Artificial Intervertebral Discs

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Artificial Disk Replacement: Guideline Note 101

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Cervical Artificial Disc Replacement

I. Cervical artificial disc replacement, at a single-level or at two contiguous levels, may be considered **medically necessary** as a treatment of cervical degenerative disc disease or herniated disc(s) when all of the following criteria (A.-H.) ae met:

A. Patient is skeletally mature (i.e. fully developed growth plates); **and**
B. The cervical intervertebral disc prosthesis is FDA-approved and will be implanted at the approved cervical level specific to the device **and** the patient has **none** of the Food & Drug Administration (FDA) contraindications for use (see Table 2); **and**
C. Medical records document that a detailed neurological examination has been performed by, or reviewed by, the operating surgeon, within 3 months prior to surgery; **and**
D. Replacement of degenerated cervical disc(s) does not exceed two contiguous levels; **and**
E. **One or more** of the following (1.-3.) was observed at each cervical level for which surgical intervention is proposed:
    1. Herniated nucleus pulposus (i.e. herniated disc); **or**
    2. Spondylosis (defined as the presence of osteophytes); **or**
    3. Visible loss of disc height compared to the adjacent levels; **and**
F. Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see Policy Guidelines)); **and**

G. At least one of the following criteria are met (1.-3.):
    1. Imaging shows severe stenosis with cord signal changes; **or**
    2. Exam shows major, progressive neurologic changes such as myelopathy or progressive weakness; **or**
    3. Patient meets all of the following (a.-c.):
        a. Persistent, debilitating, neck or cervicobrachial radicular pain (see Policy Guidelines), secondary to spinal cord or nerve root compression; **and**
        b. Documentation that age-appropriate activities of daily living have been moderately or severely impacted (see Policy Guidelines); **or** Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition); **and**
        c. Symptoms have failed to improve after 3 months of conservative treatment (see Policy Guidelines for all requirements and exceptions), as part of pre-operative surgery planning unless there is intolerable radicular pain (see Policy Guidelines) **and**

H. All other reasonable sources of pain have been formally evaluated and ruled out.

II. Surgical removal and treatment (e.g. spinal fusion) of a failed ADR may be considered **medically necessary** when imaging confirms mechanical failure of the implanted device (e.g. loosening, dislodgement, fracture, infection) and proposed surgery meets required criteria per the medical policy "Back: Fusion and Decompression Procedures."

III. Cervical artificial disc placement is considered **not medically necessary** when criteria I.-II. above are not met, including but not limited to the following (A.-C.):

A. Treatment at more than one non-contiguous cervical level;
B. Replacement/revision of a cervical artificial disc for any reason;
C. The individual has had prior surgery at the proposed level for ADR placement (e.g. decompression, fusion, prior ADR).

Cervical Artificial Disc Replacement: Subsequent Surgeries

IV. Subsequent surgical implantation of an FDA–approved artificial cervical disc at a second contiguous level in a skeletally mature individual with symptomatic cervical disc disease may be considered **medically necessary** when all of the following criteria are met (A.-D.):

A. Criterion I. above is met; **and**
B. The planned subsequent procedure is at a cervical level adjacent (contiguous) to a previously implanted cervical artificial disc; **and**
C. The cervical disc prosthesis is FDA approved for two levels; **and**
D. The combined implant level is not greater than two levels.

V. Subsequent surgical implantation of an artificial cervical disc is considered **not medically necessary** when criterion IV. above is not met.

Cervical Hybrid Procedures (Cervical Fusion with Cervical Artificial Intervertebral Disc Implantation)

VI. Concurrent (hybrid) or planned sequential artificial cervical disc replacement with prior or planned cervical spinal fusion at adjacent levels for the management of cervical spinal pathology may be considered **medically necessary** when both of the following are met (A.-B.):

A. For the artificial disc component, criterion I. above is met; **and**
B. For the cervical fusion component, when criteria in the "Back: Fusion and Decompression Procedures" policy are met.

VII. Concurrent (hybrid) procedures are considered **not medically necessary** when criterion VI. above is not met.

VIII. Concurrent (hybrid) or planned sequential artificial cervical disc replacement with prior or planned cervical spinal fusion at a non-contiguous level is considered **not medically necessary.**

Lumbar Artificial Disc Replacement

IX. Single-level lumbar artificial disc replacement may be considered **medically necessary** as a treatment of lumbar degenerative disc disease when all of the following criteria (A.-G.) are met:

A. Patient is skeletally mature (i.e. fully developed growth plates); and

B. The lumbar artificial intervertebral disc prosthesis is FDA-approved and will be implanted at the approved lumbar/sacral level specific to the device and the patient has none of the Food & Drug Administration (FDA) contraindications for use (see Table 3).
C. Replacement of degenerated lumbar disc is limited to one level; and
D. Persistent, debilitating pain (see Policy Guidelines) and either of the following criteria are met (1.-2.):
    1. Documented moderate to severe interference of pain with age-appropriate activities of daily living (see Policy Guidelines); **or**
    2. Severe disability as measured by the Oswestry Disability Index (see Policy Guidelines); **and**
E. Both of the following criteria are met (1.-2.):
    1. Physical and neurological abnormalities and symptoms, documented on a physical exam, that correlate with spinal cord or nerve root compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, cauda equina syndrome (see Policy Guidelines); **and**
    2. Imaging studies (e.g. CT or MRI) show compression of the spinal cord or nerve root at the affected level.
F. Symptoms have failed to improve after 3 months of conservative treatment (see Policy Guidelines for all requirements and exceptions), as part of pre-operative surgery planning, including but not limited to physical therapy (unless there is intolerable pain (see Policy Guidelines), significant motor dysfunction, or progressive neurologic changes); **and**
G. All other reasonable sources of pain and/or neurological changes have been ruled out.

X. Lumbar artificial disc replacement is considered **not medically necessary** when criterion IX. above is not met, including but not limited to the following:

A. Treatment at more than one lumbar level;
B. Replacement of a lumbar artificial disc for any reason. Per the FDA, prior surgery at the operative disc level(s) is an absolute contraindication; therefore, replacement and/or revision of a lumbar artificial disc is considered **not medically necessary.**.

XI. Lumbar hybrid procedures (lumbar fusion with lumbar artificial intervertebral disc implantation) are considered **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Spinal Fusion and Decompression Procedures, MP10

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Definitions

Activities of daily living: The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself.[1] Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

Conservative treatments: Conservative care must be recent (within the last year) and include all of the following, unless contraindicated by documentation indicating severe or rapidly progressive neurologic signs:

- Participation in a physical therapy program for the duration of conservative management (i.e. 3 months before surgery depending on the indication for surgery), including at least 3 physical therapy visits
- Oral analgesics (including anti-inflammatory medications, if not contraindicated) or participation in an interdisciplinary pain management program
- Oral corticosteroids (if not contraindicated)

Indications for which conservative care **may be waived** include the following:

- Spinal cord compression with corresponding neurological symptoms
- Stenosis causing cauda equina syndrome
- Stenosis causing myelopathy
- Stenosis causing severe weakness (graded 4 minus or less on Medical Research Council (MRC) Scale, **Table 1**)
- Severe stenosis associated with instability (dynamic excursion of greater than 1mm translation or greater than 5 degrees angulation at interspace)
- Progressive neurological deficit on serial examinations
- Discharge note from a physical therapist documenting lack of utility of further physical therapy

Table 1: Medical Research Council Scale

Medical Research Council (MRC) Scale	
Grade	*Description*
0	No contraction
1	Flicker or trace of contraction
2	Active movement with gravity eliminated
3	Active movement against gravity
4 minus	Active movement against gravity and slight resistance
4	Active movement against gravity and moderate resistance
4 plus	Active movement against gravity and strong resistance
5	Normal power

Myelopathy: Myelopathy refers to any neurological deficit related to a spinal cord injury. Corresponding clinical symptoms may include, but are not limited to the following:

- Bowel or bladder incontinence
- Clumsiness of the hands
- Frequent falls
- Urinary urgency

Corresponding objective neurological signs may include but are not limited to the following:

- Hoffman sign
- Hyperreflexia
- Increased tone or spasticity

Neck Disability Index: The Neck Disability Index (NDI) is a modification of the Oswestry Disability Index, and is used by clinicians and researchers to quantify neck pain.[2] Patients self-report scores across 10 categories, including pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. Each section is scored on a 6-point scale ranging from 0 (“no pain”) to 5 (“worst imaginable pain”).

