Dynamic Spinal Stabilization and Interspinous Process Decompression Devices

State(s):
☑ Idaho ☑ Montana ☑ Oregon ☑ Washington ☐ Other:

LOB(s):
☑ Commercial ☑ Medicare ☑ Medicaid

Enterprise Policy

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member’s policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member’s policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member’s policy, the Member’s policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

The traditional approach to surgical management of degenerative spinal disease has been open decompression and/or fusion techniques which attempt to stabilize the spinal column. Advances in technology have resulted in a newer class of spinal device implants which are designed to maintain or restoring intervertebral motion by restricting or dampening the motion of the spinal column without totally restricting motion as would happen in a traditional spinal fusion procedure. Dynesys is a dynamic stabilization device which is a pedicle-screw based system with a polyethylene cord and a polyurethane spacer connecting the screws instead of conventional metal rods. Other devices, such as the Wallis System, use spacers placed between the lumbar spinous processes to provider a flexion-distraction force (sometimes called IPD devices).

Examples of posterior dynamic stabilization or interspinous process decompression devices include:

- The Dynesys System (Zimmer Spine) which was given substantial equivalence FDA approval on 3/5/2004, consists of four pedicle screws, two cords and two spacers in a symmetric, bilateral arrangement. It is designed for use in skeletally mature patients to provide immobilization and stabilization of the spine.

- The Wallis Stabilization System is not FDA approved.

- The DIAM Spinal Stabilization System (Medtronic Sofamor Danek) is an interspinous spacer made of silicone which is secured around the spinous process using two laces. The rubbery nature of the device acts as a bumped between the bones.

- Isobar (Scient'X')
- AccuFlex (Globus Medical, Inc)
- Coflex (Paradigm Spine) - a U-shaped metallic device which is inserted between the spinous processes while axially compressed. This allows the device to expand on flexion.
- Superion (VertiFlex, Inc.) – a minimally invasive interspinous spacer device which was FDA cleared on 6/3/15
- ExtenSure Bone Allograft Interspinous Spacer (NuVasive, Inc.)
- Devices in use in Europe but not currently approved by the FDA:
  - The Graf System - a pedicle screw-based device with polyester bands instead of rods
  - Stabilimax NZ (Rachiotek LLC, formerly Applied Spine Technologies) is a pedicle based posterior dynamic stabilization device intended to support a degenerated spine while maintaining kinetic motion.

**Criteria**

PacificSource Health Plans considers all dynamic stabilization and interspinous process decompression devices to be experimental, investigational or unproven.

**Coding Information**

22867 Insertion of interlaminar/inter spinous process stabilization/distraction devices, without fusion, including image guidance when performed, with open decompression

22868 Insertion of interlaminar/inter spinous process stabilization/distraction devices, without fusion, including image guidance when performed, lumbar

22869 Insertion of interlaminar/inter spinous process stabilization/distraction devices, without open decompression or fusion, including image guidance when performed, lumbar

22870 Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar

22899 Unlisted procedure, spine

C1821 Interspinous process distraction device (implantable)

L8699 prosthetic implant NOS

**Related Policies**

Case Manager Determinations on Non-Coverage
References


Hayes Technology Assessment Minimally Invasive Lumbar Decompression (Mild: Vertos Medical Inc.) Device Kit for Treatment of Lumbar spinal Stenosis Winifred S. Hayes, Inc., March 26, 2019


Oregon Health Plan (OHP) Prioritized List of Health Services, Guideline note 173


Siddiqui, M; Smith, F; and Wardlow, D. One-Year Results of X STOP Interspinous Implant for the Treatment of Lumbar Spinal Stenosis. Spine. 2007: 32(12), pp.1345-1348


Appendix

Policy Number: [Policy Number]

Effective: 1/20/2020  Next review: 1/20/2021

Policy type: Enterprise

Depts: Health Services

Applicable regulation(s): N/A

External entities affected: N/A