



# CLINICAL GUIDELINES

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## CMM-602: Cervical Total Disc Arthroplasty Guidelines

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eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

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Clinical guidelines for medical necessity review of Comprehensive Musculoskeletal Management Services.

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## **CMM-602.1: General Guidelines**

- The determination of medical necessity for the performance of cervical total disc arthroplasty is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.
- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
  - ◆ Provider-directed non-surgical management
  - ◆ Absence of unmanaged significant mental and/or behavioral health disorders
- Urgent/emergent conditions for cervical total disc arthroplasty include **ANY** of the following:
  - ◆ Myelopathy or Cord signal changes on MRI due to cord compression
  - ◆ Central cord syndrome
  - ◆ Documentation of progressive neurological deficit on two separate physical examinations
  - ◆ **ANY** of the following due to a neurocompressive pathology
    - Motor weakness of grade 3/5 or less of specified muscle(s)
    - Rapidly progressive symptoms of motor loss
    - Bowel incontinence
    - Bladder incontinence/retention
  - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

## **CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty**

Initial primary cervical total disc arthroplasty is considered **medically necessary** when **ALL** of the following are met:

- The patient has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation.
- The patient is skeletally mature.
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- No previous surgeries at the operative level
- No prior fusion at an adjacent cervical level
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy.
- The planned implant(s) is/are for a single level or simultaneous two contiguous level replacement(s)
- The patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s)

- Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
- Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unrelenting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unrelenting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms and physical examination findings
  - ◆ Myelopathy when **ALL** of the following are met:
    - Subjective symptoms including **ANY** of the following:
      - Upper/lower extremity weakness, numbness, or pain
      - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
      - Urinary urgency
      - Gait disturbance
      - New-onset bowel or bladder dysfunction
      - Frequent falls

- Objective physical examination findings including at least **TWO** of the following:
  - Grip and release test
  - Ataxic gait
  - Hyperreflexia
  - Hoffmann sign
  - Pathologic Babinski sign
  - Tandem walking test demonstrating ataxia
  - Inverted brachial radial reflex
  - Increased muscle tone or spasticity
  - Clonus
  - Myelopathic hand
- Recent (within 6 months) MRI/CT findings that are concordant with the patient's symptoms and physical examination findings including **EITHER** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

### **CMM-602.3: Failed Cervical Total Disc Arthroplasty Implant**

Revision of a failed cervical total disc arthroplasty to a cervical fusion is considered **medically necessary** when the patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s). For Anterior Cervical Fusion refer to **CMM-601.5: Failed Cervical Disc Arthroplasty Implant** or for Posterior Cervical Fusion refer to **CMM 604.5: Failed Cervical Disc Arthroplasty Implant**.

- Recent (within 6 months) post-operative imaging studies of the cervical spine including flexion/extension lateral views demonstrating failure of a cervical disc arthroplasty implant (i.e., subsidence, loosening, dislocation/subluxation, vertebral body fracture without instability, dislodgement)
- Performed for **ANY** of the following conditions:
  - ◆ Unremitting neck pain when **ALL** of the following are met:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Greater than 6 months since prior cervical disc arthroplasty procedure
    - Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
    - Less than clinically meaningful improvement with prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks unless contraindicated
    - Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings

- ◆ Radiculopathy when **ALL** of the following are met:
  - Greater than 6 months since the prior cervical disc arthroplasty procedure
  - Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
  - Subjective symptoms including **BOTH** of the following:
    - Significant level of pain on a daily basis defined as **EITHER** of the following:
      - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
      - Severe, disabling, crippling, or incapacitating pain
    - Unrelenting radicular pain to shoulder girdle and/or upper extremity resulting in disability
  - Objective physical examination findings including **ANY** of the following:
    - Dermatomal sensory deficit
    - Motor deficit (e.g. biceps, triceps weakness)
    - Reflex changes
    - Shoulder Abduction Relief Sign
    - Nerve root tension sign (e.g. Spurling's maneuver)
    - Unrelenting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
  - Less than clinically meaningful improvement with any **TWO** of the following unless contraindicated:
    - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
    - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
    - Epidural steroid injection(s)/selective nerve root block(s)
  - Recent (within 6 months) post-operative MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms or physical examination findings
- ◆ Myelopathy when **ALL** of the following are met:
  - Greater than 6 months since the prior cervical disc arthroplasty procedure
  - Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
  - Subjective symptoms including **ANY** of the following:
    - Upper/lower extremity weakness, numbness, or pain
    - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
    - Gait disturbance
    - New-onset bowel or bladder dysfunction
    - Frequent falls
  - Objective physical examination findings including at least **TWO** of the following:
    - Grip and release test
    - Ataxic gait
    - Hyperreflexia
    - Hoffmann sign

- Pathologic Babinski sign
- Tandem walking test demonstrating ataxia
- Inverted brachial radial reflex
- Increased muscle tone or spasticity
- Clonus
- Myelopathic hand
- Recent (within 6 months) post-operative MRI/CT findings that are concordant with the patient's symptoms or physical examination findings including **ANY** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

