Cigna Medical Coverage Policies – Musculoskeletal Cervical Total Disc Arthroplasty Guidelines

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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.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

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CMM-602: Cervical Total Disc Arthroplasty

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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 authorization requirements, see <u>CMM-600.1: Prior Authorization Requirements</u>.

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 <u>CMM-601.4: Initial Primary Anterior</u> <u>Cervical Discectomy and Fusion (ACDF)</u>
- > 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 6 weeks
 - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 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

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 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 <u>CMM-601.4: Initial Primary Anterior</u> <u>Cervical Discectomy and Fusion (ACDF)</u>
- > 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 <u>revision</u> of a failed cervical total disc arthroplasty <u>to a cervical fusion</u>, see the applicable cervical fusion guideline below:

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

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 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 <u>CMM-601.7: Adjacent Segment Disease</u>
- > 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)
- 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 6 weeks
 - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 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
- ► <u>Absence</u> 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 <u>CMM-601.7: Adjacent Segment Disease</u>
- > 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 <u>sole</u> <u>indication</u> 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 <u>General Guidelines</u> (when applicable for urgent/emergent conditions) and the criteria in the applicable procedure-specific section (<u>initial disc arthroplasty</u> or <u>adjacent segment disease</u>) 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 <u>revision</u> 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)

Procedure (CPT®) Codes (CMM-602)

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 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with 22856 end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord +22858 decompression and microdissection), second level, cervical (List separately in addition to code for primary procedure) Revision including replacement of total disc arthroplasty (artificial disc), anterior 22861 approach, single interspace; cervical Removal of total disc arthroplasty (artificial disc), anterior approach, single 22864 interspace; cervical Removal of total disc arthroplasty (artificial disc), anterior approach, each +0095T additional interspace, cervical (List separately in addition to code for primary procedure) Revision including replacement of total disc arthroplasty (artificial disc), anterior +0098T 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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