KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Cervical Fusion (Anterior or Posterior)

- **Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cervical Fusion (Anterior or Posterior)"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery (unless there is evidence of cord compression, infection, malignancy, or progressive neurologic deficit). For persons with recent nicotine use, documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to fusion in patients without progressive neurologic deficit or cord compression

In addition to the following clinical criteria, this procedure is subject to Elective Surgical Procedures Level of Care review

I. ANTERIOR CERVICAL FUSION FOR DEGENERATIVE DISEASE

Single or multilevel anterior cervical discectomy and fusion (ACDF) is considered medically necessary for treatment of symptomatic degenerative disease when **EITHER of the following** criteria are met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** (see below), resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management *** (see below)
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
    - Herniated nucleus pulposus
    - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
    - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
    - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:

1. Clinical diagnosis of myelopathy*(see below)
2. Complex imaging studies (i.e., CT, MRI, Xray, Myelogram) demonstrate structural cord compression associated with cord signal change/myelomalacia on MRI imaging
3. Physical examination findings and imaging studies correlate with each level being considered for the fusion

II. CERVICAL FUSION FOR INSTABILITY

Single or multilevel cervical fusion is considered medically necessary for **ANY of the following** indications when there is an associated spinal instability:

- Acute spinal fracture and/or dislocation
- Neural compression after spinal fracture
- Traumatic ligamentous disruption
- Epidural compression, fracture or vertebral destruction from spinal tumor or cyst
- Spinal decompression or debridement for infection (e.g., discitis, osteomyelitis, epidural abscess, TB)
- Spinal decompression for myelopathy associated with subluxation in rheumatoid arthritis
- Cervical spinal deformity associated with neurological symptoms of myelopathy* or radiculopathy** (e.g., sagittal plane angulation of more than 11 degrees between adjacent segments, subluxation of >3.5 mm)
- As an adjunct to cyst excision of synovial facet cysts in the cervical spine
- Atlantoaxial instability (e.g., atlas and axis fracture, nonunion)
- Treatment of cervical spine fracture/dislocation associated with acute cervical radiculopathy** or myelopathy*
- Multilevel spondylotic myelopathy with kyphosis, when symptoms of myelopathy are present and

- Imaging studies correlate with symptoms and demonstrates cord compression
- Cervical instability from any **ONE of the following**:
  - Klippel-Feil syndrome
  - Down's syndrome
  - Skeletal dysplasia or connective tissue disorder

III. CERVICAL FUSION FOR IATROGENIC INSTABILITY

Cervical fusion is considered medically necessary for anticipated intraoperative iatrogenic spinal instability of the level or levels involved resulting from **ANY of the following** surgical procedures:

- Removal of 50% or more of the facets bilaterally
- Removal of 75% or more of a single facet
- Following cervical corpectomy*, as part of a stabilization procedure

***Note:** Corpectomy is a procedure in which the at least 50% or more of the body of the vertebrae is removed.

IV. POSTERIOR CERVICAL FUSION: SPINAL STENOSIS

Posterior cervical fusion is considered medically necessary for the treatment of spinal stenosis with laminectomy when **EITHER of the following** criteria are met**:**

A. Radiculopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of unremitting cervical radiculopathy**(see below) resulting in disability and/or neurological deficit
   2. Refractory to at 3 months of standard conservative physician supervised medical management ***
   3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
      - Herniated nucleus pulposus
      - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
      - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
      - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
   4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of myelopathy*
   2. Radiographic evidence of **ANY of the following**:
      - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
      - Sagittal plane angulation of more than 11 degrees between adjacent segments
      - Structural cord compression associated with cord signal change/myelomalacia on MRI

3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

V. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY:

Cervical fusion is considered medically necessary for treatment of symptomatic adjacent or same segment stenosis following prior cervical surgery, when **EITHER of the following** criteria have been met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management ***
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
   - Herniated nucleus pulposus
   - Spondylosis/ foraminal stenosis due such as an osteophyte causing nerve root compression
   - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
   - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following:**

