April 6, 2022

United Healthcare
Nicolas Stettler-Davis, MD
Medical Director
12700 Whitewater Dr.
Minnetonka, MN 55343
Nicolas.stettler@uhc.com

Re: Medicare Advantage Coverage of Interspinous Spacer Devices

Dear Dr. Stettler-Davis,

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to comment on your policy of non-coverage for interspinous spacer devices (ISD) and provide a detailed explanation of their importance to patients' quality of life.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved.

Position
We support the use of ISD in the treatment of appropriately selected patients suffering from lumbar spinal stenosis.

We strongly affirm that appropriate patient selection is essential. Stringent patient selection criteria limit the number of patients who can be offered ISD but assure that those receiving ISD have the greatest chance to benefit from the procedure with the least harm.

This document includes a brief discussion of the condition of lumbar spinal stenosis and treatment strategies commonly used for lumbar spinal stenosis, a presentation of the current evidence on the safety and effectiveness of ISD, and a measured discussion of the role of the device in the treatment of patients suffering from lumbar spinal stenosis.

Background
Medicare Advantage plans do not offer coverage for lumbar ISD implantation without fusion for patients suffering from lumbar spinal stenosis. (Note that this letter uses ISD to refer exclusively to ISD without fusion and without decompression.) This lack of coverage persists even though a device is FDA-approved [1] and the implantation is covered by Medicare [2]. In Medicare Advantage coverage plans reviewed, ISD is reported to be "experimental or investigational," despite the FDA's acceptance of the technology, the American Medical Association creating a non-investigational billing code, and Medicare's reimbursement policies.

In the medical coverage guidelines from Medicare Advantage plans, the process utilized to determine whether the device is covered first defers to a National Coverage Determination (NCD) or Local Coverage Determination (LCD), which if not found allows deference to the company's evidence analysis, generally that of their commercial policy. This led to the precipitous withdrawal and ongoing lack of coverage for a safe and effective treatment for moderate stenosis for Medicare patients.

From January 2017 until April 2020, First Coast Service Options published an LCD for ISD, leading to coverage by Medicare Advantage. However, the LCD was allowed to retire in 2020. The administrative retirement of the LCD in one locale was followed by revocation of Medicare Advantage coverage across the country, and abruptly a procedure that had received FDA approval after demonstrating safety and efficacy was withdrawn from millions of Medicare recipients and inaccurately labeled as "experimental or investigational". Since Medicare has not developed an NCD yet, Medicare Advantage programs have continued to withhold a safe and effective treatment from Medicare patients that is covered by Medicare.

As noted by the FDA, available evidence for the effectiveness and safety of the operation is favorable. Additional device registry analysis shows similar success in the treatment of stenosis symptoms in common clinical practice, free from the careful restrictions of controlled studies. Furthermore, the technology addresses a common condition that causes pain and disability, with few effective treatment options. Its use allows treatment for a group of patients who commonly do not have an effective alternative and can lead to durable reductions in pain and use of potentially harmful opioid medications while improving function and quality of life.

Lumbar Spinal Stenosis

Lumbar spinal stenosis (LSS) is a common condition with symptoms arising from limited space within the lumbar spinal column, causing compression of spinal nerves. The classic presentation of LSS is fatigue or heaviness in the legs when standing and walking, with or without low back and leg pain, that improves with sitting or bending forward, with some individuals reporting uncomfortable nerve-related sensations in the legs and poor balance [3-5]. This condition is called "neurogenic claudication" and causes considerable pain and disability, especially among the elderly for whom LSS is most common. Some people have rapidly progressive LSS or chronic and severe LSS that causes weakness or loss of bowel or bladder control, but thankfully most people do not have these serious consequences of LSS.

Imaging

Imaging findings are required to confirm the diagnosis of LSS. The findings of LSS can be graded by severity and are generally classified as mild (less than 25% decrease in canal area), moderate (25%-50% decrease in canal area), or severe (greater than 50% decrease in canal area), though there is no widely adopted standard method of classifying the degree of stenosis [6]. Mild stenosis does not generally cause symptoms, but interestingly, severe stenosis does not always cause severe neurogenic claudication [7]. It is therefore necessary

to synthesize information from the history, physical exam, and imaging findings to establish LSS as the cause of a patient's symptoms [6].

Prevalence and Cost
LSS is a common condition, and a common cause of disability. While 11% of the population has LSS [8], the prevalence increases with age, causing a greater burden of LSS neurogenic claudication among the elderly [9,10]. LSS is therefore one of the most common causes of disability among our elderly population and is resulting in increasing costs of care due to supportive care, medical management, conservative treatment, and surgery [11-14].

