Artificial Disc Replacement, Cervical

I. Description

Anterior cervical disectomy and fusion (ACDF) is currently considered the definitive surgical treatment for symptomatic single-level degenerative disc disease (DDD) of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability. Resolution of pain and neurological symptoms may be expected in more than 80% to 100% of ACDF patients.

ACDF involves an anterolateral surgical approach, decompression of the affected spinal level, discectomy, and emplacement of either autograft or allograft bone in the prepared intervertebral space to stimulate healing and eventual fusion between the vertebral endplates. A metal anterior cervical plate is attached to the adjoining vertebral bodies to stabilize the fusion site, maintain neck lordosis, and reduce the need for prolonged postoperative brace application that is needed following ACDF without an anterior plate.

Artificial intervertebral disc arthroplasty (AIDA) is proposed as an alternative to ACDF for patients with symptomatic cervical DDD. Disc arthroplasty and ACDF for single-level disease have very similar surgical indications, primarily unremitting pain due to radiculopathy or myelopathy, weakness in the extremities, or paresthesia.

In AIDA, an artificial disc device is secured in the prepared intervertebral space rather than bone. An anterior plate is not placed to stabilize the adjacent vertebrae, and postsurgical external orthosis is usually not required. The surgical procedure and perioperative complications of AIDA are nearly identical to those of anterior fusion. It is hypothesized that AIDA maintains anatomical disk space height, normal segmental lordosis, and physiological motion patterns at the index and adjacent cervical levels. This procedure has been proposed to reduce the risk of adjacent-level DDD above
Artificial Disc Replacement, Cervical

or below a fusion site, and has been the major rationale driving device development and use. However, while biomechanical modeling studies have suggested that altered adjacent segment kinematics following fusion may lead to adjacent-level DDD, the clinical relevance of these changes has not been established.

II. Criteria/Guidelines

A. Cervical intervertebral disc replacement or spinal arthroplasty is covered (subject to Limitations/Exclusions and Administrative Guidelines) when performed at one level (22856, 22861, 22864) in individuals with cervical degenerative disc disease (722.4) when all of the following criteria are met:
   1. An FDA-approved device (e.g., Prestige ST Cervical Disc, Bryan Cervical Disc, and ProDisc-C Total Disc Replacement) is used; and
   2. The operative level is C3 to C7; and
   3. The procedure is performed in a skeletally mature individual; and
   4. At least six weeks of conservative management has been tried and failed.

III. Limitations/Exclusions

A. Artificial intervertebral disc replacement is not covered for any other indication (e.g. lumbar).

B. Artificial intervertebral disc replacement is not covered when surgery is performed at more than one level.

IV. Administrative Guidelines

A. Precertification is not required. Documentation supporting the medical necessity should be legible, maintained in the patient’s medical record and must be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including disc-ectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical</td>
</tr>
<tr>
<td>22861</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
</tr>
<tr>
<td>22864</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
</tr>
</tbody>
</table>
V. Scientific Background

Murrey, et al. reported on the 2-year follow-up of the pivotal FDA randomized non-inferiority trial to determine the safety and efficacy of ProDisc-C in comparison with ACDF. In this trial, 103 patients received the ProDisc-C implant and 106 were treated with fusion; participants were blinded to intervention until following surgery. Follow-up between 6 weeks and 2 years was reported to be 85% in the summary of safety and effectiveness data presented to the FDA. Reasons for the loss to follow-up were not described but appear to have included 2 patients in the ProDisc-C group who had the implant removed and 5 patients in the fusion group who had undergone additional surgical procedures to modify the original implant. Non-inferiority was achieved for the FDA-defined combined endpoint of neurologic examination, neck disability index (NDI), adverse events, and device success, with 72% of ProDisc-C and 68% of fusion patients achieving success in all 4 component endpoints. Clinical outcomes at 24 months’ follow-up were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88%, respectively), NDI (21.4 vs. 20.5 points), reduction in pain scores (e.g., 46 mm vs. 43 mm reduction in neck pain on a visual analogue scale), and patient satisfaction (83 mm vs. 80 mm). Limitations of this study are the 2-year follow-up precluding conclusions about long-term device performance, durability, and potential need for and impact of revision surgery.