1. Clinical diagnosis of myelopathy*
2. Radiographic evidence of **ANY of the following**:
   - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
   - Sagittal plane angulation of more than 11 degrees between adjacent segments
   - Structural cord compression associated with cord signal change/myelomalacia on MRI
3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

VI. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY: PSEUDOARTHROSIS

Cervical fusion is considered medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) of the cervical spine at the same level(s) when it has been at least 12 months from the prior surgery and **ALL of the following criteria** are met:

- Mechanical neck pain that correlates to the level of the pseudoarthrosis
- Imaging studies (e.g., radiographs, CT) confirm evidence of a pseudoarthrosis (e.g., lack of bridging bone, dynamic motion on flexion-extension radiographs)

- Failure of three (3) consecutive months of physician-supervised conservative*** management which includes exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy **AND**

- Activity lifestyle modification

VII. CERVICAL FUSION NOT MEDICALLY NECESSARY

Cervical fusion is considered not medically necessary for the following indications:

- anterior or posterior cervical fusion for chronic axial neck pain
- posterior cervical fusion performed with laminectomy in the absence of kyphosis (e.g., degenerative spine) or subluxation/translation of more than 3.5 mm

Isolated cervical facet fusion, with or without instrumentation, including facet joint implants and/or bone graft substitutes used exclusively as a stand-alone stabilization device is considered experimental, investigational, or unproven.

***Cervical Myelopathy:** signs suggestive of *spinal cord* involvement:

- Upper limb weakness in more than a single nerve root distribution
- Lower limb weakness
- Loss of dexterity (e.g., clumsiness of hands)
- Bowel or bladder incontinence
- Frequent falls
- Hyperreflexia
- Hoffmann sign (overreaction to flick of the fingernail)
- Increased extremity muscle tone or spasticity
- Spastic Gait/ataxic Gait
- Positive Babinski

**** Radicular pain/suspected radiculopathy** defined as:

- Pain in a *nerve root* distribution (e.g., C6, C7)
- Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) *OR*
- EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

*****Physician-supervised conservative medical management** defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of **one or more of the following** medications:

- Non-steroidal anti-inflammatory drugs (oral or topical)
- Acetaminophen
- Epidural steroid injection of corticosteroids as appropriate

AND

- A trial of **All** of the following physical measures:

- Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
- Flexibility and muscle strengthening exercises
- Reasonable restriction of activities
- If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present

Procedure	Criteria
Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Neck pain occurs in many people and typically involves more than one component of the spine, such as the vertebrae, intervertebral discs, spinal nerves, other anatomic structures such as ligaments, muscles, and joints. Conditions that frequently result in neck pain include soft tissue injury, trauma, infection, herniated disc, degenerative spine conditions, neoplastic conditions, and deformities such as kyphosis. While the cause of neck pain is often multifactorial (e.g., originating from the vertebrae, discs, ligaments, tendons and muscles) the location of pain varies. Axial neck pain occurs along the spine, is of musculoskeletal or soft tissue origin, and is a non-radiating type of pain. The most common cause of axial neck pain is degenerative change to the cervical spine, which occurs as a natural consequence of aging. Radicular pain involves a nerve root, is due to nerve root compression, follows the nerve root distribution, and radiates to one or both upper extremities, and/or into the shoulder area. Radicular pain can include varying degrees of sensory, motor, and/or reflex changes related to nerve root(s) without evidence of myelopathy (North American Spine Society, [NASS], 2013). Myelopathy is a term that describes any neurological deficit related to the spinal cord and is often used to describe loss of function in the upper or lower extremities (NASS, 2013). Depending on the cause of neck pain associated symptoms may include numbness, tingling, weakness, and other types of neurologic dysfunction in the presence of spinal cord compression. Conservative measures for treatment of neck pain include analgesics, muscle relaxants, local injections, physical therapy, cervical bracing and home exercise. Conservative treatment is often effective for alleviating symptoms and typically lasts six to eight weeks. However, conservative therapy is not recommended in the presence of progressive neurological deficits, in the presence of unstable spinal fractures or dislocations, or for progressive spinal deformity. In the absence of progressive neurologic compromise, or when conservative management has been attempted and fails to relieve pain and disability, surgery may be required for conditions with underlying pathology confirmed by physical examination and radiological imaging. When spinal cord compression is present surgical methods to relieve the pressure on the nerves is often necessary and is referred to as decompression surgery.