- Scoring
    - 0-4 points (0-8%) no disability,
    - 5-14 points (10 – 28%) mild disability,
    - 15-24 points (30-48%) moderate disability,

- 25-34 points (50- 64%) severe disability,
- 35-50 points (70-100%) complete disability

Persistent, debilitating pain: Persistent, debilitating (or disabling) pain is defined as significant level of pain on a daily basis defined on a Visual Analog Scale as greater than "5" (moderate). The scale ranges from "0" (no pain) to "10" (as bad as it could be).

Radiculopathy: Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.[3] Signs and symptoms of radiculopathy must be confirmed by imaging studies and may include any of the following:

- Pain that radiates into the distal portion of the extremities following the nerve root distribution for the proposed intervention
- Numbness and tingling in a dermatomal distribution
- Muscular weakness in a pattern associated with spinal nerve root compression
- Increased or abnormal reflexes corresponding to affected nerve root level
- Loss of sensation in a dermatomal pattern.

Oswestry Disability Index: The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for low back pain.[4] The questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each question is scored by the patient on a scale of 0-5 (least amount of disability to most severe disability). Scores are then added and then doubled to obtain the index (range 0 to 100).

- Scoring
  - 0% –20%: Minimal disability
  - 21%–40%: Moderate disability
  - 41%–60%: Severe disability
  - 61%–80%: Crippling back pain
  - 81%–100%: Patients are either bed-bound or have an exaggeration of their symptoms

Table 2. FDA-Approved Cervical Artificial Disc Devices

Note: The list of devices below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website (product code: MJO).

Device	Disc Levels	Contraindications
Bryan® Cervical Disc System[5] (Medtronic)	Single level from C3-C7	• Active systemic infection or infection at the operating site; • Allergy to titanium, polyurethane, or ethylene oxide residues; • Osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -2.5;

		• Moderate to advanced spondylosis characterized by bringing osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50% of its normal height; • Marked cervical instability on radiographs (e.g., radiographic signs of subluxation greater than 3.5 mm or angulation of the disc space more than 11 degrees greater than adjacent segments); • Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma); • Significant kyphotic deformity or significant reversal of lordosis; or • Symptoms necessitating surgical treatment at more than one cervical level.
M6-C™ Artificial Cervical Disc[6] (Orthofix)	Single level from C3-C7	• Advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative or adjacent levels • Symptomatic facet arthrosis defined as pain in the neck that is worse when in extension and/or rotation and/or stiffness or the inability to move part of the neck attributable to the facets as confirmed by imaging (x-ray, CT, MRI, bone scan) • Advanced degenerative changes (e.g., spondylosis) at the index vertebral level as evidenced by bridging osteophytes, excessive translation or kyphotic deformity > 11° on neutral x-rays • Active systemic infection or infection at the operative site • Osteoporosis defined as DEXA bone mineral density T-score ≤ -2.5 • Known allergy to titanium, stainless steel, polyurethane, polyethylene, or ethylene oxide residuals
Mobi-C Cervical Disc®[7] (Zimmer Biomet, formerly LDR Spine USA)	Single level or **two contiguous levels** from C3-C7	• Acute or chronic infection, systemic or at the operative site; • Known allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, titanium, hydroxyapatite, or polyethylene); • Compromised vertebral bodies at the index level due to previous trauma to the cervical spine or to significant cervical anatomical deformity or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); • 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 adjacent level; • Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < -1.5; • Severe facet joint disease or degeneration

PCM® Cervical Disc[8] (NuVasive®)	Single level from C3-C4 or C6-C7	• Acute or chronic infections, local or systemic • Osteoporosis (defined as DEXA bone density measured T-Score < -2.5) or osteopenia (defined as DEXA bone density measured T-Score < -1.0) • Congenital stenosis • Allergy or sensitivity to any of the implant materials (cobalt, chromium, molybdenum, titanium, or polyethylene)
Prestige® Cervical Disc System (includes Prestige-ST)[9] (Medtronic)	Single level from C3-C7	• The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.
Prestige® -LP[10] (Medtronic)	Single level or **two contiguous levels** from C3-C7	• Active systemic infection or localized infection at the surgical site; • Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1.0; • Allergy or sensitivity to titanium, aluminum or vanadium; • Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5mm and/or >11° rotational difference from that of either level adjacent to the treated levels; • Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion); • Severe facet joint arthropathy; • Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level(s) due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); or • Significant kyphotic deformity or significant reversal of lordosis.
ProDisc® -C[11] (DePuy Synthes)	Single level from C3-C7	• Active systemic infection or infection localized to the site of implantation • Osteoporosis defined as DEXA bone density measured T-score ≤ 2.5 • Marked cervical instability on neural resting lateral or flexion/extension radiographs' translation > 3mm and/or 11° of rotational difference to either adjacent level • Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium) • Severe spondylosis characterized by bringing osteophytes or a loss of disc height > 50% or an absence of motion (<2°), as

		this may lead to limited range of motion and may encourage bone formation e.g. heterotopic ossification, fusion) • Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g. by radiographic appearance of fracture callus, malunion, or nonunion) • Patients with SCDD at more than one level
SECURE® -C[12] (Globus Medical)	Single level from C3-C7	• Active systemic infection or localized infection at the surgical site • Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score -1 • Allergy or sensitivity to cobalt, chromium, molybdenum, titanium or polyethylene • Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3mm and/or >11° rotational difference from that of either adjacent level • Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion) • Severe facet joint arthropathy • Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis) • Symptoms attributed to more than one vertebral level
Simplify Cervical Artificial Disc (NuVasive, Inc.)[13]	Single or **two contiguous** levels from C3-C7	• An active systemic infection or an infection at the operative site. • Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than -1.5. • Known allergy to the implant materials (PEEK, ceramic, titanium). • Severe facet disease or facet degeneration. • Bridging osteophytes. • Marked cervical instability on neutral lateral or flexion/extension radiographs (e.g.. radiographic signs of subluxation > 3.0mm or angulation of the disc space for than 11° greater than adjacent segments). • Significant cervical anatomical deformity at the index levels or clinically compromised cervical vertebral bodies at the index levels due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis).

Table 3. FDA-Approved Lumbar Artificial Disc Devices

Note: The list of devices below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website (product code: MJO).

