

# Cervical Artificial Disc Replacement



**DEFINING APPROPRIATE  
COVERAGE POSITIONS**

## Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy.

## Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

### [NASS Coverage Policy Methodology](#)

## Scope and Clinical Indications

**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 single 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 non-operative management.
2. **Myelopathy or myeloradiculopathy** related to single level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that is severe enough to warrant surgical intervention.

**Cervical artificial disc replacement** is **NOT** indicated in cases that do not fulfill the above criteria. Of note, CADR is not indicated in the following scenarios.

- **Symptomatic multi-level disease** (2 or more levels) that would require multiple level CADR
  - **Adjacent level disease:** degenerative disease adjacent to a previous cervical fusion
  - **Infection**
    - i. active at the site of proposed implantation
- OR

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- ii. systemic infection
- **Osteoporosis** or **osteopenia**
- **Instability** defined as:
  - i. translation greater than 3mm difference between lateral flexion-extension views at the symptomatic level
  - OR
  - ii. 11degrees of angular difference between lateral flexion-extension views at the symptomatic level
- **Sensitivity** or **allergy** to implant materials
- **Severe spondylosis** defined as:
  - i. greater than 50% disc height loss compared to minimally or non-degenerated levels
  - OR
  - ii. bridging osteophytes
  - OR
  - iii. absence of motion on flexion-extension views at the symptomatic site
- **Severe facet joint arthropathy** defined as:
  - i. Radiographic confirmation of facet joint disease or degeneration
- **Ankylosing spondylitis**
- **Rheumatoid arthritis**
- Previous **fracture** with anatomical deformity
- **Ossification of the posterior longitudinal ligament (OPLL)**
- **Malignancy**
  - i. Active, in the cervical spine

## Rationale

Cervical artificial disc replacement (CADR) is an emerging/emerged technology that has been brought to market following a number of IDE randomized controlled trials sponsored by the manufacturers of the currently available implants. Though not currently considered to be the standard of care for the treatment of cervical degenerative disorders, it has shown promising results in the available data, indicating at least equivalence to cervical fusion following adequate decompression. The proposed **Coverage Recommendation** (also known as the “Recommendation”) put forth by the North American Spine Society utilizes an evidence-based approach to spinal care when possible. In the absence of strict evidence-based

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criteria, the policy utilizes the multidisciplinary and non-conflicted experience and expertise of the task force in order to reflect reasonable standard practice indications in the United States.

**In items 1 and 2**, the rationale for coverage of CADR is based on the indications and results of many randomized controlled trials (RCTs) that have compared the procedure to what most would consider the gold standard surgical treatment, anterior cervical discectomy and fusion (ACDF).

Combining the results of these various RCTs, a number of systematic reviews with or without meta-analysis have been performed comparing CADR to ACDF for symptomatic, single level, degenerative disc disease presenting as either radiculopathy or myelopathy with or without neck pain. Importantly, neck pain was not a requirement for entry into the studies. At the current time, the optimal treatment for single level cervical radiculopathy or myelopathy has yet to be determined and will require greater long-term follow-up. Some of the proposed advantages of CADR, such as a decreased rate of adjacent level disease compared to fusion, will require long-term follow-up for conclusive results. Most published studies have been designed to compare short-term (2 year) safety and efficacy of CADR to that of ACDF.

Xing et al performed a meta-analysis of eight RCTs.<sup>10</sup> The authors concluded that the clinical outcomes of CADR were equivalent or superior to the outcomes of ACDF for the treatment of single level disc disease. There were no studies with follow-up beyond 48 months, with the majority of follow-up being 24 months. Therefore, no durability assessments could be made. From their systematic review of long-term follow up (48 to 60 months) results from two FDA IDE trials using the Bryan and Prestige implants, Mummaneni et al concluded that CADR is a viable treatment option for cervical radiculopathy from disc herniation or spondylosis.<sup>11</sup> This group also found that CADRs had better clinical outcomes, greater segmental motion, and lower rates of subsequent surgical procedures.

Jiang et al<sup>12</sup> performed a meta-analysis of 1745 patients included in RCTs comparing CADR or ACDF. They showed no statistical difference in neck disability index, neck and arm pain scores, incidence of complications related to the implant or surgical procedure, or reoperation related to the primary surgery. The analysis did reveal that CADR had lower incidence of postoperative dysphagia and reoperation related to adjacent-segment degeneration and a higher rate of neurological and overall success at two years postoperatively compared to ACDF. However, there was no long-term follow-up available.

Upadhyaya et al<sup>13</sup> analyzed 1213 patients from three FDA IDE trials with two year follow-up (Prestige ST Cervical Disc, Bryan Cervical Disc, and ProDisc-C) that compared single level CADR to ACDF. They concluded that both ACDF and CADR demonstrate excellent two-year surgical results for the treatment of single level cervical disc disease with radiculopathy. They found CADR to have a lower rate of secondary surgery and a higher rate of neurological success at two years. There was projection that arthroplasty may

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be associated with a lower rate of adjacent-level disease at two years. This suggested protective effect against adjacent segment degeneration has been questioned by meta-analyses by Chen et al<sup>14</sup> and Yang et al<sup>15</sup> and by Harrod et al's<sup>16</sup> systematic review. These three papers suggest that motion preservation may not decrease cervical adjacent segment disease that was anticipated for CADR as compared to ACDF.

A metanalysis by McCafee<sup>17</sup> compared the results of 1226 patients from 4 prospective multicenter randomized clinical trials following cervical arthroplasty or anterior cervical fusion. At 24 months overall success was achieved in 77.6% of the arthroplasty patients and 70.8% of the ACDF patients.

Sasso and Anderson<sup>18</sup> have shown level I evidence showing the sustained effectiveness of cervical disc arthroplasty over cervical spinal fusion in the treatment of single level pathology in the treatment of radiculopathy or myelopathy at 2 years. Likewise, Riew<sup>19</sup> has demonstrated level II evidence that both groups show improvement in myelopathy after surgery at 2 years, with arthroplasty being equivalent to arthrodesis for the treatment of cervical myelopathy for single level disease localized to the disc space.

High level clinical studies on the safety and efficacy of multi-level cervical disc replacement or hybrid cervical procedures combining cervical artificial disc replacement with cervical fusion are still lacking and are considered off-label uses.<sup>2-9</sup> The list of clinical scenarios in which CADR coverage recommendation is not recommended is derived from the exclusion criteria described in the published IDE studies<sup>20-25</sup>.

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