Cohere Medical Policy - Total Disc Arthroplasty

Clinical Guidelines for Medical Necessity Review

Version: 3
Effective Date: December 19, 2024

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Cohere Medical Policy - Total Disc Arthroplasty

Date of last literature review: 11/4/2024
Document last updated: 12/19/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Recommended Clinical Approach

Developed as an alternative to spinal fusion surgery, spinal disc arthroplasty has emerged to treat degenerative disease. The risk of nerve root compression and adjacent disc disease is reduced with this procedure. Patients report improved movement and flexibility compared with fusion procedures.[1-2]

Anterior cervical discectomy and fusion (ACDF) has been the standard of care for cervical radiculopathy and myelopathy that is refractory to conservative management. However, a fusion of mobile segments into non-mobile spinal units can result in biomechanical strain and degeneration. To preserve natural mobility at diseased cervical discs, cervical total disc arthroplasty (TDA) has emerged, which retains the benefits of more traditional procedures, such as disc height restoration and direct neural decompression, while improving the range of motion at the functional spinal unit and preserving near normal spinal kinematics.[3]

Multidisciplinary rehabilitation and pain medication are the initial treatment methods for symptomatic lumbar degenerative disc disease (DDD), associated with the degeneration of intervertebral discs and low back pain. Although spinal fusion is considered the gold standard in the treatment of lumbar DDD, the procedure is associated with spinal instability and the degeneration of adjacent vertebrae. Total disc arthroplasty has emerged with the aim of restoring and maintaining spine biomechanics.[4]

Medical Necessity Criteria

Indications

➔ A **total disc arthroplasty** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The procedure is a **cervical total disc arthroplasty,** and **ALL** of the following are **TRUE**[5]:
  - **ANY** of the following symptoms:
    - Intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain; **OR**
    - Myelopathy due to cord compression or neural compression localized to the disc space; **OR**
    - Progressive functional neurological deficit (e.g., motor weakness, sensory deficit); **OR**
    - Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention; **AND**
  - Advanced imaging (magnetic resonance imaging [MRI] or computed tomography [CT]) or radiographic studies reveal **ANY** of the following with evidence of corresponding nerve root or cord compression[6]:
    - Herniated nucleus pulposus (herniated disc); **OR**
    - Spondylosis (defined by the presence of osteophytes); **OR**
    - Visible loss of disc height compared to adjacent levels; **AND**
  - Third to seventh cervical spinal levels (C3-C7); **AND**
  - No more than 2 adjacent levels; **AND**
  - Implantation is performed by an anterior approach; **AND**
  - Documented skeletal maturity (the patient's age is greater than 18 years); **AND**
  - **ANY** of the following:
    - Failure of conservative management for greater than 6 weeks, including **ALL** of the following:
      - ◆ Anti-inflammatory medications, analgesics, or prescription medications (e.g., oral steroids, narcotics, neuropathic pain medications) if not contraindicated; **AND**

        - Physical therapy; **AND**
        - Epidural steroid injections (ESI):
            - If medically appropriate; **OR**
            - Corticosteroid injection is contraindicated; **OR**
    - The patient's severe pain or disability is affecting their quality of life and limiting their daily life (including working and ability to provide self-care); **OR**
    - The patient has documented neurologic deficit, progressive neurologic deficit or history, signs/symptoms/physical exam consistent with myelopathy**; OR**
- The procedure is a **lumbar total disc arthroplasty**, and **ALL** of the following are **TRUE**[7-8]:
    - The patient has symptomatic degenerative disc disease (DDD) with unremitting lower back pain and functional impairment; **AND**
    - Advanced imaging (MRI or CT) or radiographic studies reveal no more than grade I spondylolisthesis at the involved level (1% to 25% disc slippage); **AND**
    - Fourth to fifth lumbar spinal levels (L4-L5) or lumbar fifth to sacral first spinal levels (L5-S1) only; **AND**
    - No more than 1 level discectomy; **AND**
    - Anterior retroperitoneal approach; **AND**
    - Documented skeletal maturity (patient's age is greater than 18 years); **AND**
    - **ANY** of the following:
        - Failure of conservative management for greater than 6 months, including **ALL** of the following:
            - Anti-inflammatory medications, analgesics, or prescription medications (e.g., oral steroids, narcotics, neuropathic pain medications) if not contraindicated; **AND**
            - Physical therapy; **AND**
            - Epidural steroid injections (ESI) for **ANY** of the following:
                - If medically appropriate; **OR**
                - Corticosteroid injection is contraindicated; **OR**

- The patient's severe pain or disability is affecting their quality of life and limiting their daily life (including working and ability to provide self-care).