Device	Disc Levels	Contraindications
Activ-L™[14] (Aesculap Implant Systems)	Single level from L4/L5 or L5/S1	• Active systemic infection or localized infection near the surgical site • Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than or equal to -1.0 • Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate) • Isolated lumbar radiculopathy, especially due to herniated disc • Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year) • Extruded disc material with sequestrum (i.e., free disc fragment) • Myelopathy • Spinal stenosis • Spinal deformity such as scoliosis • Spondylolysis/isthmic spondylolisthesis, degenerative spondylolisthesis > Grade I, or segmental instability • Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., current or prior vertebral fracture) or disease (e.g., ankylosing spondylitis) • Facet ankylosis or facet joint degeneration • Preoperative remaining disc height < 3mm • Symptoms attributed to more than one vertebral level • Abdominal pathology that would preclude an anterior retroperitoneal approach • Involved vertebral endplate that is dimensionally smaller than 31mm in the medial-lateral and/or 26mm in the anterior-posterior directions
ProDisc® -L[15] (DePuy Synthes)	Single **or two contiguous** levels from L3-S1	• Active systemic infection or infection localized to the site of implantation • Osteopenia or osteoporosis defined as DEXA bone density measured T-score < -1.0 • Bony lumbar spinal stenosis

		• Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium) • Isolated radicular compression syndromes, especially due to disc herniation • Pars defect • Involved vertebral endplate that is dimensionally smaller than 34.5mm in the medial-lateral and/or 27mm in the anterior-posterior directions • Clinically compromised vertebral bodies at the affected level due to current or past trauma • Lytic spondylolisthesis or degenerative spondylolisthesis of grade > 1

DOCUMENTATION REQUIREMENTS

The following information must be submitted in order to determine if medical necessity criteria are met:

- Indication for the requested surgery
- Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery.
- Clinical documentation of extent and response to conservative care (see Policy Guidelines for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes
- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms
    - Imaging must be performed and read by an independent radiologist
    - If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede

BACKGROUND

Degenerative Disc Disease (DDD)

Degenerative disc disease (DDD) involves dehydration and fibrosis of the nucleus pulposus of the intervertebral disc due to aging and trauma. Consequences include disc compression, osseous spurs, and bulging or extrusion of the nucleus tissue.[16] According to Hayes, "(t)hese changes can destabilize the anterior spinal column and cause radiculopathy (nerve root compression leading to arm and neck pain and/or neurological deficit), as well as myelopathy."[16]

According to the American Association of Neurological Surgeons (AANS), a diagnosis of cervical disc disorders may require x-rays, magnetic resonance imaging (MRI), computed tomography (CT) and/or nerve conduction studies.[17] For non-trauma patients, conservative therapies are recommended as an initial approach to pain and symptom relief and may include medications (analgesics, anti-inflammatory

drugs, and muscle relaxants), exercise, physical therapy, and immobilization.[16,17] A small subset of patients will experience continued symptoms and may be referred for surgical treatment.

The standard of care surgical treatment for patients with intractable lumbar or cervical disc disease is discectomy and fusion, which is among the top 3 most frequently performed musculoskeletal procedures performed in the U.S.[16] Although initial and long-term success rates of discectomy and fusion are relatively high, the procedure has several disadvantages, which include, but are not limited to the following:[17]

- Donor bone graft site (usually the hip) is required;
- Associated complications such as pseudo-arthrosis (10% to 30% rate) and implant failure; and
- Loss of mobility.

In addition, the Hayes review of artificial cervical disc replacement noted, "cadaveric and clinical studies have shown that ACDF causes biomechanical changes in the adjacent segments, including increased shear strains, higher intradiscal pressure, and increased adjacent segment motion. These changes have the potential to cause or accelerate the natural progression of degenerative disc disease (DDD)."[16]

Artificial Disc Replacement (ADR)

Artificial lumbar and cervical disc replacements were developed as an alternative to spinal fusion in patients with DDD.[16] These intervertebral disc prostheses are designed to preserve motion lost with spinal fusion; restoring flexibility and reducing the risk of disc degeneration in adjacent segments. Implantation of the artificial disc requires a surgical procedure, typically performed by an orthopedic surgeon or neurosurgeon. After removal of the degenerated disc (i.e., discectomy), the ADR implant is placed and complete recovery is usually achieved in 4-6 weeks.

Artificial Disc Devices

The tables in the "Policy Guidelines" above include the Food & Drug Administration (FDA)-approved artificial disc devices for cervical or lumbar disc replacement identified through February 2020. There are numerous cervical and lumbar artificial discs which are currently being investigated for one and/or two level replacement; however, medical necessity criteria are only met when a device has FDA approval at the intended spinal level.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of artificial disc replacement (ADR) as a treatment for degenerative disc disease. Database searches were also conducted to evaluate the use of ADR for the reduction of adjacent segment degeneration. Below is a summary of the available evidence identified through September 2023.

Single-Level Cervical Artificial Disc Replacement

Systematic Reviews

- A 2013 Cochrane systematic review by Boselie and colleagues assessed the effects of arthroplasty (a.k.a. artificial disc replacement or ADR) versus fusion in the treatment of radiculopathy or myelopathy, or both, due to single-level cervical degenerative disc disease.[18] The outcomes of interest were arm and neck pain, neck related functional status, patient satisfaction, neurological status, and global health status.

  The authors identified nine randomized controlled trials eligible for inclusion giving a sample size of n=2,400 (treatment groups=1,262 participants; control groups=1,138 participants). In assessing the quality of selected studies, five were of good quality and had a low overall risk of bias while four had a high overall risk of bias; however, no identified studies had "fatal flaws." Patients who underwent arthroplasty with movable cervical disc prosthesis had statistically significant, but not clinically significant, improvements in arm and neck pain, neck related functional status, neurological status, and global health status compared to the fusion patients. Patient satisfaction, measured through 1-2 years after the procedure, was the only outcome of interest not significantly different between groups. This Cochrane systematic review was of very good quality and had several strengths, including:

  1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
  2. contacting authors of selected studies for additional information or data
  3. assessment of heterogeneity and publication bias
  4. meta-analyses only being conducted when studies were determined to be homogeneous with respect to population, treatment, and outcome measures
  5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

  Limitations of this systematic review are seen in the inclusion of studies with a high risk of bias and the potential for publication bias. The authors concluded, "there is a low to moderate quality evidence that results are consistently in favor of arthroplasty."[18]

- In 2021, and archived in 2022, Hayes published a comparative effectiveness review of single-level ADR for cervical degenerative disc disease.[16] The review included 11 randomized controlled trials (RCTs) in 23 publications that examined the effectiveness and safety of single-level artificial cervical ADR compared with anterior cervical discectomy and fusion (ACDF). The reviewed studies (10 fair quality, 1 poor quality) all compared single-level ADR with ACDF. Follow-up times ranged from 2 to 7 years and included outcomes of overall success, arm and neck pain, functional disability, neurological status, and complications.

The Hayes evidence review found that single-level cervical ADR was either comparable or superior to fusion for both clinical and safety outcomes in adult patients with cervical degenerative disc disease. The quality of evidence was rated as moderate and common study limitations were lack of patient blinding, lack of long-term data, no power calculations, and lack of randomization in some studies. Ultimately, Hayes gave a "B rating for single-level cervical ADR for the treatment of cervical disc disease in patients who are candidates for fusion and who do not have contraindications that would be expected to interfere with successful arthroplasty."[16] Additional recent systematic reviews that have included the same RCTs evaluated by Hayes, have reported similar results regarding the safety and efficacy of single-level cervical ADR compared to ACDF. This includes comparable radiological and overall success and reduced subsequent surgical rates post-ADR compared to ACDF.[19,20]

- In 2020 and 2021, ECRI conducted several evidence reviews assessing the safety and efficacy of various artificial cervical disc systems for treating degenerative cervical disc disease (i.e. M6-C Artificial Cervical Disc,[21] Secure-C Cervical Artificial Disc,[22] Simplify Cervical Artificial Disc,[23] and Prestige LP Cervical Disc.[24] Investigators concluded that evidence was "inconclusive" to support the efficacy of each device. Common limitations included studies' small sample sizes, lack of long-term follow-up, retrospective design and lack of relevant outcome measures.

