

MEDICAL POLICY		Back: Stabilization Devices and Interspinous Spacers	
Effective Date: 5/1/2020		Section: SUR	Policy No: 126
 <div style="text-align: right;">5/1/2020</div>		Technology Assessment Committee approved Date: 5/08; 5/2010; 9/2010; 12/11; 5/13; 12/13; 8/14; 9/14; 9/15; 5/16	
		Medical Policy Committee Approved Date: 12/16; 3/18; 1/19; 4/19; 4/2020	
Medical Officer	Date		

See Policy CPT/HPCPS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: The iFuse Implant System™ for sacroiliac joint fusion is addressed in the Providence Health Plan Back: Sacroiliac Joint Surgery medical policy.

Dynamic Stabilization Devices

I. The dynamic stabilization devices listed below (22867, 22868, 22869, 22870, C1821) are considered **investigational and are not covered**, including, but not limited to, the following (A. – AA.):

- A. Aspen Spinous Fixation System
- B. AccuFlex™ System
- C. BioFlex System
- D. Bronsard’s Ligament
- E. CD Horizon Agile™ Dynamic Stabilization Devices

- F. CD Horizon Spire Fixation System
- G. Cosmic™ Posterior Dynamic System
- H. DSS Stabilization
- I. DSS (Dynamic Soft Stabilization) System
- J. DTO (Dynesys-to-Optima)
- K. Dynabolt™ Dynamic Stabilization System
- L. Dynesys®
- M. Expedium™
- N. FASS (Fulcrum Assisted Soft Stabilization)
- O. Graf Ligament
- P. IsoBar® Spinal System
- Q. Leeds-Keio Ligamentoplasty
- R. LemiFlex Spinal Stabilization
- S. Magnetically Controlled Growing Rods (MAGEC)
- T. NFix™ II Dynamic Stabilization
- U. NFlex™ Controlled Motion System
- V. REVERE Stabilization System
- W. Satellite™ Spinal System
- X. Stabilimax NZ Dynamic Spine Stabilization System
- Y. TRANSITION® Stabilization System
- Z. Viper™
- AA. Zodiac DynaMo System

Interspinous Spacers

- II. The interspinous spacers listed below (22899, 64999, L8699) are considered **investigational and are not covered**, including, but not limited to, the following (A. – K.):
 - A. Coflex® Interlaminar Stabilization Device
 - B. Superior® Interspinous Spacer System
 - C. Aperius™ – PercLID™ System
 - D. DIAM™ Spinal Stabilization System
 - E. Falena® Interspinous Decompression Device
 - F. FLEXUS™
 - G. Helifix® Interspinous Spacer System
 - H. In-Space
 - I. NL-Prow™ Interspinous Spacer
 - J. Stenofix
 - K. Wallis System®

Link to [Policy Summary](#)

BILLING GUIDELINES

The following codes do not apply to minimally invasive dynamic stabilization procedures of the spine and should not be used to bill for these services: 22533, 22534, 22558, 22585, 22586, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22853, 22854, 22859.

CPT/HCPCS CODES

All Lines of Business	
Not Covered	
Dynamic Stabilization Devices	
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
0195T	TERMED 12/31/18 Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace
0196T	TERMED 12/31/18 Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; each additional interspace (list separately in addition to code for primary service)
C1821	Interspinous process distraction device (implantable)
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
Interspinous Spacers	
22899	Unlisted procedure, spine
64999	Unlisted procedure, nervous system
L8699	Prosthetic implant, not otherwise specified

DESCRIPTION

Lumbar Spinal Stenosis (LSS)

LSS is predominantly caused by degeneration in the intervertebral discs, ligaments and bone structures of the spine, and is characterized by a narrowing of the spinal canal, lateral spinal recesses and compressed neural elements in the lower back, resulting in pain and disability. Symptoms are typically provoked by upright exercise, including walking, and relieved with forward flexion at the waist, sitting or reclining. While conservative treatments improve symptoms in one-third of patients (e.g. physical therapy, nonsteroidal anti-inflammatory drugs), surgical options for those refractory to these therapies range from minimally invasive decompression techniques to traditional surgical laminectomy with or without spinal fusion, laminotomy, or hemilaminotomy.¹

Dynamic Stabilization Devices

Dynamic stabilization devices provide an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to lumbar spinal stenosis. In contrast to rigid devices that fully stabilize affected spinal segments, dynamic stabilization devices use flexible materials – anchored to the vertebrae by either synthetic cords or pedicle screws – which purport to preserve some measure of mobility of the spinal segment while also stabilizing the joint.

