MEDICAL POLICY

POLICY TITLE	ARTIFICIAL INTERVERTEBRAL DISC (LUMBAR AND CERVICAL)
POLICY NUMBER	MP-1.093

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I. POLICY

Artificial Disc Lumbar Spine
Artificial intervertebral discs of the lumbar spine are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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

1. The device is approved by the Food and Drug Administration (FDA).
2. The patient is skeletally mature.
3. The patient has intractable cervical radicular pain or myelopathy
   a. which has failed at least 6 weeks of conservative nonoperative treatment, including an 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.
4. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography.
5. Cervical degenerative disc disease is from C3-C7.
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 (e.g., 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.

Cervical artificial intervertebral disc implantation 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
- Translational instability
- Anatomical deformity (e.g., ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
- Malignancy

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

Artificial Intervertebral Disc: Lumbar Spine

FEP PPO - Refer to FEP Medical Policy Manual MP- 7.01.87 Artificial Intervertebral Disc: Lumbar Spine. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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Artificial Intervertebral Disc: Cervical Spine

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.108, Artificial Intervertebral Disc: Cervical Spine. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Artificial Intervertebral Disc: Lumbar Spine

Total disc replacement, using an artificial intervertebral disc designed for the lumbar spine, is proposed as an alternative to fusion in patients with persistent and disabling symptoms.

When conservative treatment of degenerative disc disease (DDD) fails, a common surgical approach is spinal fusion. More than 200,000 spinal fusions are performed each year. However, outcomes with spinal fusion have been controversial, in part due to the difficulty in determining if a patient's back pain is related to DDD and in part due to the success of the procedure itself. In addition, spinal fusion alters the spine biomechanics, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, various artificial intervertebral discs have been investigated as an alternative approach to 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 normal biomechanics of the adjacent vertebrae.

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

Use of a motion-preserving artificial disc increases the potential for various types of implant failure. They 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, pseudotumor formation).

Regulatory Status

Three artificial lumbar disc 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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographs. 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 United States.
- The Maverick™ artificial disc (Medtronic) is not marketed in the United States 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, scheduled in 2013, but was cancelled without explanation.

FDA product code: MJO.

Artificial Intervertebral Disc: Cervical Spine

Cervical Degenerative Disc Disease
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 can 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, 95% of men and 70% of women have at least 1 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.

Treatment
Cervical DDD is initially treated conservatively using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise). If symptoms do not improve or resolve within 6 weeks, or if symptoms progress, surgical intervention may be indicated. Candidates for surgical intervention have chronic pain or neurologic symptoms secondary to cervical DDD and no contraindications for the procedure.

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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 neurologic 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.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. In AIDA, an artificial disc device is secured in the prepared intervertebral space rather than an interbody cage and/or bone. An anterior plate is not used to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. It is hypothesized that AIDA will maintain anatomic 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 DDD above or below a fusion site has been the major reason 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 AIDA candidates should be radicular or myelopathic symptoms in the absence of significant spondylosis or spondylolisthesis.

Outcome Measures

The NDI is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life.[1] It is a modification of the Oswestry Disability Index, based on responses to 10 questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Response options to each question range from 1 to 5, with a lower numeric score representing a better pain and disability status for that variable. A total Neck Disability Index score is obtained by adding individual question scores and dividing by the maximum total of 50 if all questions are answered. Therefore, Neck Disability Index scores range from 0% to 100%, with a lower percentage indicating less pain and disability. Neurologic status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge whether patients are within normative parameters for those categories based on physiologic measurement. The anterior functional spinal unit height is a radiographic measure of interdiscal space. Comparison of the immediate postoperative functional spinal unit height with the 6-week postoperative

value shows whether the disc space has decreased, which indicates that graft or device subsidence has occurred. Other outcome measures may include the 36-Item Short-Form Health Survey Mental and Physical Component Summary scores, neck and arm pain status, patient satisfaction, patient global perceived effect, gait assessment, foraminal compression test, adjacent-level stability and measurements, return to work, and physician's perception.

Regulatory Status

In 2007, the Prestige® ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process as a class III device. The Prestige® ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy. The device is implanted using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least 1 of the following items 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 [MRI], computed tomography [CT], x-rays): herniated disc and/or osteophyte formation. FDA has required Medtronic (the Prestige disc manufacturer) to conduct a 7-year postapproval clinical study of the safety and function of the device and a 5-year enhanced surveillance study to more fully characterize adverse events (AEs) in a broader patient population.

In 2014, the Prestige® LP artificial cervical disc (Medtronic Sofamor Danek) was approved by FDA through the PMA process. 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 postapproval 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), was approved by FDA through the PMA process in 2007. As with the Prestige® ST Cervical Disc, FDA approval of ProDisc-C® was made conditional on 7-year follow-up of the 209 subjects included in the noninferiority trial (discussed in Rationale section), 7-year follow-up of 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. Postapproval study reports are to be delivered to 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. In 2009, the Bryan® Cervical Disc was approved by FDA for treatment using an anterior approach of single-level cervical degenerative disc disease 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 1 clinical neurologic sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using CT, myelography and CT, and/or MRI results. Patients receiving the Bryan® Cervical Disc should have failed at least 6 weeks of nonoperative treatment before implantation. As a condition for device approval, FDA required Medtronic Sofamor Danek 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 IDE study arm, as well as the patients who received the device as part of the continued-access study arm. In addition, Medtronic Sofamor Danek must perform a 5-year enhanced surveillance study of the disc to more fully characterize adverse events when the device is used in a broader patient population.

