



CLINICAL GUIDELINES

CMM-602: Cervical Total Disc Arthroplasty

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EviCore
By ~~EVERNORTH~~

EviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging 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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CMM-602.1: General Guidelines

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General Guidelines

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Application of Guideline

- The determination of medical necessity for the performance of cervical total disc arthroplasty is always made on a case-by-case basis.
- For additional timing and documentation requirements, see **CMM-600.1: Prior Authorization Requirements**.

Urgent/Emergent Indications/Conditions

- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. **Imaging findings noted in the applicable procedure section(s) 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 (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
- Urgent/emergent conditions for for cervical total disc arthroplasty include ANY of the following:
 - myelopathy or cord signal changes on MRI due to cord compression
 - central cord syndrome
 - progressive neurological deficit documented on two separate physical exams
 - neurocompressive pathology with ANY of the following:
 - motor weakness of grade 3/5 or less of specified muscle(s)
 - rapidly progressive symptoms of motor loss
 - bowel incontinence
 - bladder incontinence/retention
 - a condition otherwise meeting criteria listed in the applicable procedure section(s) with documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health,

functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty

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CMM-602: Cervical Total Disc Arthroplasty

CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty

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Initial primary cervical total disc arthroplasty is considered **medically necessary** when performed for EITHER of the following conditions when ALL of the associated criteria have been met:

Radiculopathy

- Age is at least 18 years
- Absence of osteoporosis or severe osteopenia (e.g., T-score >-1.5 [i.e., better than -1.5] on a previous dual energy x-ray absorptiometry [DEXA] scan for at-risk individuals
 - At-risk individuals include, but are not limited to, the following:
 - women age ≥ 65 years
 - men age > 70 years
 - individuals with medical conditions that could alter bone mineral density
 - individuals receiving (or expected to receive) glucocorticoid therapy for > 3 months
 - individuals aged 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma
- Cervical disc prosthesis is 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
- The planned implant(s) is/are for a single-level or contiguous two-level replacement(s)
- Documentation of nicotine-free status with EITHER of the following:
 - individual is a never-smoker
 - individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery validated by objective cotinine testing methods (serum, urinary, or saliva) verified as within the normal range for the testing method and lab at which the test was performed
- No previous surgeries at the operative level
- Symptoms include BOTH of the following:
 - significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)

- unremitting radicular pain to shoulder girdle or upper extremity resulting in disability
- Physical exam findings include 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)
 - unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical exam findings
- Less than clinically meaningful improvement with at least TWO of the following (unless contraindicated):
 - prescription strength analgesics, steroids, gabapentinoids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for six (6) weeks
 - provider-directed exercise program (prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician) for six (6) weeks
 - epidural steroid injection(s) or selective nerve root block(s) performed at the same level(s) as the requested surgery
- Absence of clinically significant cervical instability on plain x-rays with ANY of the following findings:
 - subluxation or translation >3.5mm on static lateral or dynamic flexion/extension views
 - sagittal plane angulation >11° between adjacent spinal segments on static or dynamic flexion/extension lateral views
 - kyphotic deformity/significant reversal of lordosis or spondylolisthesis
- MRI/CT shows neural structure compression at the requested level(s) that is concordant with the individual's symptoms and physical exam findings and that is caused by ANY of the following:
 - herniated disc(s) (retained disc material or a recurrent disc herniation)
 - synovial cyst or arachnoid cyst
 - central/lateral/foraminal stenosis
 - osteophytes
- 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)

Myelopathy

- Age is at least 18 years

- Absence of osteoporosis or severe osteopenia (e.g., T-score >-1.5 [i.e., better than -1.5] on a previous dual energy x-ray absorptiometry [DEXA] scan for at-risk individuals
 - At-risk individuals include, but are not limited to, the following:
 - women age ≥ 65 years
 - men age >70 years
 - individuals with medical conditions that could alter bone mineral density
 - individuals receiving (or expected to receive) glucocorticoid therapy for >3 months
 - individuals aged 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma
- Cervical disc prosthesis is 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
- The planned implant(s) is/are for a single-level or contiguous two-level replacement(s)
- No previous surgeries at the operative level
- Symptoms include 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
- Physical exam findings include ANY of the following:
 - grip and release test
 - ataxic gait
 - hyperreflexia
 - Hoffmann sign
 - Babinski sign
 - tandem walking test demonstrating ataxia
 - inverted brachial radial reflex
 - increased muscle tone or spasticity
 - clonus
 - myelopathic hand
- Absence of clinically significant cervical instability on plain x-rays with ANY of the following findings:
 - subluxation or translation $>3.5\text{mm}$ on static lateral or dynamic flexion/extension views