Bi-Level Cervical Artificial Disc Replacement

Systematic Reviews

- In 2021 and archived in 2022, Hayes published a comparative effectiveness review of multilevel ADR for cervical degenerative disc disease.[25] The review included eight studies (12 publications) that examined the effectiveness and safety of bi-level artificial cervical TDR compared with ACDF. One study evaluated hybrid surgery. The reviewed studies (2 good quality, 2 fair quality, 1 poor quality, 3 very poor quality) all compared bi-level TDR with ACDF. No studies that evaluated more than two levels (multilevel) TDR were identified that met the study inclusion criteria.
  The Hayes review reported that the overall success of bi-level cervical disc replacement at 2 years was statistically significantly better than fusion (69.7% versus 37.4%) and remained significantly better than fusion through 4 year follow-up (66% versus 36%). Bi-level cervical disc replacement also showed significant improvements compared to fusion for neck related functional status, arm and neck pain, and quality of life. Ultimately, Hayes gave a, "C rating for bi-level total disc replacement for the treatment of cervical disc disease in patients who are candidates for fusion and who do not have contraindications that would be expected to interfere with successful arthroplasty."[25] Hayes also indicated there is growing evidence that bi-level total disc replacement is generally consistent with fusion for clinical and safety outcomes, but more studies and long-term outcomes are still needed.

- In 2018, Li et al. published the results of a systematic review comparing multilevel cervical disc replacement (ACDR) and multilevel anterior discectomy and fusion (ACDF).[26] The review included 10 non-overlapping studies (four RCTs and six nonrandomized studies with 1162 patients [605 underwent ACDR and 557 underwent ACDF]). Nine studies involved 2-level surgery and one study involved three-level ACDRs and three-level ACDFs). Eight of the studies included contiguous levels and two studies included noncontiguous levels. Follow-up ranged from 18 to 84 months.

Based on pooled results for clinical efficiency, there were no significant differences between the two treatment groups in terms of blood loss, hospital stay, Japanese Orthopaedic Association scores, visual analog scale pain scores, and Neck Disability Index. Compared with ACDF, ACDR did show increased surgical time (P = 0.03; MD, 31.42; CI, 2.71–60.14). However, ACDR showed improved index range of motion (P < 0.00001; MD, 13.83; CI, 9.28–18.39), and decreased rates of adjacent segment disease (P = 0.001; odds ratio [OR], 0.27; CI, 0.13–0.59), complications (P = 0.006; OR, 0.62; CI, 0.45–0.87) and subsequent surgery (P < 0.00001; OR, 0.25; CI, 0.14–0.44) compared to ACDF. Similar conclusions regarding the efficacy of bi-level cervical ADR compared to ACDF were also reported by a second 2018 systematic review that included nine RCTs and two controlled trials.[27]

- In 2016 (updated 2020), ECRI Institute custom product brief guidance evaluated Mobi-C artificial cervical disc for treating two level degenerative cervical disc disease.[28] Mobi-C is one of two FDA-approved devices for contiguous two level cervical disc replacement. Reviewers searched research databases for literature relevant to the Mobi-C device that assessed 50 or more patients and was published between January 1, 2011, and August 11, 2016. Three studies were selected for review: a multicenter randomized controlled trial (RCT) (n=330), a post hoc analysis of the selected RCT, and a prospective nonrandomized comparison study (n=231). In comparing Mobi-C to fusion, the ECRI review found, "patients with symptomatic cervical disease who underwent two-level Mobi-C total disc replacement had greater improvement in general and disease-specific outcomes, a lower reoperation rate, and less radiographic adjacent segment pathology."[28] The review of evidence also found two-level Mobi-C to be as safe and effective as one-level Mobi-C for total cervical disc replacement at two to four year follow-up. There were also no significant differences between groups for clinical outcomes, overall complication rates, and subsequent surgery rates.

- In 2015, Zhao et al. conducted a systematic review and meta-analysis to evaluate multi-level cervical disc arthroplasty (CDA) versus single-level CDA for the treatment of cervical disc disease.[29] Authors systematically searched research databases for studies published between January 1990 and June 2014 comparing multi-level versus single-level CDA with at least one year of follow-up data. Two independent reviewers assessed the methodological quality and extracted relevant data of selected studies. The outcomes of interest were functionality, neck and/or arm pain, quality of life, reoperation, and incidence of heterotopic ossification.

  Eight studies were eligible for inclusion, and this included four prospective cohort studies and four retrospective cohort studies. The meta-analysis results found no significant differences between two-level and single-level CDA for any outcomes of interest at one to two years follow-up. Strengths of this study include the systematic review of literature following a pre-defined protocol and evaluation of methodological quality by two independent reviewers. Strength was also found in the assessment of heterogeneity to determine the appropriateness of conducting a meta-analysis. Limitations were identified in the significant lack of randomized controlled trials, the small number of studies identified for inclusion, and small sample sizes of included studies. The authors concluded, "the outcomes and functional recovery of patients performed with multi-level CDA are equivalent to those with single-level CDA, which suggests the multi-level CDA is as effective and safe as single-level invention for the treatment of cervical spondylosis."[15] The authors also indicated the need for further well-designed studies to evaluate the efficacy of multi-level CDA for treatment of cervical degenerative disc disease.

<u>Randomized Controlled Trials (RCT)</u>

Prestige LP Bi-Level Cervical Artificial Disc Device

- The Prestige LP device received FDA approval for implantation at two cervical contiguous levels in July 2016. Approval was established using a prospective, multi-center, randomized, unblinded, concurrently controlled, non-inferiority study designed to compare the safety and effectiveness of the bi-level Prestige LP cervical disc to the standard of care (bi-level cervical discectomy and fusion).[10,30,31] Patients were randomized 1:1(n=209 Prestige LP bi-level cervical artificial disc; n=188 bi-level cervical fusion) and then followed-up for 24 months to evaluate the primary outcomes of overall success (defined as a 15 point improvement on the neck disability index score), neurologic status, additional surgical procedure classified as a failure, and adverse events. Secondary outcomes of interest included the neck disability index score, neck and/or arm pain, quality of life, patient satisfaction, medication usage, range of motion, heterotopic ossification, and work status compared to the standard of care group.

  Two year follow-up data was available for 95.2% of 2-level Prestige LP patients and 88.9% of standard of care patients.[10,30] Overall success was achieved in 81.4% of Prestige LP patients and in 69.4% of fusion patients, which met pre-defined superiority criteria. The bi-level fusion group had 12 (6.4%) severe device-related adverse events compared to five (2.4%) in the Prestige LP group; however, this difference was not statistically significant. Also, more fusion patients required subsequent surgical procedures than patients in the Prestige LP group. Follow-up data for the overall success outcome was again collected at seven years (84 months), and the Prestige LP group remained superior to fusion for treatment of bi-level cervical disc disease.[31]

  Methodological strengths included the prospective, multi-center, randomized, controlled design and large sample sizes comparing the Prestige LP to the standard of care. The extended follow-up analysis was also a methodological strength; however, several losses to follow-up occurred so potential bias cannot be excluded. Limitation was observed in the unblinding of participants to the procedure (the authors deemed this to be unethical). Ultimately, Prestige LP was proven to be superior to the standard of care fusion for the treatment of bi-level cervical degenerative disc disease through seven years.