More recently, 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, other serious device-related complications, and analysis of all explanted discs.

The following have also 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 semiconstrained 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 in FDA IDE trials in the United States (see Table 1).

Table 1. Cervical Disc Prostheses Under Investigation in the United States

Prosthesis	Manufacturer	FDA Status
Kineflex/C®	Spinal Motion	FDA IDE trial complete
Freedom®	AxioMed	FDA IDE trial recruiting
M6-C	Spinal Kinetics	FDA IDE trial recruiting complete

FDA: U.S. Food and Drug Administration; IDE: investigational device exemption.

Updates on the regulatory status of these devices are available online using FDA product code MJO (available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm).

IV. RATIONALE

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Artificial Intervertebral Discs: Lumbar Spine

SUMMARY OF EVIDENCE

For individuals who have lumbar degenerative disc disease who receive a lumbar artificial intervertebral disc, the evidence includes 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. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. The superiority of ProDisc-L with circumferential fusion was achieved at 2 but not at 5 years in this unblinded trial. The potential benefits of the artificial disc (eg, faster recovery, reduced adjacent-level disc degeneration) have not been demonstrated. Also, considerable uncertainty remains whether response rates will continue to decline over longer time periods and long-term complications with these implants will emerge. Although some randomized trials have concluded that this technology is noninferior to spinal fusion, 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.

Artificial Intervertebral Discs: Cervical Spine

SUMMARY OF EVIDENCE

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, the evidence includes 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 noninferiority criteria. 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 have been consistent with the continued noninferiority 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. 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 approved by FDA for single-level AIDA. 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 AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The Food and Drug Administration 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. At 2- and 4-year follow-ups,

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 with 2-level ACDF patients. 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 that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

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ARTHROPLASTY refers to surgery to reshape or reconstruct a diseased joint. This may be done to alleviate pain, to permit normal function, or to correct a developmental or hereditary joint defect.

BIOMECHANICS is the application of mechanical forces to living organisms and the investigation of the effects of the interaction of force and the body or system.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered, artificial disc intervertebral lumbar spine procedures:

CPT Codes®								
22857	22862	22865	0163T	0164T	0165T			

Investigational; therefore not covered, artificial disc intervertebral cervical spine procedures:

CPT Codes®								
22861	0098T	0375T						

Covered when medically necessary, artificial disc intervertebral cervical spine procedures:

CPT Codes®								
22856	22858	22864	0095T					

ICD-10-CM Diagnosis Codes	Description
M50.01	Cervical disc disorder with myelopathy, high cervical region
M50.021	Cervical disc disorder at C4-C5 level with myelopathy
M50.022	Cervical disc disorder at C5-C6 level with myelopathy
M50.023	Cervical disc disorder at C6-C7 level with myelopathy
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy

IX. REFERENCES

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Artificial Intervertebral Disc: Cervical Spine

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V. POLICY HISTORY

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MP-1.093	**CAC 10/28/03**
	CAC 5/31/05
	CAC 7/26/05
	CAC 4/25/06
	CAC 9/26/06
	CAC 7/31/07
	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus Review
	CAC 5/25/10 Adopted BCBSA criteria
	CAC 4/26/11 Consensus Review
	CAC 6/26/12 Consensus review; no changes, references updated. **7/9/12-** FEP variation revised to refer to the FEP manual.
	CAC 9/24/13 Consensus review. Reference updated, but no changes to the policy statements.
	05/01/2014 Coding update only. 22864 removed from policy
	CAC 7/22/14 Consensus. No change to policy statements. References updated and rationale added. Codes reviewed.
	01/05/2015 New 2015 code added to policy.
	CAC 9/29/15 Minor revision. The artificial cervical disc is now considered medically necessary for single level cervical disc replacement when policy criteria are met. No changes to the artificial lumbar disc. Background, references and rationale updated. Codes reviewed/updated.
	CAC 7/26/16 Consensus review. No changes to the policy statements. Reference and rationale update for the artificial lumbar disc. Coding reviewed.
	Admin update 1/1/17: Product variation section reformatted.
	CAC 11/29/16 Minor revision. 2-level cervical disc replacement with a device that is FDA-approved for 2-levels (i.e., Mobi-C, Prestige LP) is considered medically necessary when criteria is met. The "Artificial Disc Cervical Spine" policy statement revisions are as follows: • # 5 within the first policy statement was revised to remove the 'single' level reference to cervical degenerative disc disease;

POLICY TITLE	ARTIFICIAL INTERVERTEBRAL DISC (LUMBAR AND CERVICAL)
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	• The second policy statement was added to outline the criteria for simultaneous cervical artificial intervertebral disc implantation at a second contiguous level; • The third policy statement was added to outline the criteria for subsequent cervical artificial intervertebral disc implantation at an adjacent level; and • The first bullet within the 4th policy statement that addresses contraindications has been updated to read "Disc implantation at more than 2 levels." Description/Background, Rationale and Reference sections updated. Coding reviewed/updated.
	CAC 11/28/17 Minor revision. Policy statement #5: • Cervical artificial intervertebral disc implantation is considered investigational rather than contraindicated for all other indications. • Multilevel disk disease removed as being contraindicated or investigational. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	7/17/18 Consensus. No change to policy statements. Rationale condensed. References updated.
	9/25/18 Retirement. Please refer to TurningPoint Healthcare for management of these services effective 1/1/2019.*

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