- sagittal plane angulation $>11^{\circ}$ between adjacent spinal segments on static or dynamic flexion/extension lateral views
- kyphotic deformity/significant reversal of lordosis or spondylolisthesis
- MRI/CT shows findings that are concordant with the individual's symptoms and physical exam findings and that are caused by EITHER of the following:
 - cervical spinal cord compression
 - cervical spinal stenosis

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CMM-602.3: Failed Cervical Total Disc Arthroplasty Implant

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For a revision of a failed cervical total disc arthroplasty to a cervical fusion, see the applicable cervical fusion guideline below:

- For Anterior Cervical Fusion, see **CMM-601.8: ACDF Following Failed Cervical Disc Arthroplasty Surgery**.
- For Posterior Cervical Fusion, see **CMM-604.7: Posterior Cervical Fusion (with or without Decompression) Following Failed Cervical Disc Arthroplasty Surgery**.

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

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

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Cervical total disc arthroplasty performed for adjacent segment disease secondary to cervical total disc arthroplasty is considered **medically necessary** when performed for EITHER of the following conditions when ALL of the associated criteria have been met:

Radiculopathy

- The prior cervical total disc arthroplasty at an adjacent level was performed at least six (6) months prior
- Age is at least 18 years
- Absence of osteoporosis or severe osteopenia (e.g., T-score >-1.5 [i.e., better than -1.5] on a previous dual energy x-ray absorptiometry [DEXA] scan for at-risk individuals
 - At-risk individuals include, but are not limited to, the following:
 - women age ≥ 65 years
 - men age > 70 years
 - individuals with medical conditions that could alter bone mineral density
 - individuals receiving (or expected to receive) glucocorticoid therapy for > 3 months
 - individuals aged 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma
- Cervical disc prosthesis is 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
- The planned implant is for a single-level adjacent segment replacement
- Documentation of nicotine-free status with EITHER of the following:
 - individual is a never-smoker
 - individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery validated by objective cotinine testing methods (serum, urinary, or saliva) verified as within the normal range for the testing method and lab at which the test was performed

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- No previous surgeries at the operative level
- Symptoms include BOTH of the following:
 - significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)
 - unremitting radicular pain to shoulder girdle or upper extremity resulting in disability
- Physical exam findings include 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)
 - unremitting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical exam findings
- Less than clinically meaningful improvement with at least TWO of the following (unless contraindicated):
 - prescription strength analgesics, steroids, gabapentinoids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for six (6) weeks
 - provider-directed exercise program (prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician) for six (6) weeks
 - epidural steroid injection(s) or selective nerve root block(s) performed at the same level(s) as the requested surgery
- Imaging studies of the cervical spine including flexion/extension lateral views demonstrate successful cervical total disc arthroplasty at the adjacent level.
- Absence of clinically significant cervical instability on plain x-rays with ANY of the following findings:
 - subluxation or translation >3.5mm on static lateral or dynamic flexion/extension views
 - sagittal plane angulation >11° between adjacent spinal segments on static or dynamic flexion/extension lateral views
 - kyphotic deformity/significant reversal of lordosis or spondylolisthesis
- MRI/CT shows neural structure compression at the requested level(s) that is concordant with the individual's symptoms and physical exam findings and that is caused by ANY of the following:
 - herniated disc(s) (retained disc material or a recurrent disc herniation)
 - synovial cyst or arachnoid cyst
 - central/lateral/foraminal stenosis
 - osteophytes

- 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)

Myelopathy

- Age is at least 18 years
- Absence of osteoporosis or severe osteopenia (e.g., T-score >-1.5 [i.e., better than -1.5] on a previous dual energy x-ray absorptiometry [DEXA] scan for at-risk individuals
 - At-risk individuals include, but are not limited to, the following:
 - women age ≥ 65 years
 - men age >70 years
 - individuals with medical conditions that could alter bone mineral density
 - individuals receiving (or expected to receive) glucocorticoid therapy for >3 months
 - individuals aged 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma
- Cervical disc prosthesis is 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
- The planned implant is for a single-level adjacent segment replacement
- No previous surgeries at the operative level
- Symptoms include 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
- Physical exam findings include ANY of the following:
 - grip and release test
 - ataxic gait
 - hyperreflexia
 - Hoffmann sign
 - Babinski sign
 - tandem walking test demonstrating ataxia
 - inverted brachial radial reflex
 - increased muscle tone or spasticity
 - clonus