Mobi-C Bi-Level Cervical Artificial Disc Device

- In 2018, Yang et al., published 81 month results from an RCT evaluating outcomes of TDR using the Mobi-C versus ACDF, enrolling 96 patients with DDD at two contiguous levels.[6] At the follow-up time point of 81 months, only 80 patients were available for analysis (38 in the TDR group and 42 in the ACDF group). The investigators reported significantly lower VAS and NDI scores in the TDR group compared to the ACDF group at the 81-month time point. In addition, the range of motion at both the superior and inferior adjacent levels was significantly greater in the TDR group. Lastly, there was a lower occurrence of adjacent segmental degeneration in the TDR group compared to the ACFD group in both the superior and inferior adjacent levels.

- In 2015, the four year results of a multi-center, prospective, RCT to evaluate the safety and effectiveness of two-level total disc replacement with the Mobi-C device versus anterior discectomy and fusion was published by Davis and colleagues.[32] Eligible patients with bi-level cervical degenerative disc disease were randomized 2:1 (n=225 Mobi-C patients and n=105 fusion patients),

blinded to treatment until after surgery, and postoperatively followed for four years. Outcomes of interest included overall clinical success (measured using the neck disability index scale, visual analog scales for neck and/or arm pain, short form health survey, and mental health survey), subsequent surgical intervention, complications, neurological function, return to work, and patient satisfaction.

Both groups showed improvements in the neck disability index score at every follow-up point through 2 years; however, the Mobi-C group had statistically significantly better improvements in neck disability index score in comparison with fusion at every postoperative time point. Patients in the Mobi-C group also had statistically significantly lower secondary surgery rates at the 48-month follow-up compared to the fusion group (4.0% vs 15.2%). Mobi-C patients also showed better improvement in neck pain, arm pain, neurologic success, return to work, patient satisfaction, and major complications compared to the fusion patients, but the differences were not statistically significant. At the two-year follow-up, there was a statistically significant difference in overall success for the Mobi-C group compared to the fusion group (66.0% vs. 36.0%).

- Strengths of this study include the multi-center randomized controlled design, the blinding of participants to surgical treatment, power analyses, and pre-defined noninferiority and superiority criteria. Limitations were identified in the small sample sizes, short follow-up period, and lack of intention-to-treat analysis. There is also potential for funding bias as this study was industry sponsored by the Mobi-C device manufacturer. The authors concluded "four-year results from this study continue to support total disc replacement as a safe, effective, and statistically superior alternative to fusion for the treatment of degenerative disc disease at two contiguous cervical levels."[32]

  In 2016, five year follow-up results of this RCT were published by Radcliffe and colleagues.[33] Follow-up data was available for 90.7% of Mobi-C patients and 86.7% of fusion patients at five years. Both groups showed improvement in all outcomes compared to baseline; however, the Mobi-C patients had statistically significantly better improvement than fusion patients for neck disability index score, SF-12 physical component summary, and overall satisfaction with treatment. Also, the reoperation rate at five years was significantly lower in Mobi-C patients compared to fusion patients (4% versus 16%). There were no significant differences in adverse event rates between groups. Ultimately, "both cervical total disc replacement and fusion significantly improve general and disease-specific measures compared with baseline. However, there was significantly greater improvement in general and disease-specific outcome measures and a lower rate of reoperation in the 2-level disc replacement patients versus fusion control patients."[33]

Nonrandomized Studies

Additional studies evaluating multilevel cervical procedures for the treatment of cervical degenerative disc disease were identified. While the collective results occasionally indicated potential efficacy and safety of this procedures, all of the studies had significant methodological limitations including but not limited to short follow-up periods, small sample sizes, and retrospective nonrandomized study designs.[34-36] Moreover, authors of these studies called for additional research to validate findings reported to date.

Cervical Artificial Disc Replacement and Adjacent Segment Degeneration (ASD)

Systematic Reviews

- In 2017, Dong et al. reported the results of a large systematic review that evaluated adjacent segment motion, degeneration, disease, and reoperation of cervical ADR compared with ACDF, including 29 RCTs.[37] Compared with ACDF, the rate of adjacent segment reoperation in the ADR group was significantly lower at 24-months follow-up (nine trials, p<.05). This reduction became more significant in the ADR group at >24 months follow-up (12 trials, p<.01). There was no statistically significant difference in ASD between ADR and ACDF treatment groups within 24-month follow-up (two trials); however, the rate of ASD in ADR was significantly lower than that of ACDF at later time points (two trials, p<.01). There were also no statistically significant differences in adjacent segment disease (eight trials) or range of motion (three trials) between ADR and ACDF.

- In 2014, Luo and colleagues published a systematic review and meta-analysis which evaluated the incidence of adjacent segment degeneration (ASD) in cervical disc arthroplasty versus cervical decompression and fusion in patients with cervical radiculopathy or myelopathy.[38] Eight RCTs were included in the meta-analysis resulting in a sample size of 1,726 patients (889 in the ADR group and 837 in the fusion group). Seven of the eight selected studies were determined to be of good methodological quality. Results indicated the fusion group had significantly more adjacent segment disease compared to the ADR group at 24 months postoperatively. Four of the eight studies also provided data on adjacent segment reoperations after ADR or fusion resulting in a sample size of 1,066 patients (536 in the ADR group and 530 in the fusion group). The ADR group had significantly fewer adjacent segment reoperations at 24 months postoperatively compared to the fusion group.

  Strengths of this study include the systematic review of literature following a pre-defined protocol and evaluation of methodological quality by two independent reviewers. Strength was also found in the assessment of heterogeneity to determine the appropriateness of conducting a meta-analysis. Limitations were seen in the lack of blinding in selected RCTs and the small number of included studies, especially for the evaluation of adjacent segment reoperations; therefore, publication bias cannot be excluded. The authors concluded "for patients with one-level cervical degenerative disc disease, total disc replacement was found to have significantly fewer adjacent segment degenerations and reoperations compared with fusion."[38]

- Two systematic reviews and meta-analyses (2012 and 2013) evaluated the incidence of adjacent segment degeneration after cervical disc arthroplasty.[39,40] Both reviews found that patients who underwent cervical ADR had lower rates of adjacent segment degeneration and adjacent-level surgery; however, these differences were not significant. Ultimately, it could not be concluded that ADR significantly reduces postoperative adjacent segment degeneration and/or adjacent level surgery. All authors recognized the need for future prospective studies to support the hypothesis that ADR reduces adjacent segment degeneration.

