Cohere Medicare Advantage Policy - Total Disc Arthroplasty

Clinical Policy for Medical Necessity Review

Version: 3
Revision Date: June 12, 2025

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Total Disc Arthroplasty
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Total Disc Arthroplasty

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-3]

- National Coverage Determination (NCD). Lumbar artificial disc replacement (LADR)(150.10).
- Local Coverage Determination (LCD). Lumbar artificial disc replacement (L37826).
  - Billing and Coding: Lumbar artificial disc replacement (A56390).
- Local Coverage Determination (LCD). Cervical disc replacement (L38033).
  - Billing and Coding: Cervical disc replacement (A57021).

Description

Developed as an alternative to spinal fusion surgery, spinal disc arthroplasty has emerged to treat degenerative disease.[4,5] 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.[6] There are several FDA-approved artificial disc replacement devices currently available.

Medical Necessity Criteria

Indications

Total disc arthroplasty is considered appropriate if **ALL** of the following are **TRUE**[2-8]:

- **ANY** of the following:
  - Current nicotine user with no product use for 6 weeks; and **ANY** of the following[12]:
    - Negative urine (cotinine) lab test within 30 days; **OR**
    - Surgery is urgently required due to documented reason; **OR**
  - No history of nicotine product use within the last 12 months; **OR**

    - No lifetime history of nicotine product use; **AND**
- **ANY** of the following:
    - The procedure is a **cervical total disc joint replacement** with an FDA-approved artificial disc, and **ANY** of the following is **TRUE**[2,6]:
        - The procedure is a single-level procedure, and **ALL** of the following are **TRUE**[2]:
            - **ANY** of the following[2]:
                - Symptomatic cervical degenerative disc disease (C3 to C7); **OR**
                - Herniated cervical disc at a single level; **AND**
            - The patient is skeletally mature[2]; **AND**
            - **ANY** of the following[2]:
                - 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)[2,7]; **OR**
        - The procedure is a two-level procedure, and **ALL** of the following are **TRUE**[2]:
            - **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 two corresponding contiguous levels; **AND**
            - The cervical disc replacement device utilized has been FDA-approved for two levels.

Non-Indications

Cervical total disc arthroplasty is not considered appropriate if **ANY** of the following is **TRUE**[1-3]:

- **ANY** of the following absolute contraindications[2]:
  - Extreme obesity (BMI greater than 40 kg/m2)[2]; **OR**
  - Significant cervical anatomical deformity[2]; **OR**
  - Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)[2]; **OR**
  - Active systemic infection or infection at the operating site[2]; **OR**
  - Osteoporosis or osteopenia[2]; **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[2]; **OR**
  - Severe spondylosis[2]; **OR**
  - Clinically compromised vertebral bodies at the affected level[2]; **OR**
- **ANY** of the following investigational indications and conditions, including[2]:
  - Disc replacement at 2 non-contiguous levels or 3 or more levels[2]; **OR**
  - Prior surgery at the treated level[2]; **OR**
  - Previous fusion at another level[2]; **OR**
  - Any anatomical deformity (e.g., ankylosing spondylitis, trauma)[2]; **OR**
  - Any autoimmune disease or rheumatoid arthritis[2]; **OR**
  - Moderate to severe facet joint arthropathy at the involved level[2]; **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)[2]; **OR**
  - Malignancy[2]; **OR**
  - Chronic renal failure.[2]

Lumbar total disc arthroplasty is not considered appropriate if **ANY** of the following is **TRUE**[1]:

- The patient is 60 years of age or older.[1]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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.
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).
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical.
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar.
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).
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar.
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).
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).

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner includes coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for **total disc arthroplasty** may include:

- Adverse effects from delayed or denied treatment, to comply with the requirements for current smokers to abstain from nicotine for at least 6 weeks, and provide a urine sample that is negative for cotinine (unless surgery is urgently required for documented reasons). Studies have shown that smokers undergoing cervical artificial disc replacement surgery had a much higher and statistically significant incidence of revision (20%) compared with nonsmokers (4.3%).[12]

The clinical benefits of using these criteria for **total disc arthroplasty** may include:

- Improved patient selection, resulting in better long-term outcomes. Ideal surgical candidates are patients who have been preoperatively evaluated for their nicotine use. Studies have shown that smokers are at an increased risk of needing revision surgery following an artificial disc replacement in comparison to nonsmokers at 2 years postsurgery.[12]

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 have been shown to be safe and effective with improved segmental motion.[5]

Gupta et al. (2020) discuss the anterior surgical decompression options for a C5-C6 disk herniation. Discectomy of the damaged disk and fusion using a bone graft is a common procedure. Alternatively, an artificial disk may be used to replace the damaged disk. Artificial disc replacement effectively provides for stabilization and preserves segmental spinal motion. The anterior approach is the most commonly used.[6]

In a recent cross-sectional study, Shafi et al. (2024) followed 1067 patients treated with elective CDA in 2009, 2014, and 2019. They found that the proportion of patients aged >65 significantly increased from 35% to 51%. Also, the proportion of patients with contraindications as defined by the original CDA investigative device exemption (IDE) criteria increased.[11]

The United States Food and Drug Administration (FDA) has approved the artificial intervertebral disc for cervical disk arthroplasty (CDA). 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.[8]

The North American Spine Society (NASS) has published the related Coverage Policy Recommendation, Cervical Artificial Disc Replacement (2015), indicating 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.[7]

References

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12. Wen-Shen L, Sheng MLW, Yeo W, Beng et al. No Difference in Functional Outcome but Higher Revision Rate Among Smokers Undergoing Cervical Artificial Disc Replacement: Analysis of a Spine Registry. *Int J Spine Surg.* 2020 Dec;14(6):916-923. doi: 10.14444/7140. Epub 2020 Dec 29. PMID: 33560251; PMCID: PMC7872401.

Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	06/10/2024	422.101 Disclaimer added
Version 3	06/12/2025	Annual review. No changes to procedure codes. Nicotine cessation requirements added in the indications section. Reviewed literature and added references.