

Cigna Medical Coverage Policies – Musculoskeletal Cervical Total Disc Arthroplasty

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Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

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CMM-602.1: General Guidelines

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 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 exams
 - ◆ **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
 - ◆ 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

CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty

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

Radiculopathy

- Individual is age 18 to 60 years old
- Individual 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
- The planned implant(s) is/are for a single-level or contiguous two-level replacement(s)
- The individual is a candidate for single-level or two-level anterior cervical decompression(s) and interbody fusion(s) per **CMM-601.4: Initial Primary Anterior Cervical Discectomy and Fusion (ACDF)**
- No previous surgeries at the operative level
- Subjective symptoms include **BOTH** of the following:
 - ◆ Significant level of pain on a daily basis defined clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)
 - ◆ Unremitting radicular pain to shoulder girdle and/or upper extremity resulting in disability
- Objective 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 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 of more than 3.5 mm on static lateral or dynamic flexion/extension views
 - ◆ Sagittal plane angulation of more than 11 degrees between adjacent segments on static or dynamic flexion/extension 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

- Individual is age 18 to 60 years old
- Individual 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
- The planned implant(s) is/are for a single-level or contiguous two-level replacement(s)
- The individual is a candidate for single-level or two-level anterior cervical decompression(s) and interbody fusion(s) per **CMM-601.4: Initial Primary Anterior Cervical Discectomy and Fusion (ACDF)**
- No previous surgeries at the operative level
- Subjective 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
- Objective 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 of more than 3.5 mm on static lateral or dynamic flexion/extension views
 - ◆ Sagittal plane angulation of more than 11 degrees between adjacent segments on static or dynamic flexion/extension 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-602.3: Failed Cervical Total Disc Arthroplasty Implant

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

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

Radiculopathy

- The prior cervical total disc arthroplasty procedure at an adjacent level was performed at least six (6) months prior
- Individual is age 18 to 60 years old
- Individual 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
- The planned implant is for a single-level adjacent segment replacement
- The individual is a candidate for single-level anterior cervical decompression and interbody fusion per **CMM-601.7: Adjacent Segment Disease**
- No previous surgeries at the operative level
- Subjective 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 and/or upper extremity resulting in disability
- Objective 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)
- ◆ Unrelenting 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 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 of more than 3.5 mm on static lateral or dynamic flexion/extension views
 - ◆ Sagittal plane angulation of more than 11 degrees between adjacent segments on static or dynamic flexion/extension 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

- Individual is age 18 to 60 years old
- Individual 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
- The planned implant is for a single-level adjacent segment replacement
- The individual is a candidate for single-level anterior cervical decompression and interbody fusion per **CMM-601.7: Adjacent Segment Disease**
- No previous surgeries at the operative level
- Subjective 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
- Objective 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 of more than 3.5 mm on static lateral or dynamic flexion/extension views
 - ◆ Sagittal plane angulation of more than 11 degrees between adjacent segments on static or dynamic flexion/extension 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

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 listed 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
 - ◆ 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
 - ◆ 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 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 of greater than 50% of its normal height
 - Severe facet joint arthropathy
 - Ossification of the posterior longitudinal ligament (OPLL)

Codes (CMM-602)

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 osteophyctomy 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 osteophyctomy 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)

Evidence Discussion (CMM-602)

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. 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 or myelopathy. 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.

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. 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*. 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.

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

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