebral disc arthroplasty of the cervical spine' to 'cervical disc arthroplasty' throughout policy. (sk)
- 11/10/20 Specialty Matched Consultant Advisory Panel review 10/21/2020. (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 and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.