Cervical Hybrid Procedures

Systematic Reviews

- In 2020, Zhang and colleagues conducted a systematic review and meta-analysis of hybrid surgery and anterior cervical discectomy and fusion in cervical diseases.[41] Independent investigators

systematically searched the literature, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 7 controlled trials were included for review (2 prospective; 5 retrospective). Outcomes of interest included functionality, neck pain, arm pain, cervical range of motion (ROM), quality of life and complications relative to patients undergoing cervical discectomy and fusion (ACDF) for the treatment of multilevel cervical spondylosis and disc diseases. The results of the meta-analysis indicated that hybrid surgery patients experience superior NDI scores (*p* =0.038), cervical ROM (*p*=0.00*)* and similar VAS score (*p*=0.058) compared with ACDF patients at 2 years follow-up. No significant difference in quality of life, complications Investigators concluded that hybrid surgery is an effective alternative invention for the treatment of multilevel cervical spondylosis to preserve cervical ROM and reduce the risk of adjacent disc degeneration. Limitations included the lack of RCTs comparing the outcomes between hybrid surgery and ACDF, the small number of included studies, lack of long-term follow-up and heterogeneous treatment parameters. Investigators called for additional, well-designed studies with large groups of patients further determine the safety and efficacy of hybrid surgery for the treatment of cervical disk diseases.

- The 2021, Hayes evidence review for multilevel cervical ADR also evaluated cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) for the treatment of cervical degenerative disc disease.[25] Only one study met the inclusion criteria for this review, by Grasso et al. (2015).[42] Hayes assigned a "D2" rating due to insufficient evidence to report on the safety, efficacy, and health outcomes of cervical hybrid procedures.

- In 2018, Zhao and colleagues conducted a meta-analysis comparing radiographic and surgical outcomes between ACDF and hybrid surgery (HS, corpectomy combined with discectomy) in the treatment for multilevel cervical spondylotic myelopathy.[43] The review included four retrospective comparative studies in Chinese patients (n= 96 to 233 patients). No randomized studies were included. Although the pooled analysis found no significant difference in the majority of outcomes between treatment groups, there were significant increases in blood loss (P < 0.00001) and total complication rate (P = 0.04, OR = 0.66 95%CI: 0.44 - 0.98) in the fusion group compared to the ACDF group. The small number of included studies prevented analysis of a large number of outcomes, and the follow-up time of 24 months precludes any conclusions regarding long-term recovery and complications of hybrid procedures.

- In 2017, Lu et al. conducted a systematic review comparing hybrid surgery (HS) with ACDF to treat multilevel cervical disc disease, including eight studies (169 patients underwent HS and 193 underwent ACDF).[20] Of the eight studies, six studies were retrospective in nature. Only one study was randomized, and it only enrolled 24 patients in total. Five studies employed hybrid procedures using ADR and ACDF, two studies combined ADR with anterior cervical corpectomy and fusion (ACCF), and one small study (n= 28 patients) was included that addressed tri-level procedures using ACCF and ACDF/ADR.

  The review found that operative time was greater for HS by 42 min (p < 0.00001), but resulted in less intraoperative blood loss by 26 mL (p < 0.00001) and shorter return to work by 32 days (p < 0.00001). In terms of clinical outcomes, HS was associated with greater C2-C7 range of motion (ROM) preservation (p < 0.00001) and less functional impairment (p = 0.008) after surgery compared to ACDF. However, there were no significant differences between HS and ACDF with respect to postoperative pain, length of stay and complication rates. The reviewers concluded that hybrid surgery is still a novel treatment option and "while it remains a viable consideration, there is a lack

of robust clinical evidence in the literature. Future large prospective registries and randomized trials are warranted to validate the findings of this study."

Author-noted limitations included heterogeneity in the components of the hybrid procedure, small sample sizes, insufficient number of studies comparing hybrid surgery to conventional ACDF, and generally low quality of evidence. In addition, the observational nature of the studies poorly controlled for selection and observation biases and limited the validity of reported outcomes.

Nonrandomized Studies

- In 2018, Laratta and colleagues conducted a systematic review assessing the safety and efficacy of single-level, multilevel and hybrid procedures for the treatment of various cervical pathologies.[44] Independent investigators systematically searched the literature, identified eligible studies, assessed study quality, extracted data and pooled results. Among the studies included for review, 3 were RCTs, 2 were systematic reviews. Authors did not detail their methodology for searching and reviewing literature. On the basis of reviewed studies, investigators concluded that single-level CDA can offer equivalent clinical outcomes with a reduction in secondary procedures relative to anterior cervical discectomy and fusion. Investigators concluded that while data regarding multilevel procedures is less robust, it appears that they may be as effective as their single-level counterparts. Limitations included the lack of a systematic review of evidence and author conflicts of interest with various medical device companies.

- Additional observational studies evaluating cervical hybrid procedures for the treatment of cervical degenerative disc disease were identified.[44-54] While the collective results did indicate potential efficacy and safety of cervical hybrid procedures, all of the studies had significant methodological limitations including but not limited to short follow-up periods, small sample sizes, and retrospective nonrandomized study designs. Of note, the more recent studies reporting 5-6 year outcomes are retrospective in design and reported on less than 35 patients per treatment group. One prospective study evaluating 40 patients reported superior outcomes for hybrid surgery at 2-year follow-up relative to anterior cervical discectomy and fusion, but noted that these improvements became non-significant at 5-year follow-up.[54]

Lumbar Artificial Disc Replacement

Systematic Reviews

- In 2022, Hayes published a comparative effectiveness review evaluating the utility of ADR for the treatment of lumbar degenerative disc disease.[55] The review included 21 studies in 38 associated publications evaluating lumbar ADR versus anterior lumbar discectomy and fusion in adults with lumbar degenerative disc disease. The review also included three high-quality comprehensive systematic reviews published in 2017 and 2018. Eight of the RCTs included patients with DDD at a single level, while two studies examined patients with > 1 level of DDD. Follow-up times ranged from 7 to 17 years, with RCTs generally following patients for 2 to 5 years.

  The Hayes evidence review found that single-level lumbar ADR was comparable to spinal fusion for both clinical and safety outcomes in adult patients with 1-level lumbar degenerative disc disease. The quality of evidence was rated as moderate and common study limitations were lack of patient

blinding, lack of long-term data, no power calculations, and lack of randomization in some studies. Ultimately, Hayes gave a, "B rating for 1-level lumbar total disc replacement as an alternative to spinal fusion, using a FDA-approved artificial disc in properly selected patients with 1-level symptomatic degenerative disc disease who have failed conservative treatment."[25] Bi-level lumbar disc replacement was rated as "D2" due to insufficient evidence, with Hayes stating "there is relatively little evidence regarding the safety and efficacy in patients with exclusively multilevel DDD."

- In 2018, ECRI conducted an evidence review of the ActivL Artificial Disc (Aesculap, Inc.) for lumbar disc arthroplasty.[56] Searching the literature through June 2018, authors included one systematic review and a network meta-analysis evaluating 6 RCTs, investigators concluded that the "activL Artificial Disc reduced back pain and improved the ability to perform daily tasks" relative to comparator discs. Limitations included a lack of evidence comparing activL with lumbar fusion and varying instruments assessing patient-oriented outcomes of disability and back pain. While assessing evidence to date as "somewhat favorable," authors also called for additional RCTs comparing activL to other total disc replacement systems and long-term RCTs comparing activL to fusion procedures.

- A 2012 Cochrane systematic review by Jacobs and colleagues assessed the effects of total disc replacement for chronic low-back pain in the presence of lumbar disc degeneration compared with other treatment options in terms of patient-centered improvement, motion preservation, and adjacent segment degeneration.[57] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcomes of interest were symptoms (specifically, pain and pain medication usage), overall improvement, patient satisfaction, back-specific functional status, quality of life, and complications.

