See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

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

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

Cervical Artificial Disc Replacement

I. Cervical artificial disc replacement, at a single-level or at two contiguous levels, may be considered medically necessary and covered as a treatment of cervical degenerative disc disease or herniated disc(s) when all of the following criteria (A.-G.) are 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 (Table 1); and
C. Replacement of degenerated cervical disc(s) does not exceed two contiguous levels; and
D. The patient has one or more of the following symptoms (1.-3.):
   1. Intractable cervical radiculopathy, including one or more of the following:
a. Arm pain with or without neck pain; or
b. A neurological deficit; or
2. Myelopathy due to an abnormality localized to the level of the disc space; or
3. Severe or rapidly progressive symptoms of nerve root and/or spinal cord compression that requires immediate surgical treatment; and
E. The diagnosis of no more than two diseased or immobile cervical spine levels that has been confirmed on complex imaging studies (i.e. CT or MRI) and 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. There is clinical documentation that a minimum of 6 weeks of non-invasive treatment failed to adequately treat the patient’s symptoms (unless there is evidence of spinal cord compression that requires immediate surgical treatment), including two or more of the following treatments (1.-3.):
   1. Alteration of activities, including but not limited to cessation of activities that exacerbate symptoms; and/or
   2. Use of narcotic or nonnarcotic pain medication, and/or nonsteroidal anti-inflammatory drugs (NSAIDS), if not contraindicated; and/or
   3. A trial of physical therapy; and
G. The patient is an appropriate candidate for cervical artificial disc replacement, and has none of the Food & Drug Administration (FDA) contraindications for use (see Table 1).

II. Cervical artificial disc replacement is considered investigational and is not covered when criterion I. above is not met, including, but not limited to the following (A.-B.):
A. Treatment at more than one non-contiguous cervical level.
B. Replacement of a cervical 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 cervical artificial disc is considered investigational and not covered.

III. Cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) are considered investigational and are not covered.

Lumbar Artificial Disc Replacement

IV. Single-level lumbar artificial disc replacement may be considered medically necessary and covered 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 (see Table 2); and
C. Replacement of degenerated lumbar disc is limited to one level; and
D. The diagnosis of lumbar degenerative disc disease has been confirmed using complex imaging studies (e.g., MRI or CT) at the lumbar level that is proposed for intervention; and
E. Patient is experiencing unremitting low back pain and significant functional impairment (defined as the direct and measurable reduction in physical performance of an organ or body part); and
F. There is clinical documentation that a minimum of 6 months of non-operative treatment failed to adequately treat the patient’s symptoms, including all of the following (1.-3.):
1. Alteration of activities, including but not limited to cessation of activities that exacerbate symptoms; and
2. Use of narcotic or nonnarcotic pain medication, and/or nonsteroidal anti-inflammatory drugs (NSAIDS), if not contraindicated; and
3. A trial of physical therapy; and
G. The patient is an appropriate candidate for lumbar artificial disc replacement, and has none of the Food & Drug Administration (FDA) contraindications for use (see Table 2).

V. Lumbar artificial disc replacement is considered investigational and is not covered when criterion IV. above is not met, including but not limited to the following (A.-B.):

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 investigational and not covered.

VI. Lumbar hybrid procedures (lumbar fusion with lumbar artificial intervertebral disc implantation) are considered investigational and are not covered.

Link to Policy Summary

POLICY GUIDELINES

Table 1. FDA-Approved Cervical Artificial Disc Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Disc Levels</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bryan® Cervical Disc System¹ (Medtronic)</td>
<td>Single level from C3-C7</td>
<td>• Active systemic infection or infection at the operating site;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Allergy to titanium, polyurethane, or ethylene oxide residues;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -2.5;</td>
</tr>
</tbody>
</table>
### MEDICAL POLICY

**Back: Artificial Intervertebral Discs**  
*(All Lines of Business Except Medicare)*

<table>
<thead>
<tr>
<th>Product</th>
<th>Eligibility</th>
</tr>
</thead>
</table>
| **M6-C™ Artificial Cervical Disc**  
(Spinal Kinetics) | 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. |
| **Mobi-C®³**  
(LDR Spine USA) | Advanced neurological deformity (e.g., ankylosing spondylitis, scoliosis) at the operative or adjacent levels  
Symptomatic facet arthropathy 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 facet 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 |
| 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); |
### MEDICAL POLICY