Non-Indications

➔ A **total disc arthroplasty** is not considered appropriate if **ANY** of the following is **TRUE**[3-6]:

- Active systemic infection or infection at operative site; **OR**
- Diagnosed osteoporosis or osteopenia; **OR**
- Allergy to implant materials; **OR**
- Severe facet joint syndrome or degeneration; **OR**
- Current or past trauma or disease has created significant deformity of the vertebral bodies at the index levels; **OR**
- Bridging osteophytes or bone spurs; **OR**
- Radiographic evidence of marked cervical instability as evidenced on imaging[9-11]:
  - Greater than 3 mm translation; **OR**
  - Greater than 11 degrees angular rotation; **OR**
  - Prior cervical decompression; **OR**
- Isolated lumbar radiculopathy, primarily due to herniated disc; **OR**
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over at least 1 year); **OR**
- Myelopathy due to cervical stenosis from facet and/or posterior hypertrophy; **OR**
- Lumbar spinal stenosis; **OR**
- Scoliosis or other spinal deformity (e.g., focal lordosis, kyphosis at the level of the planned arthroplasty); **OR**
- Compromised vertebral bodies due to trauma or disease at the affected level; **OR**
- Facet joint degeneration; **OR**
- Greater than 50% decrease in disc height[12-13]; **OR**
- Abdominal pathology that would prevent an anterior retroperitoneal approach; **OR**
- Involved vertebral endplate not compatible with the artificial disc; **OR**
- Extruded disc material with sequestrum (e.g., free disc fragment); **OR**
- Ossification of the posterior longitudinal ligament (OPLL); **OR**

- Sensitivity or allergy to implant materials.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical

22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

Medical Evidence

Fiani et al. (2021) concluded that spinal disc arthroplasty is a viable alternative to standard decompression and fusion methods for the treatment of degenerative disc disease. Both cervical and lumbar arthroplasties may be safe and effective with improved segmental motion.[1]

Gupta et al. (2020) discuss the effectiveness of artificial disc replacement, which stabilizes and preserves segmental spinal motion. The anterior approach is most commonly used.[2]

The United States Food and Drug Administration (FDA) has approved several artificial intervertebral discs to for arthroplasty, including the following:

- The Simplify Cervical Artificial Disc (2021) is indicated for use in skeletally mature patients for disc reconstruction at one level from C3-C7 for intractable radiculopathy or myelopathy.[4]
- The activL Artificial Disc (2015) is intended for one-level disc reconstruction (L4, L5, or L5-S1) in skeletally mature patients with symptomatic degenerative disc disease with no more than grade I spondylolisthesis at the involved level.[6]

The North American Spine Society (NASS) has published the following related Coverage Policy Recommendations:

- *Cervical Artificial Disc Replacement* (2015) is indicated for two-level cervical disc replacement for radiculopathy related to nerve root compression in C3-C4 to C6-C7. The procedure is also recommended for myelopathy or myeloradiculopathy related to central spinal stenosis from one- or two-level degenerative disease in C3-C4 to C6-C7.[3]
- *Lumbar Artificial Disc Replacement* (2019) is recommended for discogenic low back pain at a single level for L3-L4, L4-L5, or L5-S1 in individuals who have failed at least 6 months of nonoperative treatment.[5]

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Clinical Guideline Revision History/Information

Original Date: September 29, 2023		
Review History		
Version 2	9/20/2024	Updated language regarding conservative treatment.
Version 3	12/19/2024	• Annual review • Indications updated • Non-indications updated • References updated • Structure aligned to the template • Medical evidence updated