Medical Management Policy

**Service:** Artificial Disc Replacement (Intervertebral Disc Prosthesis, Hybrid TDR-ACDF)

*PUM 250-0040*

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<th>Medical Policy Committee Approval</th>
<th>02/27/2020</th>
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<tr>
<td>Effective Date</td>
<td>06/01/2020</td>
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<tr>
<td>Prior Authorization Needed</td>
<td>Yes</td>
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**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may or may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

**Description:** Artificial disc replacement is a surgical procedure in which a diseased or damaged intervertebral disc of the spine is replaced with an artificial, man-made (prosthetic) disc. Artificial disc replacement is proposed as an alternative to spinal fusion.

**Indications of Coverage:**

A. **Single level or two level cervical (neck)** artificial disc replacement in a skeletally mature individual is considered medically necessary in adults when **ALL (1 through 7)** of the following criteria are met:

1. Cervical degenerative disc disease or herniated disc with intractable radiculopathy and/or myelopathy at each level to be replaced.

   **AND**

2. Imaging study (computed tomography [CT], magnetic resonance imaging [MRI], or x-ray) demonstrates single-level or two contiguous level (touching/neighboring) disc degeneration with at least one of the following:
   a. Osteophytes
   b. Herniated nucleus pulposus
   c. Loss of disc height (compared to adjacent levels)
   d. Disc desiccation or degeneration

   **AND**

3. The artificial disc replacement is for one to two contiguous spinal levels from cervical 3 through cervical 7 (C3 through C7).

   **AND**
4. The individual has trialed at least 6 weeks of physician-directed non-operative treatment which did not improve the radiculopathy or myelopathy symptoms. The non-operative treatment trial must include a 6-week trial of physical therapy or chiropractic treatment specific to the cervical area of concern AND a trial of anti-inflammatory medication, analgesics, or muscle relaxants.

Note: The non-operative treatment requirement does not apply to individuals with severe or rapidly progressing symptoms of spinal cord or nerve root compression requiring emergent hospitalization or emergent surgery.

AND

5. The individual has not had a prior spinal surgery at the same level(s)

AND

6. The individual must also meet the criteria for an anterior cervical decompression fusion (ACDF) (the reviewer will reference MCG Guideline for Cervical Spinal Fusion)

AND

7. The artificial disc must be Food and Drug Administration (FDA)-approved and used in accordance with FDA labeling. It is the responsibility of the surgeon to choose an FDA-approved device.

B. **Single level lumbar** artificial disc replacement is considered medically necessary when ALL of the following criteria are met:

1. Individual is at least 18 years old

AND

2. The artificial disc replacement is for degenerative disc disease at one level between L3 and S1 (L3-L4, or L4-L5, or L5-S1)

AND

3. Degenerative disc disease with unremitting discogenic lumbar back pain and/or functional disability have been present for at least one year.

AND

4. Computed tomography (CT) or magnetic resonance imaging (MRI) verifies moderate to severe single level degenerative disc disease limited to the one level between L3 and S1 that is targeted for replacement.

AND

5. Within the past 12 months, the individual has failed 6 months of physician supervised conservative medical management, which includes all of the following:

   a. At least 6 weeks of physical therapy (PT) or chiropractic treatment specific to the lumbar area of concern
   
   b. Home exercises to improve core stabilization
   
   c. Anti-inflammatory, analgesic, or muscle relaxant medications (unless contraindication is documented)
AND

6. The artificial disc must be Food and Drug Administration (FDA)-approved and used in accordance with FDA labeling. It is the responsibility of the surgeon to choose an FDA-approved device.

Limitations of Coverage:

A. Review health plan and endorsements for exclusions and prior authorization or benefit requirements

B. If requested/used for a condition or diagnosis other than is listed in the Indications of Coverage, it will be denied as experimental, investigational, and unproven to affect health outcome

C. If requested/used for a condition or diagnosis that is listed in the Indications of Coverage; but the criteria are not met, it will be denied as not medically necessary

D. Artificial intervertebral disc replacement will be denied as experimental, investigational, and unproven to affect health outcomes if the prosthetic intervertebral disc (implant) used is not Food and Drug Administration (FDA)-approved (or if FDA-approved implant is not used in accordance with FDA labeling).

E. If requested/used For thoracic level(s), it will be denied as experimental, investigational, or unproven to affect health outcomes

F. Combined total disc replacement with fusion (TDR-ACDF Hybrid) surgery will be denied as it is considered experimental, investigational, and unproven to affect health outcomes

G. Cervical artificial intervertebral disc replacement will be denied as experimental, investigational, and unproven to affect health outcomes in any of the following circumstances:

1. Individuals with symptomatic degenerative disc disease or herniated disc beyond the proposed surgical location (e.g. at more than one level for single disc or 2 contiguous levels for 2-level disc replacement)

2. If requested/used for more than two (2) contiguous levels

3. Previous spinal surgery at level(s) being treated

4. Previous fusion at adjacent cervical level(s)

5. In the presence of any of the following:
   a. Tumor or metastatic disease at site(s) of implant(s) or area that could affect the safe exposure of spine required for the procedure.
   b. Active Infection (systemic or at implantation site)
   c. Radiographic evidence of cervical instability such as greater than 3.5 mm subluxation or greater than 11 degrees of angulation or kyphotic deformity.
H. Lumbar artificial intervertebral disc replacement will be denied as experimental, investigational, and unproven to affect health outcomes in any of the following circumstances:

1. The individual is less than 18 years old
2. It is requested/used for more than one lumbar spinal level
3. The individual has a history of previous lumbar fusion
4. Lumbar artificial disc replacement is combined with a fusion at any lumbar spinal level
5. Presence of lumbosacral fracture
6. Presence of lumbosacral scoliosis
7. Presence of lower extremity radiculopathy (nerve root compression) or lumbar spine stenosis
8. Presence of Grade 2 or higher spondylolisthesis at targeted level or any degree of listhesis at non-targeted level.
9. Presence of multi-level lumbar degenerative disc disease
10. Presence of tumor or metastatic disease at site of implant or area that could affect the safe exposure of spine required for the procedure
11. Presence of infection at the implantation site or active systemic infection

**Documentation Required:**

- Office notes and procedure reports
- Evidence (therapy/treatment notes) of at least 6 weeks of participation in physical therapy or chiropractic treatment directed at the spinal area/level(s) of concern.
- Documentation of the specific prosthesis/implant to be used
- History of previous spinal procedures
- Imaging (MRI, CT, CT myelogram) reports
WPS/Arise Review History:

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<tr>
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For Artificial Disc review prior to this policy see MCG 20th edition (effective 3/16/16) and, prior to 3/16/16, Medical Policy PUM 250-0008 Artificial Disc Replacement and Other Intervertebral Disc Therapies

Approved by the Medical Director