**Back: Artificial Intervertebral Discs (All Lines of Business Except Medicare)**

<table>
<thead>
<tr>
<th>Artificial Intervertebral Discs</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCM® Cervical Disc</strong>&lt;sup&gt;4&lt;/sup&gt; (NuVasive®)</td>
<td>Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or &gt;11° angular difference to that of either adjacent level; Osteoporosis or osteopenia defined as DEXA bone mineral density T-score &lt; -1.5; Severe facet joint disease or degeneration</td>
</tr>
<tr>
<td><strong>Prestige® Cervical Disc System</strong> (includes Prestige-ST)&lt;sup&gt;5&lt;/sup&gt; (Medtronic)</td>
<td>Acute or chronic infections, local or systemic; Osteoporosis (defined as DEXA bone density measured T-Score &lt; -2.5) or osteopenia (defined as DEXA bone density measured T-Score &lt; -1.0); Congenital stenosis; Allergy or sensitivity to any of the implant materials (cobalt, chromium, molybdenum, titanium, or polyethylene)</td>
</tr>
<tr>
<td><strong>Prestige® -LP&lt;sup&gt;6&lt;/sup&gt; (Medtronic)</strong></td>
<td>The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.</td>
</tr>
<tr>
<td><strong>ProDisc® -C&lt;sup&gt;7&lt;/sup&gt; (DePuy Synthes)</strong></td>
<td>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 &gt;3.5mm and/or &gt;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 &gt;50%, an absence of motion (&lt;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.</td>
</tr>
</tbody>
</table>

### Definitions

- **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:**
  - Translation >3.5mm
  - Angular difference >11°

- **Osteoporosis or osteopenia defined as DEXA bone mineral density T-score < -1.5:**
  - T-score < -1.5

- **Severe facet joint disease or degeneration:**
  - Angular difference >11°

- **Congenital stenosis:**
  - Congenital narrowing of the spinal canal

- **Active systemic infection or localized infection at the surgical site:**
  - Infection affecting the surgical site

- **Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1.0:**
  - T-score ≤ -1.0

- **Allergy or sensitivity to any of the implant materials:**
  - Cobalt, chromium, molybdenum, titanium, or polyethylene

- **Active systemic infection or localized infection to the site of implantation:**
  - Infection involving the site of implantation
Table 2. FDA-Approved Lumbar Artificial Disc Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Disc Levels</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activ-L™9</td>
<td>Single level from L4/L5 or L5/S1</td>
<td>- Active systemic infection or localized infection near the surgical site</td>
</tr>
</tbody>
</table>

- Osteoporosis defined as DEXA bone density measured T-score ≤ 2.5
- Marked cervical instability on neutral 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 spondylodiscitis 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® -C⁸
(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 spondylodiscitis 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
<table>
<thead>
<tr>
<th>Requirements</th>
<th>ProDisc® -L¹⁰ (DePuy Synthes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than or equal to -1.0</td>
<td>Single level from L3-S1</td>
</tr>
<tr>
<td>• Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate)</td>
<td></td>
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<tr>
<td>• Isolated lumbar radiculopathy, especially due to herniated disc</td>
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<tr>
<td>• Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)</td>
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<tr>
<td>• Extruded disc material with sequestrum (i.e., free disc fragment)</td>
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<tr>
<td>• Myelopathy</td>
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<tr>
<td>• Spinal stenosis</td>
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<tr>
<td>• Spinal deformity such as scoliosis</td>
<td></td>
</tr>
<tr>
<td>• Spondylylosis/isthmic spondylolisthesis, degenerative spondylolisthesis &gt; Grade I, or segmental instability</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
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<tr>
<td>• Facet ankylosis or facet joint degeneration</td>
<td></td>
</tr>
<tr>
<td>• Preoperative remaining disc height &lt; 3mm</td>
<td></td>
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<tr>
<td>• Symptoms attributed to more than one vertebral level</td>
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<tr>
<td>• Abdominal pathology that would preclude an anterior retroperitoneal approach</td>
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</tr>
<tr>
<td>• Involved vertebral endplate that is dimensionally smaller than 31mm in the medial-lateral and/or 26mm in the anterior-posterior directions</td>
<td></td>
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<tr>
<td>• Active systemic infection or infection localized to the site of implantation</td>
<td></td>
</tr>
<tr>
<td>• Osteopenia or osteoporosis defined as DEXA bone density measured T-score &lt; -1.0</td>
<td></td>
</tr>
<tr>
<td>• Bony lumbar spinal stenosis</td>
<td></td>
</tr>
<tr>
<td>• Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)</td>
<td></td>
</tr>
<tr>
<td>• Isolated radicular compression syndromes, especially due to disc herniation</td>
<td></td>
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<tr>
<td>• Pars defect</td>
<td></td>
</tr>
<tr>
<td>• Involved vertebral endplate that is dimensionally smaller than 34.5mm in the medial-lateral and/or 27mm in the anterior-posterior directions</td>
<td></td>
</tr>
<tr>
<td>• Clinically compromised vertebral bodies at the affected level due to current or past trauma</td>
<td></td>
</tr>
</tbody>
</table>
BILLING GUIDELINES

0098T may be billed in conjunction with 22861.

CPT/HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business Except Medicare</th>
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<tbody>
<tr>
<td><strong>Prior Authorization Required</strong></td>
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<td><strong>Not Covered</strong></td>
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</tbody>
</table>
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. 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.”

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. 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. 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. 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:

- Donor bone graft site (usually the hip) is required;
- Associated complications such as pseudo-arthritis (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).”
Artificial Disc Replacement (ADR)

Artificial lumbar and cervical disc replacements were developed as an alternative to spinal fusion in patients with DDD. 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., disectomy), 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.

REVIEW OF EVIDENCE

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 March 2020.

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. 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
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.”

