


MEDICAL POLICY	Back: Stabilization Devices and Interspinous Spacers
Effective Date: 9/1/2022  <div style="text-align: right;">9/1/2022</div>	Medical Policy Number: 19
	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; 06/2021; 6/2022
Medical Officer _____ Date _____	

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

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin 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 Medical Policy, Back: Sacroiliac Joint Surgery.

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. NFix™ II Dynamic Stabilization
- T. NFLex™ Controlled Motion System
- U. REVERE Stabilization System
- V. Satellite™ Spinal System
- W. Stabilimax NZ Dynamic Spine Stabilization System
- X. TRANSITION® Stabilization System
- Y. Viper™
- Z. Zodiak DynaMo System

*Investigational services are considered “**not medically necessary**” for **Medicare Plan members**.
Link to [Centers for Medicare and Medicaid Services \(CMS\)](#).

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®

*Investigational services are considered “not medically necessary” for Medicare Plan members. Link to [Centers for Medicare and Medicaid Services \(CMS\)](#).

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)
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.

Dynamic Stabilization Devices

Dynamic stabilization devices provide an adjunct or alternative to spinal fusion for the treatment of chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including, but not limited to, degenerative spondylolisthesis or previous failed spinal fusion. 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.¹ 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.³ The device theoretically preserves motion of the treated segment while also alleviating pain by restricting loading on adjacent discs and facet joints.

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.

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.

Coflex® Interlaminar Stabilization Device

The Coflex Interlaminar Stabilization Device is a U-shaped titanium alloy implant that is inserted after decompression of stenosis.⁵ 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).

Superion Interspinous Spacer System (ISS)

The Vertiflex™ Superion Interspinous Spacer (ISS) (Boston Scientific Corporation) first attained FDA premarket approval (PMA) in 2015 (P140004), and was the predicate device to what is now marketed as the Superion™ Indirect Decompression System (IDS).⁶ The Vertiflex™ Superion™ IDS is a minimally invasive treatment option for lumbar spinal stenosis (LSS).⁸ No surgical decompression is used in this surgery. The system is indicated for skeletally mature patients experiencing pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by X-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least six months of nonoperative treatment. FDA PMA Product Code: NQO.

The Vertiflex™ Superion is one of only two interspinous spacer or spinous process plates with full FDA-approval. Following worldwide recalls, the formerly approved X-STOP devices had FDA-approval formally withdrawn in 2015.¹¹

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 May 2022, 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.^{12,13} 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.¹⁴ 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.¹⁵ 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.^{16,17} 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.¹⁸ 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.

Interspinous Spacers

Coflex® Interlaminar Stabilization Device

In 2020, Hayes updated a health technology assessment evaluating the safety and efficacy of Coflex Interlaminar Stabilization Device for the treatment of lumbar spinal stenosis (LSS).²⁰ 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.²¹ 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).²² 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.²³ 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.²⁴ 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 January 2021, ECRI published an updated clinical evidence assessment of the Superion IDS for treating lumbar spinal stenosis.²⁵ The ECRI authors evaluated full-text of 9 studies reporting on 4,107 unique patients published between January 1, 2010 and December 16, 2020. Their findings included:
 - “One RCT (Patel et al. 2015; n = 391), the Superion U.S. pivotal trial that provided data for Superion’s FDA Premarket Approval (PMA), compared Superion (n = 190) with X-Stop interspinous spacer (n = 201) and reported on pain, physical function, QOL, and reoperation rates at 3-year follow-up in patients with LSS.
 - Four before-and-after studies (Nunley et al. 2018a, n = 189; Nunley et al. 2017, n = 88; Bini et al. 2011, n = 121; Shabat et al. 2011, n = 53) compared pain, physical function (ZCQ, ODI scores), QOL (SF-12 or SF-36 scores), and AEs before and at 1, 2, and 5 years after Superion treatment in patients with LSS.
 - Two historical control studies (Nunley et al. 2016, n = 597; Lauryssen et al. 2015, n = 1,235) compared Superion with laminectomy and reported on pain and ODI and ZCQ scores at 1- and 2-year follow-up in patients with LSS. For patients treated with laminectomy, study authors used data reported in published studies.
 - One patient registry (Tekmyster et al. 2019; n = 2,090) reported on leg and back pain severity and AEs at 12-month follow-up in patients with LSS who received Superion.
 - One case series (Nunley et al. 2018b; n = 98) of patients in the Superion arm of the Superion pivotal trial reported on opioid medication use at 5-year follow-up.
 - The 2 historical control studies, 2 before-and-after studies (Nunley et al. 2018a, Nunley et al. 2017), and 1 case series (Nunley et al. 2018b) reported on patients who participated in Superion’s pivotal trial. However, we include these publications because they report on additional patient-oriented outcomes.”

ECRI reported that the evidence is “somewhat favorable” with the following limitations:

“The case series, historical control studies, and before-and-after studies are at high risk of bias due to 3 or more of the following: single-center focus, small sample size, retrospective design, and lack of randomization and independent controls. Two historical control and 2 before-and-after studies assessed the same group of Superion-treated patients; thus, independent RCTs comparing Superion with other devices and laminectomy are needed to validate findings.”