Aspen Spinous Fixation System

The Aspen Spinous Fixation System is designed for posterior fixation to promote fusion from T1 to S1 vertebrae. The System consists of a “spiked plate” implant that fixates the spine in single- or multi-level constructs, supporting the formation of fusion and decompression by fixation, load sharing and interspinous process spacing. The device is used as an adjunct to interbody fusion and/or posterior fusion with decompression.

DSS Stabilization System

The DSS Stabilization System is a single-level, pedicle-based fixation system from the T4 to S1 vertebrae, consisting of polyaxial, cannulated pedicle screws, slotted couplers, and rigid couplers. The System purports to immobilize and stabilize spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.²

Dynesys®

Dynesys is a semi-rigid pedicle-based dynamic stabilization system consisting of three components: titanium screws anchor the system to the spine; polycarbonate urethane spacers limit spinal extension; and polymer cords that act as a tension band to limit spinal flexion. The device theoretically preserves motion of the treated segment while also alleviating pain by restricting loading on adjacent discs and facet joints.³

Isobar Spinal System

Isobar is a semi-rigid, pedicle-based system intended to immobilize and stabilize spinal segments as an adjunct to fusion, for the treatment of spondylolisthesis.

Magnetically Controlled Growing Rods (MAGEC)

The MAGEC System is a distraction-based system comprising an adjustable, titanium rod and a handheld external remote controller (ERC). The rod is surgically implanted and secured using spinal fixation components. The rod contains a small magnet that the ERC, when placed over the patient's spine, can noninvasively rotate, allowing for lengthening or shortening of the implanted titanium rod. The rod is thought to distract the spine and provide adequate bracing during growth to minimize the progression of scoliosis. The rod is removed from the patient once the physician determines the implant has achieved its desired effect.⁴

Interspinous Spacers

Interspinous spacers are small devices, implanted between vertebral spinous processes at one or two vertebral levels, that stabilize or distract adjacent lamina and/or spinous processes. The spacers are thought to alleviate pain in patients with spinal stenosis and neurogenic claudication by expanding the neural foramen, decompressing the nerves and limiting painful lumbar extension, while maintaining the flexion of the spinal interspace.⁵

Coflex® Interlaminar Stabilization Device

The Coflex Interlaminar Stabilization Device is a U-shaped titanium alloy implant that is inserted after decompression of stenosis. The device is positioned horizontally and is appropriate for 1 level or 2 contiguous levels from lumbar (L) vertebrae L1 to L5. Theoretically, the device alleviates pain by limiting lumbar spinal extension, unloading facet joints and stabilizing the motion segment at the treated vertebral level(s).¹

Superion Interspinous Spacer System (ISS)

The Superior ISS is an expandable implant, delivered through a proprietary, minimally invasive approach that may be performed on an outpatient basis under local anesthesia. The device may be implanted at 1 or 2 adjacent levels from L1 to L5 and acts as an extension blocker, preventing repetitive compression of nerves during back extension.^{5,6}

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of instrumentation/stabilization devices and interspinous spacers. Below is a summary of the available evidence identified through February 2020, for devices with Food and Drug Administration approval.

Dynamic Stabilization Devices

Aspen Spinous Fixation System

Evidence for the Aspen Spinous Fixation System is limited to two cadaveric studies describing the device's biomechanical effects.^{7,8} No studies published within the past five years were identified.

DSS Stabilization System

In 2018, Bieri and colleagues conducted a retrospective cohort study of clinical outcomes for dynamic posterior stabilization.⁹ Patients (mean age: 67 years) were treated with either the DSS Stabilization System (n=202) or underwent posterior lumbar intervertebral fusion (PLIF) (n=269). Median follow-up was 3.3 years. The primary outcome of interest was the change in the patient-reported Core Outcome Measures Index score (COMI; a 0-10 scale). Investigators reported no difference between groups in improved COMI score, back pain relief, leg pain relief, blood loss and complications. Compared to the PLIF group, patients treated with DSS experienced longer hospital stays ($p = 0.03$) but fewer repeat surgeries ($p = 0.01$), and shorter surgery times ($p < 0.001$). Investigators concluded that while DSS may be a viable alternative to PLIF at mid-term follow-up, multicenter studies were needed to confirm reported findings. Limitations include the study's retrospective design, heterogeneity of patient characteristics between groups at baseline, potential underreporting of complication rates, and the lead author's financial conflict of interest with the manufacturer of the DSS Stabilization System.