  The authors identified 40 publications, describing seven unique RCTs with follow-up through 24 months (one study extended follow-up to 5 years). In assessing the quality of the RCTs, 5 were of good quality and had a low overall risk of bias while 2 had a high overall risk of bias; however, no identified studies had "fatal flaws." Patients who underwent arthroplasty with movable lumbar disc prosthesis had statistically significant differences in back and/or leg pain, back-specific functional status, and patient satisfaction compared to the fusion patients. Lumbar total disc replacement patients also had better range of motion or range of motion comparable to preoperative status. There were no statistically significant differences between groups for adjacent segment degeneration, reoperation rates, and complications. This Cochrane systematic review was of very good quality and had several strengths, including:

  1. the systematic gathering of evidence, assessment of quality, and extraction of data by several independent reviewers following a pre-defined protocol
  2. contacting authors of selected studies for additional information or data
  3. assessment of heterogeneity, reporting bias, and publication bias
  4. meta-analyses only being conducted when studies were determined to be homogeneous
  5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

  Limitations of this systematic review were the inclusion of studies with a high risk of bias and the potential for publication bias. The authors concluded, "total disc replacement seems to be effective

in treating low-back pain in selected patients, and in the short-term is at least equivalent to fusion surgery."[57] The authors also identified the need for further research and recommended the spine surgery community be sensible about adopting this technology on a large scale.

- Two more recent systematic reviews and meta-analyses were also identified that evaluated artificial total disc replacement versus fusion for lumbar degenerative disc disease.[58,59] Two independent reviewers systematically search research databases to identify relevant studies, assess quality, and extract data. Both studies showed that lumbar total disc replacement had significant safety and efficacy results comparable to lumbar fusion through two years; however, it was not demonstrated that lumbar ADR was superior to fusion. All authors recognized the need for future prospective studies to support the hypothesis that ADR is superior to fusion for the treatment of one-level lumbar degenerative disc disease.

Randomized Controlled Trial (RCT)

- In 2013, the five year results of a multi-center, prospective, RCT to evaluate the safety and effectiveness of lumbar total disc replacement versus anterior discectomy and fusion was published by Skold and colleagues.[60] Eligible patients with lumbar degenerative disc disease were randomized [n=80 lumbar ADR (randomized to one of three FDA-approved devices: Charite, ProDisc-L, or Maverick) and n=72 fusion patients] and were postoperatively followed-up at 1, 2, and 5 years. Outcomes of interest included global assessment of back pain, low back pain visual analog scale, disease-specific pain and disability, work status, complications, and reoperations.

  Almost 100% (99.3%) of randomized patients were available for follow-up at 5 years. Both groups showed improvements in the global assessment of back pain through 5 year follow-up; however, the ADR group had statistically significant better improvements in the global assessment of back pain score in comparison with fusion. Patients in the ADR group also had statistically significant better improvement in low back pain visual analog scale and a lower level of disability than the fusion group through 5 year follow-up. No significant differences were identified between groups for patient satisfaction, complication, and reoperation rates.

  Strengths of this study include the randomized controlled design, power analyses, similar characteristics between groups at baseline, and comparison of technology to standard of care. Limitations were identified in the small sample sizes, short follow-up period, and lack of intention-to-treat analysis. The authors concluded that although further studies are needed, a majority of patients with lumbar degenerative disc disease can benefit from ADR.

Lumbar Artificial Disc Replacement and Adjacent Segment Degeneration (ASD)

- In 2012, Wang and colleagues published a systematic review to evaluate the incidence of adjacent segment degeneration (ASD) in lumbar total disc replacement (TDR) versus fusion.[61] The authors sought to answer three key questions:

  1. Is there evidence that TDR is associated with a lower risk of radiographical or clinical symptomatic ASD compared with fusion?
  2. Is there evidence that other motion preservation devices are associated with a lower risk of radiographical or clinical ASD compared with fusion?

3. Is one type of motion preservation device associated with a lower risk of radiographical or clinical ASD compared with other devices?

Authors systematically searched databases for RCTs and cohort studies published between January 1990 and February 2012 aimed at answering these three questions. Two independent reviewers also assessed the quality of selected studies using the Grades of Recommendation Assessment, Development and Evaluation (GRADE) methodology.

Ultimately, eight studies were included in the systematic review that reported on adult patients who had lumbar degenerative disc disease, herniated disc, radiculopathy, kyphosis, scoliosis, or spondylolisthesis and were treated with total disc replacement, another motion-sparing procedure, or fusion. Two of the selected RCTs reported statistically significant between groups differences for ASD (1.2% of TDR patients versus 7.0% of fusion patients). Overall, the authors found moderate evidence that indicated patients who undergo fusion may be 6 times more likely to be treated for ASD compared to patients who undergo total disc replacement; however, there was insufficient evidence to answer all key questions.

Strengths of this study include the systematic review of literature following a pre-defined protocol and evaluation of methodological quality by two independent reviewers. Strength was also found in the assessment of heterogeneity to determine the inappropriateness of conducting a meta-analysis. Limitations were seen in the lack of blinding in selected RCTs and the small number of included studies; therefore, significant bias cannot be excluded. The authors concluded, "the evidence suggests that the risk of clinical ASD following fusion is higher when compared to TDR, but there is limited evidence that fusion may increase the risk of developing clinical ASD compared with other motion-sparing procedures."[61]

- In 2008, Harrop et al. published a systematic review to evaluate lumbar adjacent segment degeneration and disease after arthrodesis (also named fusion) and total disc arthroplasty.[62] Adjacent Segment Degeneration (ASDeg) is the radiographic presence of disc deterioration adjacent to a surgically treated disc while Adjacent Segment Disease (ASDis) is the development of clinically symptomatic junctional degeneration. Authors systematically searched the MEDLINE research database for literature published between 1996 and 2006 evaluating the incidence of ASDeg and ASDis after lumbar arthrodesis or arthroplasty. Two independent reviewers assessed the methodological quality and extracted relevant data of selected studies.

  After systematic review, 27 publications met the inclusion criteria (20 focused on arthrodesis and 7 on arthroplasty) producing a sample size of 2,490 patients (1,732 from the arthrodesis manuscripts and 758 from the arthroplasty manuscripts). All selected studies received a quality grade of 3 or 4 out of five. Results indicated a statistically significant difference in ASDeg between the arthrodesis and total disc replacement groups (34% versus 9%, $P < 0.0001$). Multivariate logistic regression also showed increased odds of ASDeg with increased age, arthrodesis, and longer follow-up. For ASDis, results indicated a statistically significant difference between the arthrodesis and arthroplasty patients (14% versus 1%, $P < 0.0001$). Multivariate logistic regression also showed increased odds of ASDis in studies with fusion, more male patients, and shorter follow-up periods.

  Strengths of this study include the use of a pre-defined protocol for the systematic review of literature, the inclusion of a large number of publications, and the evaluation of methodological

quality by two independent reviewers. Limitations were seen in the lack of randomization and blinding in the selected studies, so significant bias cannot be excluded. The use of only the MEDLINE database to identify relevant literature is another significant limitation due to the increased potential for publication bias. The authors concluded, "the data supports only a class C recommendation (lowest tier) for the use of arthroplasty to reduce adjacent segment disc degeneration and disease compared to arthrodesis."[62]

Lumbar Hybrid Procedures

Three studies evaluating lumbar hybrid procedures (lumbar fusion with lumbar artificial intervertebral disc implantation) for the treatment of lumbar degenerative disc disease were identified.[49,50,63] All studies were of poor-quality and had significant methodological limitations including but not limited to short follow-up periods, small sample sizes, and retrospective nonrandomized study designs and significant loss to follow-up; therefore, there is insufficient evident to support the use lumbar hybrid procedures. Additional, high-quality clinical trials are needed to establish the clinical utility of lumbar hybrid procedures for the treatment of lumbar degenerative disc disease.

