I. Description

Several prosthetic devices are currently available for artificial intervertebral disc arthroplasty (AIDA) of the cervical spine. AIDA is proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for patients with symptomatic cervical degenerative disc disease.

For individuals who have cervical radicular pain or myelopathy who receive single-level AIDA of the cervical spine, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met noninferiority criteria as measured by the Neck Disability Index (NDI) and overall success composite outcome. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [porous coated motion]). At 4 to 5 years, the trial results are consistent with continued noninferiority of AIDA for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige and ProDisc-C pivotal trials continues to show lower secondary surgery rates, although this is not a consistent finding in other reports. Longer term results for other discs are expected, given the U.S. Food and Drug Administration (FDA) requirement for 7-year postapproval studies of the safety and function of the devices, and 5- to 10-year enhanced surveillance to more fully characterize adverse events in a broader patient population. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs, but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of ACDF. There have been no safety signals with discs that have been approved by the FDA for single-level AIDA. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level AIDA of the cervical spine, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to ACDF for NDI scores, NDI success rates, reoperation rates, and overall success composite outcome. At 5
years, trial results were consistent with the continued superiority of 2-level AIDA for clinical outcomes and lower cumulative reoperation rates. Adjacent segment degeneration with Mobi-C was found in a significantly lower percentage of patients compared to 2-level ACDF patients. FDA approval for the Prestige LP was based on superiority to 2-level ACDF in overall success at 2 years. The increase in overall success rates at 2 years has been maintained for those patients who have reached the 5- and 7-year follow-ups. Based on this evidence, it can be concluded that 2-level AIDA with either of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

II. Criteria/Guidelines

A. Cervical intervertebral disc implantation is covered (subject to Limitations and Administrative Guidelines) when performed at one level or two contiguous levels in individuals with symptomatic cervical degenerative disc disease (e.g., with radicular neck and/or arm pain and/or functional/neurological deficit) when all of the following criteria are met:

1. The device is FDA-approved (e.g., Prestige ST Cervical Disc, Bryan Cervical Disc, and ProDisc-C Total Disc Replacement, Mobi-C and Prestige LP are the only FDA-approved device for 2 levels) is used; and
2. The patient is skeletally mature; and
3. The patient has intractable cervical radicular pain or myelopathy who has:
   a. failed at least 6 weeks of conservative nonoperative treatment, including an active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources AND physical therapy; OR
   b. severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment.
4. Degeneration is documented by radiologic studies (e.g., CT, MRI, x-rays, or myelography); and
5. The operative level is C3 to C7; and
6. The patient is free from contraindication to cervical artificial intervertebral disc implantation

B. Subsequent cervical artificial intervertebral disc implantation at an adjacent level is covered (subject to Limitations and Administrative Guidelines) when all of the following are met:

1. Criteria 1 to 6 above are met; AND
2. The device is FDA-approved for 2 levels; AND
3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; AND
4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.
III. Limitations
   A. Artificial intervertebral disc replacement in any other part of the vertebra is not covered.
   B. Cervical artificial disc replacement at one level combined with cervical spinal fusion at another level (adjacent or non-adjacent) is not covered as it has not been shown in the scientific literature to improve health care outcomes.
   C. Cervical artificial intervertebral disc implantation is not covered for any other indication including those listed below as it has not been shown in the scientific literature to improve health care outcomes:
      1. Disc implantation at more than 2 levels
      2. Combined use of an artificial cervical disc and fusion
      3. Prior surgery at the treated level
      4. Previous fusion at another cervical level
      5. Translational instability
      6. Anatomical deformity (e.g., ankylosing spondylitis)
      7. Rheumatoid arthritis or other autoimmune disease
      8. Presence of facet arthritis
      9. Active infection
     10. Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
    11. Malignancy

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>
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<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophysectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical</td>
</tr>
<tr>
<td>22858</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophysectomy for nerve root or spinal cord decompression and microdissection); second level 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>
<tr>
<td>0095T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical</td>
</tr>
</tbody>
</table>
V. Scientific Background

Click on Link – for Background

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.

VI. References


