Total Disc Arthroplasty - Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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

Literature review current through: 9/29/2023
Document last updated: 9/29/2023
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Total Disc Arthroplasty

General Guidelines

- **Units, Frequency, & Duration:** There is no clearly established consensus or criteria regarding surgical intervention timing.
- **Criteria for Subsequent Requests:** Revision or replacement may be required related to device failure.
- **Recommended Clinical Approach[1]:** 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[2]. There are a number of FDA-approved artificial disc replacement devices currently available.
- **Exclusions:** See Non-Indications

Medical Necessity Criteria

Indications

➔ **Total Disc Arthroplasty** is considered appropriate if **ANY** of the following is **TRUE**:

◆ The procedure is a **cervical total disc arthroplasty** with an FDA-approved artificial disc and **ALL** of the following are **TRUE**[3]:

- **ANY** of the following symptoms:
  - Intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain; **OR**
  - Myelopathy due to abnormality localized to the disc space; **OR**
  - Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention; **AND**
- Advanced imaging (MRI or CT) or radiographic studies reveal **ANY** of the following that provide evidence of corresponding nerve root or cord compression[4]:
  - Herniated nucleus pulposus (herniated disc); **OR**
  - Spondylosis (defined by the presence of osteophytes); **OR**

        - Visible loss of disc height compared to adjacent levels; **AND**
    - Spinal levels C3-C7; **AND**
    - No more than two (2) adjacent levels; **AND**
    - Anterior approach; **AND**
    - Documented skeletal maturity (age greater than 18); **AND**
    - **ANY** of the following**:**
        - No significant improvement in pain or disability level due to symptoms, despite receiving non-surgical management interventions for more than six (6) weeks, including **ALL** of the following (unless medically contraindicated):
            - Physical therapy including home exercise program; **AND**
            - Anti-inflammatory medications or oral steroids; **AND**
            - Epidural steroid injections (ESI); **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 procedure is a **lumbar total disc arthroplasty** with an FDA-approved artificial disc and **ALL** of the following are **TRUE**[5-6]:
    - **ANY** of the following symptoms:
        - Symptomatic degenerative disc disease with unremitting lower back pain and functional impairment; **AND**
    - Advanced imaging (MRI or CT) or radiographic studies reveal **ANY** of the following:
        - No more than Grade I spondylolisthesis at the involved level (1-25% disc slippage); **AND**
    - Spinal levels L4-L5 or L5-S1 only; **AND**
    - No more than one (1) level discectomy; **AND**
    - Anterior retroperitoneal approach; **AND**
    - Documented skeletal maturity (age greater than 18); **AND**
    - **EITHER** of the following:
        - No significant improvement in pain or disability level due to symptoms, despite receiving non-surgical management interventions for more than six (6) months, including **ALL** of the following (unless medically contraindicated):
            - Physical therapy including home exercise program; **AND**
            - Anti-inflammatory medications or oral steroids; **AND**
            - Epidural steroid injections (ESI); **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

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

- Active systemic infection or infection at operative site; **OR**
- Diagnosed osteoporosis or osteopenia; **OR**
- Allergy to implant materials; **OR**
- Severe facet disease or degeneration; **OR**
- Current or past trauma or disease has created significant cervical vertebral bodies at the index levels; **OR**
- Bridging osteophytes; **OR**
- Radiographic evidence of marked cervical instability; **OR**
- Isolated lumbar radiculopathy, especially due to herniated disc; **OR**
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year); **OR**
- Myelopathy; **OR**
- Spinal stenosis; **OR**
- Scoliosis or other spinal deformity; **OR**
- Compromised vertebral bodies due to trauma or disease at the affected level; **OR**
- Facet joint degeneration; **OR**
- Remaining disc height less than 3 millimeters preoperatively; **OR**
- Abdominal pathology that would prevent an anterior retroperitoneal approach; **OR**
- Involved vertebral endplate not compatible with artificial disc; **OR**
- Extruded disc material with sequestrum (such as free disc fragment)

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

HCPCS/CPT 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)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (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

The United States Food and Drug Administration (FDA) has granted approval for several artificial intervertebral discs to be used 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
- 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

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

- Cervical Artificial Disc Replacement (2015), indicated for two level cervical disc replacement for radiculopathy related to nerve root compression in C3-4 to C6-7. The procedure is also recommended for myelopathy or myeloradiculopathy related to central spinal stenosis from one or two level degenerative disease in C3-4 to C6-7.
- 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 six (6) months of nonoperative treatment.

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 have been shown to be safe and effective with improved segmental motion.

Gupta et al. (2020) discusses the effectiveness of artificial disc replacement which serves to stabilize as well as preserving segmental spinal motion. The anterior approach is most commonly used.

References

1. Fiani B, Nanney JM, Villait A, Sekhon M, Doan T. Investigational Research: Timeline, Trials, and Future Directions of Spinal Disc Arthroplasty. Cureus. 2021;13(7):e16739. Published 2021 Jul 29. doi:10.7759/cureus.16739
2. Gupta et al. Chapter 23: Procedures for Decompression of the Spinal Cord and Nerve Roots. *Spine Secrets-Procedures for Decompression.* Elsevier.com. 2020.
3. North American Spine Society. NASS Coverage Recommendation-Cervical Artificial Disc. Spine.org. 2015.
4. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED) - Simplify® Cervical Artificial Disc. accessdata.fda.gov. 2021.
5. North American Spine Society. NASS Coverage Recommendations Lumbar Artificial Disc Replacement. Spine.org. 2019.
6. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED) - activL® Artificial Disc (activL). Accessdata.fda.gov. 2015.

Clinical Guideline Revision History/Information

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