Decompression typically includes surgical procedures such as discectomy (removal of the disc), laminectomy (removal of the lamina), corpectomy (removal of the vertebral body), or osteotomy (removal of a piece of bone). When performed, these procedures may result in spinal instability. As such, decompression is often performed as part of cervical fusion in order to regain stability of the spine. For example, anterior cervical fusion is usually performed with decompression. Posterior cervical fusion is typically performed with stabilization (using rods, screws) although may be performed with decompression in some instances (NASS, 2014). Instability of the cervical spine can also result from trauma and/or disease, or a combination of all (White, Panjabi, 1980), which may or may not require a decompression. Instability of the cervical spine has been defined by White, Panjabi (1980) and is well-accepted in the medical literature as sagittal plane translation of >3.5 mm, and/or rotation between motion segments of 11˚, in addition to other notable factors such as destruction of elements or inability to function, a positive stretch test, spinal cord or nerve root damage, and abnormal disc narrowing (White, Panjabi, 1980). In the absence of instability, evidence in the published peer-reviewed scientific literature does not provide strong support that when used for this indication cervical fusion is clinically effective for reducing pain and disability. 2011; Persson, et al., 1997). Psychological assessment and treatment as part of a multidisciplinary approach to conservative pain management is recommended. Risk factors, such as drug or alcohol abuse and depression may act as a barrier to recovery following spinal fusion (Washington State Department of Labor and Industries, 2002; Hanley, David, 1999; Tang, et al., 2001). Authors have recommended psychological screening, and treatment if applicable, of patients with neck and/or back pain prior to surgery for identification of risk factors that may be associated with chronic disability. Cervical spinal fusion is in many situations an elective surgery, therefore it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. Modifiable risk factors and the influence on outcomes of spine surgery has been studied, modification of such risk factors can assist with improved patient selection for spine surgery and better postoperative management (Shahrestani, et al., 2021). Along with alcohol and opioid use, tobacco/nicotine increases the risk of perioperative complications, cardiopulmonary complications, pseudoarthrosis and infection (Shahrestani, et al., 2021) furthermore it is well-established that smoking is a preventable cause of morbidity and mortality. Tobacco use in particular is considered a risk factor for poor healing and has been associated with nonunion. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis (Brown, et al., 1986). The American Academy of Orthopedic Surgeons (AAOS) supports avoidance and cessation of all tobacco products and cigarette smoking due to the harmful impact on musculoskeletal health, as well as overall health (AAOS, 2016).

Medical Technology Assessment Committee (MTAC)

Percutaneous posterior cervical fusion with the CAVUX Cervical Cage-I or DETRAX System

BACKGROUND

Date: 10/17/2017

Evidence Conclusion: The literature was limited for single-level cervical radiculopathy and studies comparing posterior cervical fusion using DTRAX with standard practice (anterior cervical discectomy and fusion, total disc replacement) were scarce. However, two studies were reviewed. These studies were prospective in design. The aims of these studies were to assess clinical and radiographic outcomes of DTRAX on patients with single level cervical radiculopathy. Patients were enrolled consecutively and underwent surgery using DTRAX. Follow-up occurred at one and two-year post-surgery. Clinical as well as imaging evaluations were also performed. Patients who failed conservative management were recruited and a total of 60 patients were enrolled. Patients' mean age was 53 years with a range of 40 to 75years. The most common level treated was C5-C6 followed by C6-C7. Clinical outcomes have improved at one and two-year after the surgery. First, neck and arm pain, assessed by VAS, have significantly decreased (P<0.0001 in one study; P-value not reported in the second study). Second, the neck disability index has significantly decreased (P<0.0001). Third, quality of life, measured by both mental and physical component, has improved (P<0.0001). Radiographic assessments were equivocal and not consistent. Segmental lordosis did not significantly change 2 years after the surgery; at 1-year post-surgery, this outcome was not reported. In addition, no change was reported for posterior disc height 1 year after surgery, but at 2 years post-surgery, a small decrease was reported (P=0.001). Anterior disc height has decreased 1-year post-surgery (P<0.01). Fusion rate was high. No major complications were reported; however, the most common procedure-related adverse events were postoperative pain, nausea, pain from the bone graft harvest site. Limitations included the non-randomized nature of the