#### **CMM-602.4: Adjacent Segment Disease Secondary to Cervical Total Disc Arthroplasty**

Cervical total disc arthroplasty for adjacent segment disease secondary to cervical total disc arthroplasty is considered **medically necessary** when **ALL** of the following are met:

- The patient has degenerative cervical disc disease with intractable radiculopathy and/or myelopathy, producing symptomatic nerve root and/or spinal cord compression due to herniated disc and/or osteophyte formation.
- The patient is skeletally mature
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy
- Recent (within 6 months) imaging studies of the cervical spine including flexion/extension lateral views demonstrating successful cervical total disc arthroplasty at the adjacent level
- The prior total disc arthroplasty procedure at an adjacent level was performed at least 6 months prior.
- No previous surgeries on the disc(s) involved
- Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)

- Performed for **EITHER** of the following conditions:
  - ◆ Radiculopathy when **ALL** of the following are met:
    - Subjective symptoms including **BOTH** of the following:
      - Significant level of pain on a daily basis defined as **EITHER** of the following:
        - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as  $\geq 7$
        - Severe, disabling, crippling, or incapacitating pain
      - Unrelenting radicular pain to shoulder girdle and/or upper extremity resulting in disability
    - Objective physical examination findings including **ANY** of the following:
      - Dermatomal sensory deficit
      - Motor deficit (e.g. biceps, triceps weakness)
      - Reflex changes
      - Shoulder Abduction Relief Sign
      - Nerve root tension sign (e.g. Spurling's maneuver)
      - Unrelenting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
    - Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
      - Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
      - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
      - Epidural steroid injection(s)/selective nerve root block(s)
    - Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms and physical examination findings
  - ◆ Myelopathy when **ALL** of the following are met:
    - Subjective symptoms including **ANY** of the following:
      - Upper/lower extremity weakness, numbness, or pain
      - Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
      - Gait disturbance
      - New-onset bowel or bladder dysfunction
      - Frequent falls
    - Objective physical examination findings including at least **TWO** of the following:
      - Grip and release test
      - Ataxic gait
      - Hyperreflexia
      - Hoffmann sign
      - Pathologic Babinski sign
      - Tandem walking test demonstrating ataxia
      - Inverted brachial radial reflex
      - Increased muscle tone or spasticity
      - Clonus
      - Myelopathic hand

- Recent (within 6 months) MRI/CT findings that is concordant with the patient's symptoms or physical examination findings including **EITHER** of the following:
  - MRI/CT demonstrates cervical spinal cord compression
  - MRI/CT identifies cervical spinal stenosis

## **CMM-602.5: Non-Indications**

### **Not Medically Necessary**

- Cervical total disc arthroplasty for degenerative disc disease as the sole indication is considered **not medically necessary**.

### **Experimental, Investigational, and/or Unproven (EIU)**

- Cervical total disc arthroplasty is considered **experimental, investigational, or unproven (EIU)** when **ANY** of the following are present:
  - ◆ Patient is under age 18 or over age 60
  - ◆ Any prior surgery at the operative level
  - ◆ The planned procedure includes the combined use of a prosthesis and spinal fusion
  - ◆ A prior fusion at an adjacent cervical level
  - ◆ The planned procedure will lead to cervical total disc arthroplasty at more than two (2) levels
  - ◆ The planned procedure involves 2 or more levels that are not contiguous
  - ◆ Decreased bone mineral density defined by a T-score less than (worse than) -1.5 on a previous dual energy X-ray absorptiometry (DEXA) scan.
  - ◆ Allergy or sensitivity to titanium, aluminum or vanadium
  - ◆ Chronic non-specific neck or arm pain of unknown etiology
  - ◆ Absence of radiculopathy or myelopathy
  - ◆ Active systemic infection
  - ◆ Revision of an infected cervical disc arthroplasty
  - ◆ Rheumatoid arthritis or other autoimmune disease
  - ◆ Paget's disease, osteomalacia or any other metabolic bone disease
  - ◆ Severe poorly controlled diabetes mellitus requiring insulin treatment
  - ◆ There is radiological evidence of **ANY** of the following:
    - Clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal of lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
    - Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g. ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
    - Spinal metastases
    - Severe spondylosis at the level to be treated characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50% of its normal height
    - Severe facet joint arthropathy
    - Ossification of the posterior longitudinal ligament (OPLL)

## CMM-602.6: Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

| CPT®                                                                                                                                                                                                                                                                                                 | Code Description/Definition                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>22856</b>                                                                                                                                                                                                                                                                                         | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical                                                        |
| <b>+22858</b>                                                                                                                                                                                                                                                                                        | Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), second level, cervical (List separately in addition to code for primary procedure) |
| <b>22861</b>                                                                                                                                                                                                                                                                                         | Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical                                                                                                                                                                  |
| <b>22864</b>                                                                                                                                                                                                                                                                                         | Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical                                                                                                                                                                                         |
| <b>+0095T</b>                                                                                                                                                                                                                                                                                        | Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)                                                                                                                    |
| <b>+0098T</b>                                                                                                                                                                                                                                                                                        | Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)                                                                                             |
| This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules. |                                                                                                                                                                                                                                                                                              |

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