ARTIFICIAL INTERVERTEBRAL DISC REPLACEMENT

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersedes this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member's EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:
This policy describes the use of artificial total disc replacement that involves removal of a diseased disc in either the lumbar or cervical region of the spine and insertion of an artificial disc. The goal of this procedure is to reduce or eliminate back pain while maintaining spinal curvature, flexibility, and load bearing.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

CERVICAL ARTIFICIAL INTERVERTEBRAL DISC

- Cervical artificial total disc replacement may be considered MEDICALLY NECESSARY for the treatment of single-level degenerative disc disease in adult patients when used according to U.S. Food and Drug Administration (FDA) labeled indications:
  1. Disc will be used for single-level reconstruction following cervical discectomy within the C3-C7 region, AND
  2. Patient has intractable radiculopathy and/or myelopathy due to herniated disc or osteophyte formation, AND
  3. Patient has failed at least six weeks of conservative therapy, AND
  4. Symptomatic nerve root and/or spinal cord compression are documented by ALL the following:
     - Neck and/or arm pain; and
     - Functional and/or neurological deficit; and
     - Radiographic imaging (e.g., Computed Tomography (CT), Magnetic Resonance Imaging (MRI), X-Rays, etc.).

- Cervical artificial total disc replacement is considered INVESTIGATIONAL for all other indications, including symptoms necessitating surgical treatment at more than one cervical spine level. There is insufficient clinical evidence evaluating the safety and efficacy of multiple-level disc replacement or single-level disc replacement with cervical fusion at another level. Well designed studies are needed to establish the long-term safety of cervical disc replacements done at multiple cervical levels.

LUMBAR ARTIFICIAL INTERVERTEBRAL DISC

- Lumbar artificial total disc replacement is considered INVESTIGATIONAL for the treatment of degenerative disorders of the lumbar spine, single or multiple-level disc disease, or for any other indication. At the present time, there is insufficient clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature demonstrating their impact on improved health outcomes. While the early results are encouraging, there is inadequate follow-up to evaluate long-term outcomes, effect of the device on adjacent-level disc degeneration, durability, adverse events, and complications with these implants.

Clinical Considerations:
There are some possible complications that could necessitate removal of an existing artificial disc such as:
- Allergic reaction to the implant materials
- Material failure (e.g., implants that bend, break, loosen or move)
- Local and or systemic infection
Revision including removal and replacement of an existing failed artificial disc (and the necessary stabilization of the spine by conventional methods, such as fusion) requires prior authorization. A medical director will determine that removal of the artificial disc is medically necessary.

**BACKGROUND:**

Subacute and chronic back pain is a significant health problem, affecting 60% to 80% of adults in the United States at some time in their lives. In most cases, back pain is temporary and can be relieved through rest, pharmacology and physical therapy, but for 5% of patients it becomes a chronic and disabling condition. In addition to being one of the leading reasons for visits to primary-care physicians, back pain is one of the most common diagnoses for nonsurgical hospital admissions in adults.

For those cases of low back pain that are related to disc degeneration, the disease process often involves a fissure and herniation of one of the gelatinous discs that separate the vertebrae. In some cases, a protruded disc or herniated disc material compresses a spinal nerve root, causing numbness and pain along the neural pathway. Symptoms of lumbar disc disease can include acute or chronic back pain, referred leg pain, sensory changes, leg weakness, reflex changes, or a combination of these symptoms. The most common presenting symptom is severe lower back and/or leg pain that develops immediately or shortly after an injury.

Degenerative disc disease (DDD) is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. These changes can destabilize the anterior spinal column and cause radiculopathy (nerve compression leading to arm and neck pain and/or neurological deficit), as well as myelopathy (compression of the spinal cord). Symptoms of cervical DDD include arm pain, weakness, and paresthesias associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord result in myelopathy, which is manifested by subtle changes in gait or balance, weakness in the arms or legs, and numbness of the arms or hands, in severe cases. The prevalence of DDD secondary to cervical spondylosis increases with age.

The extent of disc disease is determined with diagnostic tools such as plain radiography, myelography, electrodiagnosis, discography, computed tomography (CT) scanning with and without contrast medium, magnetic resonance imaging (MRI) with and without contrast medium, and bone scintigraphy.

Standard therapy for cervical and lumbar disc disease involves a period of conservative treatment, using noninvasive measures (e.g., rest, heat, ice, analgesics, anti-inflammatory agents, exercise), physical therapy and reduced activity, followed by gradually increasing mobilization and exercise. Surgical treatment is undertaken only for those patients who have not improved with conservative treatment or who have a severe neurological impairment such as cauda equina syndrome. A common surgical approach is spinal fusion; over 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining whether a patient's back pain is related to degenerative disc disease and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients.

As an alternative, to avoid the problems associated with spinal fusion, a variety of artificial intervertebral discs have been investigated over the past 30 years as an alternative to fusion. This approach, also referred
to as total disc replacement or spinal arthroplasty, is intended to reduce or eliminate back pain while maintaining motion at the operative level once the damaged disc has been removed, maintaining the normal biomechanics of the adjacent vertebrae.

Artificial discs may consist of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disk that is inserted between the metal endplates, may be metal on metal, metal on plastic, ceramic on ceramic or titanium on polyurethane. Discs are implanted through an anterior approach and are attached to vertebrae with screws, teeth, ridges, or pins.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   - The ProDisc - L Total Disc Replacement: The ProDisc-L received FDA Premarket Approval on August 14, 2006 Additional information is available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077620.htm.
   - Secure-C Artificial Cervical Disc: The Secure-C Artificial Cervical Disc (Globus Medical, Inc.) was approved on September 28, 2012 (P100003). The FDA-approved clinical trial has not yet been published.
   - PCM Cervical Disc System: The PCM Cervical Disc System (NuVasive Incorporated) was approved October 6, 2012 (P100012). The FDA-approval clinical trial has not yet been published. PCM stands for porous coated motion.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Minnesota DHS does not have a policy statement regarding artificial spinal disc replacement in its Provider Manual or other specific provider references.

**CLINICAL EVIDENCE:**

**SUMMARY:**
The available evidence suggests that total artificial disc replacement (TDR) provides improvement in signs and symptoms of cervical degenerative disc disease that is similar to that provided by anterior discectomy and fusion (ACDF), for at least 2 years. In addition, TDR may maintain cervical motion at the treated level, although at the present time, there is insufficient evidence to determine whether TDR will prevent or reduce the development of adjacent-segment disease. Long-term efficacy and safety are also unknown, especially those with device-related complications such as device loosening or breaking.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>0092T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical (List separately in addition to code for primary procedure)</td>
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<td>0095T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)</td>
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<td>0098T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)</td>
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<td>22856</td>
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cord decompression and microdissection), single interspace, cervical

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**ICD-9 Procedure Code** | **Description**
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84.60 | Insertion of spinal disc prosthesis, not otherwise specified
84.61 | Insertion of partial spinal disc prosthesis, cervical
84.62 | Insertion of total spinal disc prosthesis, cervical
84.64 | Insertion of partial spinal disc prosthesis, lumbosacral
84.65 | Insertion of total spinal disc prosthesis, lumbosacral
84.66 | Revision or replacement of artificial spinal disc prosthesis, cervical
84.68 | Revision or replacement of artificial spinal disc prosthesis, lumbosacral
84.69 | Revision or replacement of artificial spinal disc prosthesis, not otherwise specified

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**REFERENCES:**

8. Bertagnoli R, Yue JJ, Shah RV, et al. The treatment of disabling multilevel lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year...


POLICY HISTORY:

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<td>Approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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