Dynesys®

In 2016, Lee and colleagues conducted a meta-analysis evaluated the efficacy of the Dynesys system versus posterior lumbar interbody fusion (PLIF) for the treatment of degenerative lumbar spinal disease.³ In total, 7 studies (n=506) (1 RCT, 2 prospective cohort studies and 4 retrospective cohort studies), all of which compared clinical and radiological outcomes, were included for review. Average follow-up was 2 years. Pooled analysis found no significant difference in disability, back pain, leg pain, complication rates and length of hospital stay between the two groups. Limitations include differences in treatment parameters across studies, and the low-middle income treatment context (i.e. China) for 4 out of 7 studies. No eligible studies were conducted in the United States.

Isobar Spinal System

- In 2016, two retrospective studies in China (n=37) evaluated the efficacy of the Isobar Spinal System.^{10,11} Follow-up ranged from 12 to 53 months. Both studies reported significant pain relief compared to baseline. Investigators of both studies called for larger, prospective studies with longer follow-up to better establish Isobar's safety and efficacy.
- In 2014, Fu and colleagues prospectively evaluated the functional and radiological outcomes of Isobar in conjunction with spinal fusion.¹² In total, 36 patients underwent posterior Isobar dynamic stabilization for single-level degenerative lumbar disc disease with instability and mild adjacent level degeneration. At 24-months follow-up, patients experienced significant improvement compared to baseline in both mean visual analog scale scores, and Oswestry Disability Index scores. While intervertebral angle (IVA) at the adjacent level increased, disc height at the index and adjacent levels

and intervertebral angle (IVA) at the index level decreased (i.e. degenerated) at each follow-up, No adverse events or reoperations were reported. Limitations include the study's small sample size, inadequate follow-up and lack of comparator groups. Investigators concluded that additional studies with long-term follow-up were necessary to establish Isobar's safety and efficacy.

Magnetically Controlled Growing Rods (MAGEC)

In 2018, Hayes conducted an evidence review evaluating MAGEC for the treatment of early-onset scoliosis in patients younger than 10 years old.⁴ Hayes systematically searched the literature, identified eligible studies, assessed quality and extracted data. In total, 11 studies (4 retrospective cohort studies, 4 pretest/posttest studies, 2 repeated-measures time series, 1 case series) were included for review. Sample sizes ranged from 20 to 44, and follow-up ranged from 24 to 47 months. Each study was assessed to be of either "poor" or "very poor" quality. Results did not significantly differ between MAGEC and traditional growing rod (TGR) groups among comparative studies evaluating curve correction; kyphosis; spine and thoracic height; and quality of life. Across 11 studies, rate of unplanned surgery did not significantly differ between groups, although one study reported twice as many unplanned surgeries among TGR patients (no reported *p*-value). Hayes assessed the evidence quality as "very-low" and insufficient to adequately assess the health and safety on MAGEC ("D2 rating"). Limitations included heterogeneous study populations, retrospective study designs, small sample sizes, a lack of patient-oriented outcomes, and a lack of comparator groups. Hayes concluded that while MAGEC may improve curve correction and spinal height, "substantial uncertainty remains regarding the comparative safety of MAGEC compared with TGRs and the impact that MAGEC has on outcomes related to patient and family quality of life and burden of care."^{4,13}

Interspinous Spacers

Coflex® Interlaminar Stabilization Device

In 2018, Hayes conducted an evidence review evaluating the safety and efficacy of Coflex Interlaminar Stabilization Device for the treatment of lumbar spinal stenosis (LSS).¹ Hayes systematically searched the literature through August 2018, identified eligible studies, assessed quality and extracted data. In total 12 publications were included for review, each of which compared treatments with more than 50 patients for at least 12-months. Sample sizes ranged from 62 to 254 patients. Outcomes of interest included disability, pain, function, quality of life, radiographic outcomes of range of motion and stability; secondary surgical interventions; procedural outcomes and safety.

