

# Medical Policy

<b>Policy:</b>	<b>200813</b>	<b>Initial Effective Date:</b>	<b>11/25/2008</b>
<b>SUBJECT:</b>	<b>Artificial Intervertebral Disc Replacement</b>	<b>Annual Review Date:</b>	<b>02/05/2024</b>
	<ul style="list-style-type: none"><li>• <b>Cervical</b></li><li>• <b>Thoracic</b></li><li>• <b>Lumbosacral</b></li></ul>	<b>Last Revised Date:</b>	<b>02/05/2024</b>

**Prior approval is required for some, or all procedure codes listed in this Corporate Medical Policy. Some or all procedure codes listed in this Corporate Medical Policy may be considered experimental/investigational.**

**Definition:** Artificial intervertebral disc replacement (AIDR) is a surgical procedure that involves removal of a degenerated intervertebral disc followed by implantation of an artificial intervertebral disc. AIDR was developed as an alternative to spinal fusion for the treatment of symptomatic degenerative disc disease (DDD) that has not responded to conservative treatment. The goal of AIDR is to relieve pain, restore disc height, maintain motion of the natural spine, and prevent degeneration of adjacent discs. Artificial disc devices have been developed for use in cervical, thoracic and lumbosacral portions of the spine.

**I. Medical Necessity: Cervical AIDR:** The Company considers cervical AIDR (**CPT Codes 22856, 22858, 22861, Category III Codes 0095T, 0098T, and applicable ICD-10-PCS Codes**) at *1 or 2 contiguous levels* between C3 and C7 **medically necessary** and eligible for reimbursement providing that *all* of the following medical criteria are met:

- FDA-approved artificial disc (vertebra-specific); and
- Age  $\geq 18$  years and skeletally mature; and
- Candidate for anterior cervical discectomy and fusion (ACDF); and
- Symptomatic cervical disc disease (neck or arm [radicular] pain and/or a functional/neurological deficit with  $\geq 1$  of the following conditions confirmed by imaging [CT, MRI, or x-rays]: herniated nucleus pulposus, spondylosis [defined by the presence of osteophytes], and/or loss of disc height); and
- Significant vertebral osteophyte formation and/or herniated nucleus pulposus believed to be responsible for the clinical findings; and
- Failure of, intolerance to, or unable to receive  $\geq 6$  weeks of conventional medical therapy including *all* of the following:
  1. Physical therapy; and
  2. Anti-inflammatory medication; and
  3. Analgesic medication; and

# Medical Policy

4. Avoidance of exacerbating activities.

## AND

- *None* of the following is present:
  1. Active systemic infection or infection at the operating site; or
  2. Allergy or sensitivity to implant materials; or
  3. Osteopenia or osteoporosis (bone density T-score -2.5 or lower measured by dual energy x-ray absorptiometry [DEXA]); or
  4. Moderate to advanced spondylosis characterized by any bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of >50% of its normal height.
  5. Marked cervical instability on imaging (e.g., signs of spondylolisthesis >3.5 mm or angulation of the disc space >11° greater than adjacent segments); or
  6. Severe facet joint arthropathy; or
  7. Significant cervical anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, diffuse idiopathic skeletal hyperostosis, ankylosing spondylitis, degeneration, trauma, and surgery related trauma
  8. Significant kyphotic deformity, significant reversal of lordosis significant spondylolisthesis; or
  9. Symptoms necessitating surgical treatment at > 2 cervical level; or
  10. Congenital stenosis; or
  11. Previous surgery at the involved level; or
  12. Spinal metastases; or
  13. Current medical condition requires long-term use of medications affecting bone quality and fusion rates (e.g., systemic corticosteroids); or
  14. Medical-surgical clearance not obtained from appropriate specialty provider(s).

**II. Thoracic AIDR:** Based upon our findings, the Company has determined thoracic AIDR, implantation, removal and revision have not demonstrated equivalence or superiority to currently accepted standard means of treatment. The Company considers thoracic AIDR, implantation, removal and revision (**CPT Code 22899 and applicable ICD-10-PCS Codes**) **investigational** and **not** eligible for reimbursement.