- In 2017 (updated 2019), Hayes published a comparative effectiveness review of single-level ADR for cervical degenerative disc disease. 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 disectomy 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.” 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.

- In 2020, ECRI conducted an evidence review of the M6-C artificial cervical disc (Spinal Kinetics, LLC) for treating degenerative disc disease. Searching the literature through February 2020, 1 retrospective comparative cohort study was included for review, assessing overall flexion among 69 patients. At 3-month follow-up, overall flexion did not differ statistically between groups (M6-C versus Mobi-C.) Findings were also limited by the study’s small sample size, lack of long-term follow-up, retrospective design and lack of relevant outcome measures. Investigators concluded that “evidence is inconclusive” for the safety and efficacy of the M6-C artificial cervical disc.
Bi-Level Cervical Artificial Disc Replacement

Systematic Reviews

- 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. 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.”

- A 2016 ECRI Institute custom product brief guidance evaluated Mobi-C artificial cervical disc for treating two level degenerative cervical disc disease. 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.” 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 2017 (updated 2020), Hayes published a comparative effectiveness review of multilevel ADR for cervical degenerative disc disease. The review included eight studies (12 publications) that examined the effectiveness and safety of bi-level artificial cervical TDR compared with ACFD. 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.”19 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).20 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.21

Randomized Controlled Trials (RCT)

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).6,22,23 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. 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.

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 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. 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.”

In 2016, five year follow-up results of this RCT were published by Radcliffe and colleagues. 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.”

- 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. 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.

Cervical Artificial Disc Replacement and Adjacent Segment Degeneration (ASD)

Systematic Reviews

- Two systematic reviews and meta-analyses (2012 and 2013) evaluated the incidence of adjacent segment degeneration after cervical disc arthroplasty. 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.

- 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. 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.”

- 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. 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.

Cervical Hybrid Procedures

Systematic Reviews

- The 2017 (updated 2020) 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. Only one study met the inclusion criteria for this review, by Grasso et al. (2015). Hayes assigned a “D2” rating due to insufficient evidence to report on the safety, efficacy, and health outcomes of cervical 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). 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.

- 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. 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.

Nonrandomized Studies

- Additional observational studies evaluating cervical hybrid procedures for the treatment of cervical degenerative disc disease were identified. 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.

Based on the low quality of available evidence and lack of randomized controlled trials, current evidence is insufficient to establish the clinical utility of cervical hybrid procedures for the treatment of cervical degenerative disc disease.
Lumbar Artificial Disc Replacement

Systematic Reviews

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. 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.” 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. 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.

- In 2018, ECRI conducted an evidence review of the ActivL Artificial Disc (Aesculap, Inc.) for lumbar disc arthroplasty.\textsuperscript{46} 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.

- In 2019, Hayes published a comparative effectiveness review evaluating the utility of ADR for the treatment of lumbar degenerative disc disease.\textsuperscript{19} 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.”\textsuperscript{19} 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.”

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.\textsuperscript{47} 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.\(^4^8\) 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."^{48}

• 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.\textsuperscript{49} 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.”\textsuperscript{49}

Lumbar Hybrid Procedures

Two observational studies evaluating lumbar hybrid procedures (lumbar fusion with lumbar artificial intervertebral disc implantation) for the treatment of lumbar degenerative disc disease were identified.\textsuperscript{36,37} Both 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; therefore, there is insufficient evident to support the use lumbar hybrid procedures. Future, good-quality randomized controlled 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 2015, NASS revised their coverage policy recommendation in support of cervical ADR for patients with cervical back pain, publishing the following criteria:50

“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 one or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2 level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain.

There is not significant evidence at this time to support its use for 3 or more levels or in the case of adjacent segment disease following an index fusion.

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)

HERC issued coverage guidance for cervical ADR in 2014 and recommended coverage only when all of the following criteria are met:

- 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.”

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.”

American College of Occupational and Environmental Medicine (ACOEM)

ACOEM issued an evidence-based guideline in 2011 for cervical and thoracic spine disorders and recommended, “artificial disc replacement for subacute or chronic radiculopathy and myelopathy.”

Lumbar Artificial Disc Replacement

North American Spine Society (NASS)

In 2019, NASS updated their coverage policy recommendation in support of lumbar ADR for patients with low back pain, publishing the following criteria:

“Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria (from the Lumbar Fusion Coverage Recommendation):
1. Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
2. Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
3. Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
4. 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 one level
3. Presence of spinal instability with spondylolisthesis greater than Grade I
4. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least one year)
5. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0
6. Poorly managed psychiatric disorder
7. Significant facet arthropathy at the index level
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)

The 2015 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.” 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, 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.
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.” 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.”

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.” 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.

POLICY 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 good-quality evidence is needed to confirm the use of ADR for the reduction of adjacent segment degeneration. Evidence remains lacking in both quantity and quality to support the use of hybrid procedures (spinal fusion with artificial disc implantation) for the treatment of degenerative disc disease.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.
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.

**REGULATORY STATUS**

Mental Health Parity Statement

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.

**REFERENCES**

47. Sköld C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. *European spine journal*. 2013;22(10):2288-2295