Pathoanatomy and Pathophysiology
The most common cause of stenosis comes from degenerative changes that occur in the spine over many years of life. The joint tissues of the spine wear out over time and collapse, causing overgrowth of the facet joints and thickening and infolding of the ligamentum flavum. This can be coupled with bulging of discs and growth of bone spurs. Together, these degenerative changes result in narrowing around the nerves that pass through the spinal canal [15,16]. These structures directly compress spinal nerves to cause pain and neurogenic claudication, and they can also decrease the blood supply to the spinal nerves or prevent used blood from leaving the spinal nerves, causing the symptoms of neurogenic claudication. [5] Standing upright, walking, and bending backwards increase the pressure on these tissues and cause them to bulge into the spine, increasing the symptoms of neurogenic claudication. Conversely, bending forward and sitting can spread these spinal tissues out and decrease the pressure on the nerves and improve the blood supply, which is why these movements reduce the symptoms of neurogenic claudication.

Conservative Treatment
Conservative treatments for LSS include all the treatments that are non-surgical. This includes many different treatment strategies, commonly mixed based on the training of the treating physician and the local resources available. This can include physical therapy, activity modification, bracing, education, cognitive-behavioral treatments, medication, acupuncture, epidural steroid injections, and many other non-surgical treatments. Overall, conservative treatments have not been noted to dramatically improve function, decrease pain, or address the limitations LSS causes on patients' ability to walk, and they come at considerable cost [12].

There is some indication that bracing and medication management can be helpful, but the low level quality of evidence requires a careful risk/benefit analysis [17]. Some authors suggest that serotonin-norepinepherine reuptake inhibitors and tricyclic antidepressants may have an effect on symptoms of LSS based on very low-quality evidence [18]. Physical therapy and acupuncture may help treat the symptoms of LSS, though the quality of evidence for acupuncture is low and the long-term effects (greater than 12 months) of physical therapy have not been studied [18].

Epidural Steroid Injections for Treatment of Neurogenic Claudication
Epidural steroid injections have been used in treatment of neurogenic claudication when previous conservative management has failed. Numerous reviews support the use of

injection therapy for the treatment of lumbar spinal stenosis [19-21], though there are limited high-quality data and some conflicting data [22,23]. Despite inconsistent clinical evidence, epidural steroid injection is commonly used to provide short-to-intermediate term relief of neurogenic claudication symptoms for patients with LSS without severe neurological deficits who do not have adequate symptom relief with other conservative therapy. Epidural steroid injections come with risks (including rare procedural risks) and contraindications, but more commonly clinicians must consider the systemic consequences of repeated exposure to corticosteroid medication (*e.g.,* hyperglycemia, hypertension) [24].

Surgery

Surgery is indicated if LSS symptoms remain limiting and do not respond adequately to conservative treatments [14]. Surgical treatment generally targets the removal of the tissues of the spine that are compressing spinal nerves, such as the ligamentum flavum and the overgrown facet joints. Sometimes surgical treatments distract the bones of the spine, causing the tissues to be stretched away from the spinal nerves. When there is spinal instability, or when the tissue removal would cause spinal instability, a fusion may be performed.

Laminectomy is the traditional surgical treatment for LSS, where the posterior part of the spine is removed to make space for the spinal nerves. This surgery can lead to instability and deformity. Less invasive procedures such as hemilaminectomy, laminotomy, microscopic laminotomy, endoscopic laminotomy, and foraminotomy have been developed to preserve more of the structural bones and ligaments of the spine and minimize postoperative instability. Fusion can be used to treat or to prevent future instability and can thereby facilitate a more aggressive decompression where necessary.

Surgical decompression is usually considered the definitive treatment for LSS but requires balancing potential risks and benefits. Surgical complication rates increase with the complexity of the surgical procedure and the medical complexity of the patient; they decrease with surgeon experience [25]. Mortality occurs in 0.5 to 5.6 percent of patients, and rehospitalization within 30 days occurs in 7.8%-13% [26]. Overall, significant complications occur after 10-24% of surgeries, though many of these complications do not lead to lasting harm to patients [27]. Additionally, reoperation for recurrent stenosis or for new stenosis occurs after about 20% of decompressive surgeries for LSS [28]. Despite these potential risks, surgical decompression with or without fusion is the definitive treatment for symptomatic spinal stenosis that does not respond to conservative care. It improves the symptoms of stenosis and is widely performed [29].

Interspinous Spacer Device Implantation Without Decompression or Fusion

ISD technology was developed as an alternative to posterior decompression with or without fusion. ISD implants open the interspinous space at the posterior spine, favoring flexion at the targeted spinal level. This increases the cross-sectional area of the central canal, the subarticular zones, and neural foramina by distracting and tightening of the ligamentum flavum and the posterior disc and separating the pedicles [30].

There is an ISD that is FDA-approved for treatment of skeletally mature patients with neurogenic claudication in the presence of no more than moderate degenerative LSS [1]. It has a very specific set of indications to ensure its effectiveness and safety. The implant may be used in one or two adjacent levels from L1-L5, but not at L5-S1. The patient should have failed six months of conservative management and have flexion-based relief of neurogenic claudication symptoms. Additionally, there should be 25-50% narrowing of the dimensions of the central canal and/or neural foramen based on imaging findings. Contraindications included in the FDA approval include prior fusion at the index level, spondylolisthesis grade II or higher, dynamic translation of > 3mm on flexion-extension radiographs, lumbar scoliosis with Cobb angle > 10 degrees at the level(s) to be treated, a bony defect that would prevent safe insertion of ISD, severe osteoporosis, morbid obesity (BMI over 40), allergy to implant materials, or any medical contraindication [1].