- In 2021, Hayes published an evolving evidence review of full-text clinical studies evaluating the Superion Interspinous Spacer for the treatment of lumbar spinal stenosis with neurogenic claudication.²⁶ The authors identified “minimal support” for using the Superion ISS system. This level of support was reflected by their findings:
 - “Studies were of very poor or poor quality and no comparative studies were identified
 - Post-surgical improvements in pain and disability are reported at up to 3 years follow-up

- Studies do not demonstrate equal or superior benefits or advantages over commercially available alternatives or fusion surgery”

The Hayes authors found conflicting information in professional society guidelines, noting that “several organizations recommend minimally invasive interspinous distraction procedures, in general, for carefully selected patients. This level of support reflects:

- Recommendations from guidelines are mixed, with some determining evidence to be sufficient to support use, while others determined evidence is insufficient to support use.
- One of the 2 guidelines finding sufficient evidence was published prior to the publication of any of the studies included in this report; the other is based on the Investigating Superior™ In Spinal Stenosis study
- No guidelines specifically naming the Superior Interspinous Spacer were identified, although the 2019 MIST guideline refers to a study on the Superior device in its recommendation.”

The overall impressions summarized by the authors identified suggested improvements at up to 3 years follow-up (based on four studies); however, current evidence does not inform whether clinical outcomes associated with the Superior Interspinous Spacer are the same, better, or worse than other currently available minimally invasive interventions, or with more established surgeries involving spinal fusion. Although one randomized controlled trial was identified, it compares Superior with a product no longer on the U.S. market (X-Stop). Two registered ongoing studies do not have control groups and are therefore unlikely to address the gaps in this evidence base. No clinical practice guidelines address Superior specifically, and guidance on use of spacers in general is mixed.

Additionally, final outcomes from a single RCT with the Superior device (FDA noninferiority trial versus X-stop) was reported in four publications and post-hoc analysis in three additional reports.²⁷⁻³³ This single-study with five-year follow-up initially randomized 189 patients to the Superior treatment group. Interpretations from these study data are limited by the lack of blinding and lack of control groups treated by surgical decompression or medical management. Additionally, the FDA-mandated primary endpoint of this trial was non-inferiority to X-STOP at 2 years, with additional postmarket surveillance for 10 years. As stated in the Hayes report, the comparison group (X-Stop) has been pulled off the U.S. market.

CLINICAL PRACTICE GUIDELINES

Dynamic Stabilization Devices

North American Spine Society (NASS)

In 2016, the NASS addressed dynamic stabilization without arthrodesis for the treatment of degenerative lumbar spondylolisthesis.^{34,35} 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.

Interspinous Spacers

North American Spine Society (NASS)

In 2018, the North American Spine Society (NASS) published a coverage policy recommendation for lumbar interspinous device without fusion and with decompression.³⁷ To highlight the scope of their recommendation, the authors state, “Interspinous process (ISP) devices have been available in the US market for quite a few years. While they were initially introduced as a less invasive method of indirect decompression of lumbar spinal stenosis via posterior segmental distraction, more recently ISP devices have been used in conjunction with direct decompression via laminotomy. Some devices, such as Coflex, according to its FDA labeling and available published data, are specifically approved for use in this manner. For the purposes of this document, recommendations will apply to ISP devices that are intended to be used in conjunction with a direct decompressive procedure.”

The policy recommendation states:

“Stabilization with an ISP without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.
2. A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.
3. A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.
4. Previous lumbar fusion has not been performed at an adjacent segment.
5. Previous decompression has been performed at the intended operative segment.

ISP devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

1. Degenerative spondylolisthesis of Grade 2 or higher.
2. Degenerative scoliosis or other signs of coronal instability.
3. Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
4. Iatrogenic instability or destabilization of the motion segment.
5. A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.

6. A laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy.”

In 2014, NASS published revised clinical guidelines for degenerative lumbar spondylolisthesis.³⁵ For the clinical question, “Does the use of interspinous spacers in the treatment of degenerative lumbar spondylolisthesis improve outcomes compared to nonoperative treatment,” the guidelines concluded: There is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/ interventional treatment in the management of degenerative lumbar spondylolisthesis patients. (Grade of Recommendation I - Insufficient Evidence). The authors stated a need for large studies with long-term follow-up comparing interspinous spacers to medical/interventional treatment to better assess the safety and efficacy of interspinous spacers.

The 2011 revised clinical guidelines from NASS on lumbar spinal stenosis stated: There is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis.³⁸ (Grade of Recommendation I - Insufficient Evidence)

CENTERS FOR MEDICARE & MEDICAID

As of May 20, 2022, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified for the Company’s service area which addresses dynamic stabilization devices or interspinous spacers. In the absence of a NCD, LCD, or other Medicare policy, Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*) Therefore, this Company coverage review will be applied for medical necessity decision-making.

Under Medicare, only medically reasonable and necessary services are covered (*Title XVIII of the Social Security Act, §1862(a)(1)(A)*). Procedures, devices, or other medical technologies which lack scientific evidence regarding safety and efficacy because they are investigational or experimental are considered **“not medically reasonable or necessary” for Medicare Plan members.** (*Medicare Claims Processing Manual, Ch. 23, §30 A*).

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 System³⁹
- DSS Stabilization System⁴⁰
- Dynesys^{®41}
- Isobar Spinal System⁴²
- Coflex[®] Interlaminar Stabilization Device⁴⁴
- Superion Interspinous Spacer System⁶

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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

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