Cohere Medicare Advantage Policy - Total Disc Arthroplasty

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Total Disc Arthroplasty

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Service: Total Disc Arthroplasty

Benefit Category

Inpatient Hospital Services
Physicians' Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

Recommended Clinical Approach

Developed as an alternative to spinal fusion surgery, spinal disc arthroplasty has emerged to treat degenerative disease.[2] 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.[3] There are a number of FDA-approved artificial disc replacement devices currently available.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of total disc arthroplasty. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Inadequate management of degenerative disc disease due to inappropriate denials. The cervical disc has been FDA approved for use in skeletally mature patients for disc reconstruction at one level from C3-C7 for treatment of intractable radiculopathy or myelopathy. The North American Spine Society (NASS) indicated two-level cervical disc replacement for radiculopathy related to nerve root compression in C3-4 to C6-7 is recommended.[5]
- Risks with inappropriate surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic

risk and need for repeat or additional procedures due to disc implant failure and ongoing pain.
- Adverse effects from delayed or denied treatment, which can worsen patient outcomes, such as increased lumbar or cervical pain, progression of degenerative disease, worsening myelopathy or radiculopathy and decreased mobility. If spine pain persists, patients can become opiate dependent.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to total disc arthroplasty procedures. Disc arthroplasty is intended to preserve cervical motion, thus preventing complications from cervical fusion such as adjacent level disease and pseudoarthrosis, according to Fiani et al.[2] By proceeding with a motion sparing procedure additional degenerative changes in the cervical spine could be slowed or prevented. Long term clinical studies indicate single level disc arthroplasty has superior outcomes compared to the traditional anterior cervical decompression and fusion. According to Siepe et al, overall results from total disc arthroplasty reveal significant improvement from baseline pain scores and function.[8] Patient satisfaction is 63.6% with 13.7% of patients not satisfied.
- Reduction in complications and adverse effects from unnecessary procedures. Siepe et al reported on the complications from total disc arthroplasty and noted an overall complication rate of 14.4% with patients requiring revision surgeries for device related complications.[8] Careful patient selection with mild stenosis and only one or two levels results in the best long term outcomes. Thus, selection criteria is necessary to ensure good clinical outcomes.[8] Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Total disc arthroplasty** is considered appropriate if **ANY** of the following is **TRUE**[4-6]:
  - ◆ The procedure is a **cervical total disc arthroplasty** with an FDA-approved artificial disc and **ANY** of the following are **TRUE**[3]:
    - The procedure is a single-level procedure, and **ALL** of the following are **TRUE**:
      - **ANY** of the following:
        - ◆ Symptomatic cervical degenerative disc disease (C3 to C7); **OR**
        - ◆ Herniated cervical disc at a single level; **AND**
      - The patient is skeletally mature; **AND**
      - **ANY** of the following:
        - ◆ Intractable cervical radicular pain or myelopathy with failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) which must be documented for a period of greater than 6 weeks. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **OR**
        - ◆ The patient has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention; **AND**
      - The patient must have clinical evidence of corresponding nerve root or spinal cord compression documented by computed tomography (CT),

myelography, or magnetic resonance imaging (MRI)[5]; **OR**

- The procedure is a two-level procedure, and **ALL** of the following are **TRUE**:
  - **ALL** criteria listed above for single-level procedure have been met; **AND**
  - There is objective clinical evidence of radiculopathy, myelopathy, or spinal cord compression at 2 corresponding contiguous levels; **AND**
  - The cervical disc replacement device utilized has been FDA-approved for 2 levels; **OR**

◆ The procedure is a **lumbar total disc arthroplasty** with an FDA-approved artificial disc and **ALL** of the following are **TRUE**:[1,5-8]:

- Patient is less than 60 years of age; **AND**
- Symptomatic degenerative disc disease 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 (1-25% 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:
  - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than six weeks. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **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 is **TRUE**[3-8]:

◆ **ANY** of the following absolute contraindications[4]:

- Extreme obesity (BMI greater than 40 kg/m^2); **OR**

- Significant cervical anatomical deformity; **OR**
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium); **OR**
- Active systemic infection or infection at the operating site; **OR**
- Osteoporosis or osteopenia; **OR**
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5 mm, and/or greater than 11° angular difference to that of either level adjacent to the treated level; **OR**
- Severe spondylosis; **OR**
- Clinically compromised vertebral bodies at affected level; **OR**

◆ **ANY** of the following investigational indications and conditions including[4]:

- Lumbar level disc replacement for adult patients greater than 60 years of age[1,7]; **OR**
- Disc replacement at 2 non-contiguous levels or 3 or more levels; **OR**
- Prior surgery at the treated level; **OR**
- Previous fusion at another level; **OR**
- Any anatomical deformity (e.g., ankylosing spondylitis, trauma); **OR**
- Any autoimmune disease or rheumatoid arthritis; **OR**
- Moderate to severe facet joint arthropathy at the involved level; **OR**
- Metabolic bone disease (e.g., osteoporosis, Paget's disease, osteomalacia, osteogenesis imperfecta) or use of medications known to potentially interfere with bone/soft tissue healing (e.g., steroids); **OR**
- Malignancy; **OR**
- Chronic renal failure.

NOTE: Services will be deemed medically reasonable and necessary only when conducted by appropriately trained and licensed providers.

All Cervical Disc Replacement (CDR) procedures must be performed by a qualified physician, defined as follows:

1. The physician must have received training and acquired expertise within an accredited residency or fellowship program in the relevant specialty or subspecialty (e.g., neurosurgery, orthopedic spine), or possess equivalent education, training, and expertise endorsed by an academic institution or recognized specialty/subspecialty society.

2. The physician must demonstrate proficiency in the performance and management of Cervical Disc Replacement (CDR) and Cervical Disc Degenerative Disease (CDDD) procedures.

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)
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)

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 the following artificial intervertebral disc to be used for cervical arthroplasty:

- 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.[6]

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

- Cervical Artificial Disc Replacement (2015), indicated 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.[5]

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.[2]

Gupta et al. (2020) discuss the effectiveness of artificial disc replacement which serves to stabilize as well as preserve segmental spinal motion. The anterior approach is most commonly used.[3]

References

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Clinical Guideline Revision History/Information

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