CLINICAL PRACTICE GUIDELINES

Cervical Artificial Disc Replacement

North American Spine Society (NASS)

In 2024, NASS revised their coverage policy recommendation in support of cervical ADR for patients with cervical back pain, publishing the following criteria:[64]

"Cervical artificial disc replacement (CADR), also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate.

1. Radiculopathy related to nerve root compression from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3 to C7 in the following scenarios:
   a. Persistent symptoms despite at least 6 weeks of nonoperative management.
   b. Progressive or functionally limiting weakness correlating with the compressed nerve root.
   c. Inability to perform normal work duties or necessary activities of daily living because of severity of symptoms, despite nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from 1- or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3 to C7.
3. Use can be considered for radiculopathy or myeloradiculopathy due to multilevel degenerative disease (either herniated disc or spondylotic osteophyte) as part of a hybrid construct, ie, in concert with an anterior cervical discectomy and fusion (ACDF) for cervical levels that do not satisfy the stringent criteria for TDA [total disc arthroplasty].

There is not significant evidence at this time to support its use for 3 or more levels, nor is there evidence for its use for isolated axial neck pain.

CADR is contraindicated in the following scenarios.

1. Infection
    a. active at the site of proposed implantation, OR
    b. systemic infection
2. Osteoporosis or osteopenia
3. Instability defined as:
    a. translation greater than 3mm difference between lateral flexion-extension views at the symptomatic level, OR
    b. 11 degrees of angular difference between lateral flexion-extension views at the symptomatic level
4. Sensitivity or allergy to implant materials
5. Severe spondylosis defined as:
    a. greater than 50% disc height loss compared to minimally or non-degenerated levels, OR
    b. bridging osteophytes, OR
    c. absence of motion on flexion-extension views at the symptomatic site
6. Severe facet joint arthropathy defined as radiographic confirmation of facet joint disease or degeneration
7. Ankylosing spondylitis
8. Rheumatoid arthritis
9. Previous fracture with anatomical deformity
10. Ossification of the posterior longitudinal ligament (OPLL)
11. Malignancy: active, in the cervical spine"

Regarding the use of ADR adjacent to a previous fusion, the NASS guidelines state the following:

> "Currently, use of cervical ADR adjacent to a previous fusion is a common but off label procedure. While these hybrid procedures may be efficacious, they have not yet been studied in a rigorous manner. Therefore strong evidence based recommendations for CADR adjacent to a previous fusion cannot be made at this time."

Health Evidence Review Commission (HERC)

In 2014, the Oregon HERC issued coverage guidance for cervical ADR and recommended coverage only when all of the following criteria are met:[65]

- Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
    - Skeletally mature patient
    - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

National Institute for Health and Care Excellence (NICE)

The 2010 evidence-based NICE guideline for cervical ADR stated, "current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long

term."[66] NICE also noted the evidence indicates no safety issues that are not already known with spinal fusion; thus, "this procedure may be used provided that normal arrangements are in place for clinical governance, consent, and audit."[66]

American College of Occupational and Environmental Medicine (ACOEM)

In 2016, the ACOEM issued an evidence-based guideline for cervical and thoracic spine disorders and recommended, "artificial disc replacement for subacute or chronic radiculopathy and myelopathy."[67]

Lumbar Artificial Disc Replacement

North American Spine Society (NASS)

In 2024, NASS updated their coverage policy recommendation in support of lumbar ADR for patients with low back pain, publishing the following criteria:[68]

> "Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria:
>
> 1. Pain arising from 1- or 2-level disc disruption involving L3-4, L4-5, and/or L5-S1 segments.
> 2. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period, which should include a physical therapy/rehabilitation program, and may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.
> 3. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain.
>
> Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:
>
> 1. Any case that does not fulfill ALL of the above criteria
> 2. Presence of symptomatic degenerative disk disease at more than two levels
> 3. Significant facet arthropathy at the index level or signs that the source of pain is primarily facet mediated
> 4. Presence of spinal instability with spondylolisthesis greater than Grade I
> 5. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)
> 6. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
> 7. Poorly managed psychiatric disorder (any underlying psychiatric disorder, such as depression, should be diagnosed and the management be optimized before surgical intervention)
> 8. Age greater than 60 years or less than 18 years
> 9. Presence of infection or tumor"

International Society for the Advancement of Spine Surgery (ISASS)

- In 2021, the ISASS published a position statement on cervical and lumbar disc replacement.[69] On the basis of a non-systematic review of literature, authors "strongly" endorsed both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, as safe and effective treatment alternatives to fusion in appropriately selected patients.

- In 2015, the ISASS published policy statement regarding lumbar ADR stated, "there is sufficient evidence-based scientific evidence to support the safety and efficacy of single level lumbar total disc replacement for patients meeting well established selection criteria."[70] The policy statement also noted that lumbar disc replacement is a well-tested technology and should predictably lead to better outcomes and fewer complications in comparison to fusion surgery.

Health Evidence Review Commission (HERC)

In 2014, the Oregon HERC issued coverage guidance for lumbar ADR and recommended coverage only when all of the following criteria are met:

- Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
- Patients must be 60 years or under;
- Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
    - Failure of at least six months of conservative treatment
    - Skeletally mature patient
    - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging.[65]

National Institute for Health and Care Excellence (NICE)

The 2010 evidence-based NICE guideline for lumbar ADR stated, "current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent, and audit."[71] The guideline also recommended lumbar disc replacement should only be performed in patients who have undergone unsuccessful conservative treatment options. NICE also noted the importance of, "a multidisciplinary team with specialist expertise in the treatment of degenerative spine disease be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine."[71]

American Pain Society (APS)

The 2009 APS evidence-based clinical practice guideline for low back pain concluded, "insufficient evidence to adequately evaluate long-term benefits and harms of lumbar total disc replacement."[72] However, this recommendation was based on literature searches through July 2008 and other evidence-based scientific evidence to support the safety and efficacy of single level lumbar total disc replacement has been published since then.

EVIDENCE SUMMARY

Moderate-quality evidence assessed by multiple systematic reviews suggests the safety and clinical efficacy of single- or bi-level cervical disc replacement is similar or superior to fusion as a treatment of cervical degenerative disc disease in skeletally mature patients. In addition, current evidence is sufficient to suggest lumbar ADR is comparable to fusion for both clinical and safety outcomes in adult patients

with single-level lumbar degenerative disc disease. Both cervical and lumbar artificial discs appear to have better degeneration outcomes than fusion; however, recent evidence is conflicting and does not verify the use of these devices for the reduction of adjacent segment degeneration. More high-quality evidence is needed to confirm the use of ADR for the reduction of adjacent segment degeneration.

Low-quality but consistent evidence suggests that cervical hybrid procedures (spinal fusion with artificial disc implantation) are at least as safe and effective as cervical fusion procedures for the treatment of cervical degenerative disc disease.

BILLING GUIDELINES AND CODING

0098T may be billed in conjunction with 22861.

CODES*		
CPT	0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
	0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
	0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
	0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
	22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
	22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
	22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
	22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
	22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

	22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy, then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
11/2023	Annual review. Title update. No coding or criteria changes.
11/2024	Annual review. No coding or criteria changes.