study, consulting relationship between surgeons and study sponsor, the small sample size, and the short follow-up. For these reasons, the quality of evidence is deemed low. **Other studies and conclusion** (See Evidence Table 1): Bilateral cervical cage with a posterior approach can increase foraminal area and decompress nerve roots; but studies showing correlation between increased in foraminal area and clinical outcomes are warranted. (See Evidence Table 1)): Posterior bilateral cervical cage led to 6% (N=53) of adjacent segment degeneration 2 years after surgery; 12% of existing degeneration showed moderate progression and long-term adjacent segment degeneration incidence was unknown.
A retrospective study (See Evidence Table 2) of 10 patients with one-year follow-up, on whom cervical fusion using bilateral posterior cervical cages was performed reported favorable improvements in pain and function in patients with single-level cervical radiculopathy. See Evidence Table 1 & 2
Conclusion:

- Studies were scarce; two studies were reviewed; studies comparing posterior cervical fusion using DTRAX with standard practice (anterior cervical discectomy and fusion, total disc replacement) were not identified
- The quality of evidence is low
- Clinical outcomes have improved at one and two-year post-surgery
- Radiographic findings were not consistent and ambiguous at one and two-year after the procedure
- Adverse events were minimal
- The available evidence is insufficient to recommend for or against the effectiveness and safety of posterior cervical fusion with DTRAX in patients with single level cervical radiculopathy who failed conservative management.

Articles: The literature revealed 7 articles, however 4 were relevant, but 2 studies with the largest sample size were extensively reviewed.

The use of Percutaneous posterior cervical fusion with the CAVUX Cervical Cage-l or DETRAX System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Cervical Fusion: Anterior

CPT® or HCPCS Codes	Description
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

Cervical Fusion: Posterior

CPT® or HCPCS Codes	Description

22590	**Arthrodesis, posterior technique, craniocervical (occiput-C2)**
22595	**Arthrodesis, posterior technique, atlas-axis (C1-C2)**
22600	**Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment**
22614	**Arthrodesis, posterior or posterolateral technique, single interspace; each additional vertebral segment (List separately in addition to code for primary procedure)**
22800	**Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments**
22802	**Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments**

Considered Experimental, Investigational or Unproven when used to report isolated cervical facet fusion, including facet joint implants and/or bone graft substitutes used exclusively as stand-alone stabilization devices for treatment of facet joint pain:

CPT® or HCPCS Codes	Description
22899	**Unlisted procedure, spine**
0219T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical**
0222T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure**

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/05/2022	07/05/2022[MPC], 07/11/2023[MPC]	12/04/2023

[MPC] Medical Policy Committee

Revision History	Description
07/05/2022	MPC approved to adopt criteria for Cervical Fusion for non-Medicare members. Requires 60-day notice, effective date 12/01/2022.
10/04/2022	MPC approved to include quantifying number of 3 visits for conservative treatment. 60-day notice required.
10/28/2022	Merged criteria set with Percutaneous Cervical Fusion.
12/15/2022	Standardized approach to clinical myelopathy to remove conservative treatment as a prerequisite for surgery.
12/04/2023	Effective 12/05/2023 Lumbar Spinal Fusion will require Level of Care review when procedure is performed as an elective procedure

Back to Top