**III. Lumbosacral AIDR:** The Company considers lumbosacral AIDR (**CPT Codes 22857, 22860, 22862, Category III Codes 0164T, 0165T, and ICD-10-PCS Codes**) at any *single level* between L3 and S1 **medically necessary** and eligible for reimbursement providing that *all* of the following medical criteria are met:

- FDA-approved artificial disc (vertebra-specific); and
- Age ≥18 years and skeletally mature; and
- Spondylolisthesis at the involved level per the FDA-approved artificial disc specific limits; and
- Candidate for lumbosacral spinal fusion; and

# Medical Policy

- Symptomatic lumbosacral DDD (discogenic back pain with degeneration of the disc confirmed by imaging [CT, MRI, or x-rays]), which has failed at least 6 months of conservative treatment, including *all* of the following:
  1. Physical therapy; and
  2. Anti-inflammatory medication; and
  3. Analgesic medication; and
  4. Avoidance of exacerbating activities.

## AND

- *None* of the following is present:
  1. Active systemic infection or infection at the operating site; or
  2. Allergy or sensitivity to implant materials; or
  3. Osteopenia or osteoporosis (bone density T-score -2.5 or lower measured by dual energy x-ray absorptiometry [DEXA]); or
  4. Moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of >50% of its normal height; or
  5. Marked lumbosacral instability on imaging (e.g., signs of spondylolisthesis >3.5 mm or angulation of the disc space >11° greater than adjacent segments); or
  6. Severe facet joint arthropathy; or
  7. Significant lumbosacral anatomical deformity or compromised vertebral bodies at the index level due to systemic disease, diffuse idiopathic skeletal hyperostosis, ankylosing spondylitis, degeneration, trauma, and surgery related trauma.
  8. Significant kyphotic deformity, significant reversal of lordosis, or significant spondylolisthesis; or
  9. Symptoms necessitating surgical treatment at > 1 lumbosacral level; or
  10. Congenital stenosis; or
  11. Previous surgery at the involved level; or
  12. Spinal metastases; or
  13. Nerve root compression; or
  14. Stenosis; or
  15. Current medical condition requires long-term use of medications affecting bone quality and fusion rates (e.g., systemic corticosteroids); or
  16. Medical-surgical clearance not obtained from appropriate specialty provider(s).

# Medical Policy

## **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**Prior approval is required for CPT Codes 22856, 22857, 22858, 22860, 22861, 22862, Category III Codes 0095T, 0098T, 0164T, 0165T and applicable ICD-10-CM Procedure Codes.**

**CPT Code 22899 (when unlisted procedure, spine [22899] is determined to be thoracic artificial disc replacement) and applicable ICD-10-CM Procedure Codes are considered investigational and not eligible for reimbursement.**

**NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the service, or procedure, supply, product, or accommodation performed or furnished regardless of how the service, or procedure, supply, product, or accommodation was coded by the Provider.**

*Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.*

*Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.*

# Medical Policy

## Sources of Information:

- American Association of Neurological Surgeons (AANS) (2023) Artificial Lumbar Disk Surgery. Retrieved from: <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Artificial-Lumbar-Disc> Accessed January 19, 2024.
- American Academy of Orthopaedic Surgeons (AAOS). (2016). *Artificial disk replacement in the lumbar spine*. Retrieved from: <http://orthoinfo.aaos.org/topic.cfm?topic=A00502>. Accessed November 21, 2021.
- Biswas JK, Rana M, Malas A, Roy S, Chatterjee S, Choudhury S. (2022) Effect of single and multilevel artificial inter-vertebral disc replacement in lumbar spine: A finite element study. *Int J Artif Organs*. Feb;45(2):193-199.
- Chou, Roger M.D., Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment. In: UpToDate, Hirsch IB (Ed), UpToDate, Waltham, MA.
- Boselie TFM, Willems PC, van Mameren H, de Bie RA, Benzel EC, van Santbrink H. (2013). Arthroplasty versus fusion in single-level cervical degenerative disc disease: a Cochrane review. *Spine (Phila Pa 1976)*, 38(17):E1096-1107.
- Centers for Medicare & Medicaid Services. Lumbar Artificial Disc Replacement (LADR) (150.10). Version number 2. Effective date August 14, 2007.
- Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, ... American Pain Society Low Back Pain Guideline Panel. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine*, 34(10):1066–1077.
- Davis RJ, Nunley PD, Kim KD, Hisey MS, Jackson RJ, Bae HW, ... Stone MB. (2015). Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *J Neurosurg Spine*, 22(1):15–25.
- Goldstein ZH, Boody B, Sasso R. (2020). Two-Level Anterior Cervical Discectomy and Fusion Versus Cervical Disc Arthroplasty-Long-Term Evidence Update. *Int J Spine Surg*, 14(s2):S36–S40.
- Hayes, Inc., (November 18,2021) Comparative Effectiveness Review Of Lumbar Total Disc Replacement For Degenerative Disc Disease, Annual update January 19 2024.
- Hayes, Inc., (August 21, 2017) Single-Level Artificial Disc Replacement for Cervical Degenerative Disc Disease. Annual update January 19 2024.
- Hayes, Inc., (October 03,2017) Multilevel Artificial Disc Replacement for Cervical Degenerative Disc Disease. Annual update January 19 2024.
- Hayes, Inc., (April 1,2019) Lumbar Total Disc Replacement for Degenerative Disc Disease. Annual update January 19 2024.
- International Society for the Advancement of Spine Surgery. (2020). Position Statement on Cervical and Lumbar Disc Replacements. Retrieved from: <https://www.isass.org/position-statement-on-cervical-and-lumbar-disc-replacements-2019/>. Accessed November 22, 2021. Updated Search (January 19,2024)
- Murtagh R, Castellvi AE. (2014). Motion preservation surgery in the spine. *Neuroimaging Clin N Am*, 24(2):287–294.
- Radcliff K, Guyer RD. (2020). Economics of Cervical Disc Replacement. *Int J Spine Surg*, 14(s2):S67–S72.
- Robinson Y, Sandén B. (2009). Spine imaging after lumbar disc replacement: pitfalls and current recommendations. *Patient Saf Surg*, 3(1):15.

# Medical Policy

- Schroeder G, Vaccaro R, Srikanth N. (2019). International Society for the Advancement of Spine Surgery .Position statement on cervical and lumbar disc replacements. Retrieved from: <https://isass.org/position-statement-on-cervical-and-lumbar-disc-replacements-2019/> Accessed January 04, 2023 Updated Search (January 19, 2024),
- Thavaneswaran P, Vandeppeer M. (2014). Lumbar artificial intervertebral disc replacement: a systematic review. *ANZ J Surg*, 84(3):121–127.
- Yue JJ, Garcia R, Blumenthal S, Coric D, Patel VV, Dinh DH, ... Ferko NC. (2019). Five-year Results of a Randomized Controlled Trial for Lumbar Artificial Discs in Single-level Degenerative Disc Disease. *Spine (Phila Pa 1976)*, 44(24):1685–1696.
- Zigler J, Gornet MF, Ferko N, et.al., (2018) Comparison of Lumbar Total Disc Replacement With Surgical Spinal Fusion for the Treatment of Single-Level Degenerative Disc Disease: A Meta-Analysis of 5-Year Outcomes From Randomized Controlled Trials. *Global Spine J*. 2018;8(4):413-423.

<b>Applicable Code(s):</b>	
<b>CPT:</b>	<b>22856, 22857, 22858, 22860, 22861, 22862 and 22899 Category III 0095T, 0098T, 0164T, and 0165T</b>
<b>HCPCS:</b>	<b>N/A</b>
<b>ICD10 Procedure Codes:</b>	<b>0RR30JZ, 0RR50JZ, 0RP90JZ, 0RPB0JZ, 0RR50JZ, 0RR90JZ, 0RRB0JZ, 0RW50JZ, 0RW53JZ, 0RW54JZ, 0RW90JZ, 0RW93JZ, 0RW94JZ, 0RWB0JZ, 0RWB3JZ, 0RWB4JZ, 0SR20JZ, 0SR20JZ, 0SR40JZ, 0SR40JZ, 0SW20JZ, 0SW23JZ, 0SW24JZ, 0SW40JZ, 0SW43JZ and 0SW44JZ</b>

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx>. If printed, this document is subject to change. Always verify with the most current version of the official document at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx>.