- myelopathic hand
- Absence of clinically significant cervical instability on plain x-rays with ANY of the following findings:
 - subluxation or translation >3.5mm on static lateral or dynamic flexion/extension views
 - sagittal plane angulation >11° between adjacent spinal segments on static or dynamic flexion/extension lateral views
 - kyphotic deformity/significant reversal of lordosis or spondylolisthesis
- MRI/CT shows findings that are concordant with the individual's symptoms and physical exam findings and that are caused by EITHER of the following:
 - cervical spinal cord compression
 - cervical spinal stenosis

CMM-602.5: Non-Indications

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Non-Indications

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Not Medically Necessary

- Cervical total disc arthroplasty performed for degenerative disc disease as the sole indication is considered **not medically necessary**.
- Cervical total disc arthroplasty following a failed cervical total disc arthroplasty at the same level is considered **not medically necessary**.
- Cervical total disc arthroplasty performed without meeting the criteria in the **General Guidelines** (when applicable for urgent/emergent conditions) and the criteria in the applicable procedure-specific section (**initial disc arthroplasty** or **adjacent segment disease**) is considered **not medically necessary**.
- Cervical total disc arthroplasty is considered **not medically necessary** when ANY of the following contraindications are present:
 - performed for the **revision** of a failed cervical artificial total disc arthroplasty
 - allergy or sensitivity to titanium, aluminum, or vanadium
 - 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
 - imaging evidence of ANY of the following:
 - 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 >50% of its normal height
 - severe facet joint arthropathy
 - ossification of the posterior longitudinal ligament (OPLL)

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Codes (CMM-602)

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The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	Code Description/Definition
22856	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
+22858	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)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
+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)

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CMM-602: Cervical Total Disc Arthroplasty

Evidence Discussion (CMM-602)

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Cervical Total Disc Arthroplasty

Risks of cervical disc arthroplasty include, but are not limited to, the following: infection; dysphagia; dysphonia; bleeding; recurrent laryngeal nerve injury; esophageal or tracheal injury; dural tear; hematoma; nerve root injury; spinal cord injury; paralysis; and, death.^{87,104} Complications related to the implant (e.g., migration, subsidence) are also possible. Indications for surgery include individuals with underlying cervical degenerative disc disease with the clinical presentation of cervical radiculopathy and/or myelopathy.^{87,99} Given the possibility of significant surgical complications, proper surgical candidacy selection is crucial to minimize the risk benefit ratio. Supportive subjective symptoms and physical exam findings should be present and concordant with imaging findings as abnormal advanced imaging findings are not uncommon in asymptomatic individuals.^{25,92,100}

Multiple studies have shown that the vast majority of individuals with cervical radiculopathy will improve with a 4-6 week course of non-operative treatment.^{33,90,142} At least six (6) weeks of non-operative management is also noted as a recommendation in the North American Spine Society (NASS) *Coverage Policy Recommendations: Cervical Artificial Disc Replacement*.⁹⁹ However, for individuals with myelopathy or other urgent/emergent conditions (e.g., progressive neurologic deficit), a trial of non-operative treatment would not be necessary.

Contraindications to cervical disc arthroplasty, as noted in the North American Spine Society (NASS) *Coverage Policy Recommendations: Cervical Artificial Disc Replacement*, include the following: infection; osteoporosis/osteopenia; instability; allergy or sensitivity to implant materials; severe spondylosis; severe facet joint arthropathy; rheumatoid arthritis; ankylosing spondylitis; deformity; ossification of the posterior longitudinal ligament; and malignancy.⁹⁹

Jackson et al. (2020) noted higher rates of postoperative complications and worse functional outcomes in individuals with psychological disorders undergoing spinal surgery.⁶⁷ It was concluded that proper identification and treatment of these conditions prior to surgery may significantly improve many outcome measures in this population.

Evidence supports that the various methods of cotinine testing (serum, saliva, urinary) are sufficiently equivalent in accuracy to confirm nicotine abstinence. Serum testing cutoff values ranged from 3.0ng/mL to 20ng/mL. Salivary testing cutoff values ranged from 10ng/mL to 44ng/mL. Urinary testing cutoff is 10ng/mL.^{2,13,37,58}

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