Across 7 studies, Coflex was generally associated with clinically important improvements in patient disability, with few significant between-group differences in 5 studies comparing Coflex with fusion at ≤60 month follow-up. Among 2 studies comparing Coflex with decompression alone at 2-year follow-up, no significant differences were reported. Coflex was associated with significant improvements in pain (assessed by visual analog score) from baseline at 60-months. Studies reported no significant differences between Coflex and fusion or decompression alone. Studies reported improvements in functional outcomes, quality of life, narcotic use, secondary surgical interventions and safety among both Coflex and comparator groups. Compared to fusion and

decompression, Coflex was favored for both radiographic outcomes of range of motion and stability, and procedural outcomes.

Hayes judged the overall evidence base evaluating Coflex to be of low-quality and assigned a “C” rating (potential but unproven benefit). Results indicated that Coflex was associated with improvements in pain, function and disability comparable to fusion or decompression alone, yet results’ validity was limited by heterogeneous patient populations, small sample sizes, a lack of randomization, inadequate follow-up, inadequate blinding, and the lack of patient selection criteria. Hayes concluded that there was insufficient evidence to draw conclusions regarding the use of the Coflex device for the treatment of LSS.

- In 2018, Mo and colleagues conducted a network meta-analysis and systematic review evaluating the efficacy and safety of posterior lumbar interbody fusion compared to interspinous process devices (IPD), including Coflex.¹⁴ Investigators systematically searched appropriate databases, identified relevant studies, assessed quality, extracted data and pooled results. In total, 27 studies (n=2,241) were included for review. Investigators found no significant differences between groups in Oswestry Disability Index, visual analogue scale, Japanese Orthopedic Association Scores, and posterior disc height. Patients receiving IPDs experienced significantly more range of motion and less adjacent segment degeneration, but no improvements in pain relief, quality of life, disc space height and lumbar function. Limitations include the low-middle income treatment context of 24 of the included 27 studies (i.e. China), which may limit results’ generalizability.
- In 2017, Zhao and colleagues conducted a systematic review and meta-analysis evaluating the efficacy of Coflex and other interspinous process devices (IPD) alone versus bony decompression surgery for the treatment of lumbar spinal stenosis (LSS).¹⁵ Investigators systematically searched appropriate databases, identified relevant studies, assessed quality, extracted data and pooled results. In total, 7 publications deriving from 4 high-quality RCTs were included for review (n= 400). Follow-up was ≤24 months. Investigators reported no significant difference between the two groups in length of hospital stay, visual analog score (VAS) leg pain scores, and complication rates, but higher VAS low back pain scores and reoperation rates for IPD patients. Two studies demonstrated inferior quality of life improvements relative to bony decompression. Study limitations included the variety of IPD devices used across trials, inadequate follow-up among individual RCTs and the inability of investigators to conduct sub-group analyses given the lack of relevant data. Investigators concluded that while both IPD and bony decompression were “acceptable treatment strategies” for LSS, results did not indicate IPD’s superiority to bony decompression – current gold standard treatment. Investigators called for larger studies with longer follow-up to better establish the safety and efficacy of IPDs.
- In 2017, Machado and colleagues conducted a Cochrane review to evaluate the efficacy of surgery in the management of patients with lumbar spinal stenosis (LSS) and the comparative efficacy between commonly performed surgical techniques.¹⁶ Investigators searched the literature through June 2016 for RCTs that compared efficacy and safety of surgery compared with no treatment, placebo or sham surgery, or with another surgical technique. Follow-up ranged from 1 to 2 years. Outcomes of interest were pain intensity, physical function or disability status, quality of life and recovery. Secondary outcomes included measurements related to surgery (e.g. perioperative blood loss, length of hospital stay, reoperation rates).

In total, 39 RCTs were included for review (n=2352), all of which compared two or more surgical techniques. All trials were assessed to be at high risk of bias due to inadequate blinding, incomplete randomization and a lack of intention-to-treat analyses. Overall, investigators reported no differences for primary and secondary outcomes. Three trials compared interspinous process spacer devices, including Coflex, to conventional bony decompression. Spacers achieved similar reductions in pain, disability, and perioperative blood loss, but longer operation times and incurred higher risks of reoperation. Two trials compared interspinous spacer devices, including Coflex, with decompression plus fusion. Among patients receiving spacer devices, investigators found no difference in pain relief or rate of reoperations, but significant improvements in disability reduction, operation time and perioperative blood loss. Investigators concluded that evidence is insufficient to recommend interspinous process spacers over decompression alone.

