



## Kaiser Foundation Health Plan of Washington

### Percutaneous Posterior Cervical Fusion

- CAVUX® Cervical Cage
- DTRAX® Spinal System
- Corus™ Spinal System

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### Criteria For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <b>Percutaneous Posterior Cervical Fusion</b> , for medical necessity determinations. Use the Non-Medicare criteria below.

### For Non-Medicare Members

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.

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

Cervical radiculopathy is the most common cause of neck pain with annual incidence rates per 100,000 people of 107 in men and 63 in women (Radhakrishnan, Litchy, O'Fallon, & Kurland, 1994). People aged 50 to 54 years are the most affected and C7 is the most frequently involved (Radhakrishnan et al., 1994). Clinical manifestations include neck, shoulder, scapula, and hand pain, as well as neurologic symptoms. The diagnosis is based on clinical findings; however, neuroimaging and electrodiagnostic tests can be performed in the presence of important neurologic deficits or when symptoms persist after four to six weeks of conservative treatment. Initial treatment consists of conservative therapy including analgesics, corticosteroids, physical therapy, cervical traction (Carette & Fehlings, 2005). If symptoms persist, surgery is required. The most common surgery is anterior cervical discectomy and fusion (ACDF); other types of surgeries encompass posterior cervical discectomy and fusion and disc replacement. Despite the effectiveness of these options, potential complications include root nerve injury, destruction of carotid

artery, transient dysphagia, recurrent laryngeal nerve injury, esophageal perforation, vertebral artery injury, and superficial wound infection (Carette & Fehlings, 2005; Fountas et al., 2007; Hacker, Cauthen, Gilbert, & Griffith, 2000; Inamasu & Guiot, 2005). To overcome these complications, posterior cervical fusion with DTRAX has been developed.

The DTRAX implant is a titanium screw and expandable washer that is inserted between two vertebrae in the cervical facets through minimal incision. This opens the neural foramina and the facet is stabilized with instrumented distraction. Similarly, to DTRAX implant, CAVUX cervical cage is an implant that is inserted between two cervical facets to indirectly decompress the nerve and allow fusion at the treated level. The DTRAX system is composed of instrument for access, decortication, and implant and bone graft delivery. There are 2 titanium components including a screw with shaft and a washer that has two base plates. These components are held by a delivery tool with the screw engaging the washer. The screw is then inserted and advanced in the washer while the base plates separate; this allows the teeth to attach to the subchondral bone. From (McCormack et al., 2013; Siemionow, Janusz, & Glowka, 2016). Instrumentation consists of access chisel, decortication trephine, fork mallet, guide tube, decortication rasp, decortication burr, and bone graft tamp (McCormack & Dhawan, 2016). The procedure begins with incision generally below the target level; and under fluoroscopy, the access chisel is placed into the facet joints. Then the decortication trephine is utilized to remove fibrous tissue. This step is followed by the insertion of the guide tube into the facet joint. The access chisel is then removed and with the rasps and burrs, fibrous tissues are removed from the articular surfaces. Finally, the implant and bone graft material are inserted into the facet joints (McCormack & Dhawan, 2016; Siemionow, Janusz, Phillips, et al., 2016).

The technology is intended to be used in patients with cervical radiculopathy. The technique is to relieve pressure on the spinal nerves by opening the joints, and then insert the implants and graft material to heal the joints (<http://providencemt.com/patients/>). According to the manufacturer, the technology is believed to provide numerous benefits; these include immediate improvement in symptoms, no removal of tissue, possibility of performing surgery in the future, quicker return to function, eliminates dysphagia that may occur with other types of neck surgery, and it is less invasive than most cervical procedures (<http://providencemt.com/patients/>). It is manufactured by Providence Medical Technology; Lafayette, CA.

Posterior cervical fusion with DTRAX facet system for cervical radiculopathy is FDA approved approach and is being reviewed for the first time in MTAC.

## **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 75 years. 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-I or DETRAX System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

### Considered Not Medically Necessary

CPT® or HCPC Codes	Description
	No specific codes for percutaneous posterior cervical fusion

**\*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](#).

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02/06/2018	02/06/2018 <sup>MPC</sup> , 02/05/2019 <sup>MPC</sup> , 02/04/2020 <sup>MPC</sup> , 02/02/2021 <sup>MPC</sup> , 02/01/2022 <sup>MPC</sup>	

<sup>MPC</sup> Medical Policy Committee

Revision History	Description