Nabhan et al. reported 1-year clinical and radiological results of 49 patients randomized to receive a ProDisc-C artificial disc or fusion. Measurements taken at 3, 6, 12, 24, and 52 weeks showed a decrease in segmental motion at the index level in both groups over the first 12 weeks after surgery; at 52 weeks, segmental translation (xyz axis) was about 1 mm greater in the ProDisc-C group. Clinical results were similar in the two groups, with a 70% reduction in neck pain and 86% reduction in arm pain in the ProDisc-C group and a 68% reduction in neck pain and 83% reduction in arm pain in the ACDF group. As noted by the authors, longer follow-up is needed to determine the effect of this implant on cervical motion and stress at adjacent levels.

Two-year follow-up results from the IDE trial were reported for the not yet approved Bryan disc. The trial employed inclusion/exclusion criteria and a composite outcome identical to the ProDisc-C trial. A total of 582 patients were randomized to the Bryan disc (n=290) or ACDF (n=292); AIDA was performed in 242 (37 declined surgery, 12 crossed over to ACDF, and 1 moved from control to AIDA); ACDF was performed in 221 (80 declined surgery, 1 crossed over to ACDF from AIDA, 12 crossed over from ACDF to AIDA, and 2 were excluded “per FDA protocol”). In the AIDA and ACDF arms, mean age (44.4 and 44.7 years), sex (45.5% and 51.1% men) and NDI scores (51.4 and 50.2) were similar. All but 1 patient undergoing AIDA and 3 patients in the ACDF arm had documented neurological abnormalities. After 2 years, follow-up data were available for 95% and 88% undergoing AIDA and ACDF, respectively. Adverse event rates were similar in the two arms—1.7% in AIDA and 3.2% in ACDF arms, requiring revision. AIDA was judged superior to ACDF with “overall success” achieved in 72.7% and 82.6% (p=.01) and NDI success achieved in 86% and 79% (p=0.052, 2-sided), respectively.
A post hoc subgroup analysis (Riew) of 199 participants with myelopathy from the Prestige ST (n=111) and Bryan (n=88) trials found similar improvement in postoperative neurological status and gait at 24 months (Prestige ST: AIDA 90% [95% CI: 79% to 97%] and ACDF 81% [95% CI: 65% to 92%]; Bryan: AIDA 90% [95% CI: 76% to 97%] and ACDF 77% [95% CI: 76% to 97%]).

The Prestige ST trial found non-inferiority for the NDI outcome and superiority for the composite “overall success” (i.e., 15-point or greater NDI improvement, maintained or improved neurological status, no serious implant- or procedure-associated adverse event, and no additional surgical procedure classified as a failure). Superiority was attributable to the neurological status component endpoint assessed by examiners not clearly blinded to the study arm. As previously noted, the ProDisc-C trial demonstrated non-inferiority with respect to the composite endpoint at 2 years. Neither trial provided adequate direct evidence over the relevant follow-up period (suggested to be 5 to 7 years) on subsequent adjacent-level DDD in control and investigational group patients.

Two year results indicate that AIDA is no worse than ACDF. Evidence to date has not shown a beneficial effect of any cervical disc product on the development of adjacent level disease, whereas long-term complication rates with artificial discs remain unknown.

Artificial disc replacement devices are FDA-approved and have been recommended by North American Spine Society as a standard of care despite the lack of long-term data (beyond two years). Long-term data is still being accumulated but this therapy has become standard of care in surgery because it shows superiority or equivalence for symptomatology in symptomatic patients in the short term and studies suggest artificial discs are robust and safe over long term use.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA consider the application of this Medical Policy to the case at issue.
VII. References