- In 2015, Moojen and colleagues published results from their double-blind RCT evaluating the efficacy of interspinous process devices (IPDs), including Coflex, versus conventional surgical decompression for lumbar spinal stenosis.¹⁷ In total, 211 participants were randomized to one of two groups – IPD (n=80) and spinal bony compression (n=79) – and treated at one of five treatment centers across The Netherlands. At 2-year follow-up, investigators found no significant differences in success rates between groups, but significant increases in reoperations and visual analog scale back pain among the IPD group. Investigators concluded that these increases in the IPD group “suggest inferiority [of IPD] compared to classical decompression.”

Superion Interspinous Spacer System (ISS)

In 2018, Hayes conducted a review of abstracts evaluating Superion Interspinous Spacer System (SISS) for spinal stenosis.⁵ In total, the abstracts of 16 studies were included for review (1 RCT, 4 retrospective analyses of the RCT, 2 retrospective comparative studies, 1 meta-analysis, 2 systematic reviews, 1 cost-effectiveness analysis, and 2 review articles). The RCT included 391 patients with moderate lumbar spinal stenosis, who had previously failed 6 months of conservative care. Patients were implanted with either Superion ISS (n=190) or X-Stop (n=144) across 29 treatment centers. Among the SISS group 28.4% were lost to follow-up (n=136). Among patients available for follow-up at 3 years, composite clinical success was obtained in 52.5% of patients in the SISS group and 38.0% in the X-Stop group (p=0.023). Limitations among abstracts included a lack of blinding, the absence of decompression, lack of comparator groups receiving medical management, and potential confounders from varying postoperative care regimens among individual patients. Hayes concluded that evidence was insufficient to demonstrate the safety and efficacy of SISS.

CLINICAL PRACTICE GUIDELINES

Dynamic Stabilization Devices

North American Spine Society (NASS)

In 2014, the NASS addressed dynamic stabilization without arthrodesis for the treatment of degenerative lumbar spondylolisthesis.¹⁸ The workgroup made no recommendation due to the lack of

quality evidence. Authors called for large, prospective studies with long-term follow-up comparing dynamic stabilization to medical or interventional treatment.

National Institute for Health and Care Excellence (NICE)

In 2014, NICE issued a “medical technologies guidance” (i.e. not a systematic review of evidence) addressing magnetic growing rods (MAGEC) for the treatment of early onset scoliosis.¹⁹ The guidance concluded that:

- “The case for adopting the MAGEC system for spinal lengthening in children with scoliosis is supported by the evidence. Using the MAGEC system would avoid repeated surgical procedures for growth rod lengthening. This could reduce complications and have other physical and psychological benefits for affected children and their families.
- The MAGEC system should be considered for use in children with scoliosis aged 2 years and over who need surgery to correct their spinal curvature, for example when conservative methods such as bracing or casting have failed.”¹⁹

Interspinous Spacers

North American Spine Society (NASS)

In 2014, the NASS stated that there is “insufficient and conflicting evidence” evaluating the efficacy of interspinous spacers for the treatment of degenerative lumbar spondylolisthesis.¹⁸ Authors called for larger studies with long-term follow-up comparing interspinous spacers to medical/interventional treatment to better assess the safety and efficacy of interspinous spacers.

CENTERS FOR MEDICARE & MEDICAID

As of 3/24/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which address either dynamic stabilization devices or interspinous spacers for any indication.

POLICY SUMMARY

Evidence does not support the safety and efficacy of dynamic stabilization devices and interspinous spacers. All systematic reviews to date note a paucity of long-term evidence from high-quality trials. The literature largely comprises small, uncontrolled studies with short-term follow-up. Moreover, no evidence-based clinical practice guidelines recommend dynamic stabilization devices or interspinous spacers in lieu of, or in addition to, interbody fusion and/or decompression fusion for the treatment of lumbar spinal stenosis.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Food and Drug Administration (FDA)

The following dynamic stabilization devices and interspinous spacers have received FDA clearance:

- Aspen Spinous Fixation System²⁰
- DSS Stabilization System²¹
- Dynesys^{®22}
- Isobar Spinal System²³
- Magnetically Controlled Growing Rods (MAGEC)²⁴
- Coflex[®] Interlaminar Stabilization Device²⁵
- Superion Interspinous Spacer System²⁶

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

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