ISD Procedure Description and Evidence

A small incision is made over the interspinous space after x-rays are used to confirm the level. An access tube is placed between the spinous processes and the interspinous ligament is debrided. A sizer is used to choose the size of the ISD implant, then the ISD is inserted between the spinous processes. Vertical cam lobes are then deployed on both sides of the superior and inferior spinous process, and the device is advanced and malleted into its final location just dorsal to the laminae and between the spinous processes. The procedure may be performed under either general anesthesia with endotracheal intubation or sedation with local anesthesia.

The efficacy of the only ISD currently available is supported by favorable 2-year outcomes in LSS patients in a prospective, multicenter, randomized, controlled investigational device noninferiority trial in comparison with a control ISD that had already achieved FDA approval. The control ISD had already demonstrated effectiveness compared to conservative care for moderate LSS. Of 391 patients randomly implanted with either the novel ISD (n=190) or the control ISD (n=201) at 29 sites in the United States [31]. At two-year follow-up, non-inferiority was demonstrated using the primary endpoint (a composite index of patient reported measures and clinical outcomes), indicating that the novel ISD was as effective as the control ISD. In the novel ISD group, leg pain was reduced by 76%, back pain severity decreased by 65%, ODI clinical success rate was 63%, ZCQ Patient Satisfaction (ZCQps) score was 1.66, ZCQ symptom severity (ZCQss) mean improvement was 1.15, and ZCQ physical function (ZCQpf) improvement was 0.89. There were no instances of device fracture, disassembly, collapse, or migration with the novel ISD. There were no neurological complications. The reoperation rate for decompression and novel ISD removal was 11.6%. The rate for subsequent fusion was 6.8%. Based on the results of this study, the novel ISD received FDA approval [1].

The favorable outcomes for the novel ISD continued at 36-month and 48-month follow-up in cohort analyses. VAS leg pain, VAS back pain, and ODI responder rates were 84%, 77%, and 70% at 36-months and 77%, 67%, and 61% at 48-months, respectively. There were no reoperations at the index level, no major implant/procedure-related complications, and no clinically significant confounding treatments, from 24-months to 48-months in these patients [32,33]. Results were sustained at 60-month follow-up, which also noted a trend

toward durability of results among patients who had an initially favorable response, noting that reoperation precipitously declined after the first two years post-implantation [34]. Improvements in quality of life and decreased opioid use up to 60 months were reported as well among those receiving the ISD [35]. Each of these longer-term follow-up studies was limited by loss of patients to follow-up, so confidence in these results should be proportionally decreased.

After FDA approval, a post-market registry was implemented at 86 sites across the US involving 316 physicians. The aim of this registry was to collect real-world data on clinical outcomes of the novel ISD. The registry data show mean VAS score leg and back pain reduction from 76.6 ± 22.4mm and 76.8 ± 22.2 mm preoperatively to 30.4 ± 34.6mm and 39.9 ± 32.3 mm respectively at 12 months, resulting in 60% and 48% overall improvement. The patient satisfaction was 80% at 12 months. In contrast to the FDA study, the first 12 months only demonstrated a 3.6% rate of reoperation or revision [36].

When evaluating the use of ISD for symptoms of LSS, it should be clear that a direct comparison to surgical decompression with or without fusion has not been performed. The mechanism of action of ISD is indirect decompression by separating the spinous processes of the vertebrae slightly and stretching the ligaments of the spine, while also preventing extension of the vertebral level where it is placed. In contrast, spine surgery often involves directly removing the tissue causing stenosis and may include a fusion operation that prevents movement in any direction of the vertebral level. ISD is not indicated for cases of instability, significant deformity, or severe stenosis. It is less common for surgical decompression to be performed for patients with moderate stenosis – the indication for the use of ISD - compared to severe stenosis. There may be potential advantage in the morbidity of ISD implantation compared to spine surgery [12,37], but it must be noted that direct comparison of patients in a carefully designed trial has not been performed.

ISDs were tested in patients with no more than moderate stenosis. [31,38]. This limits our ability to apply the technology to patients with severe stenosis, or to patients with severe symptoms, who were likewise excluded from these studies.

While there are several manuscripts that purport to compare surgical decompression to ISD, whether it be with respect to outcomes, safety, or cost effectiveness, the inclusion criteria for the comparison decompression studies were not congruent to those in the ISD studies, rendering such an analysis moot until ISD is studied in those with more severe symptoms and radiographic findings or decompression is performed in patients with moderate or milder stenosis [12,39,40]. One study also attempts to compare costs for ISD to conservative care, based on data from historical studies with heterogeneous inclusion criteria, rather than from direct comparison [40]. The lack of similarity of inclusion criteria in the groups that were analyzed should caution against confidence in the results.

Please note that this document considers only ISD without fusion or decompression and does not address ISDs without fusion but with decompression or ISDs with fusion, as each of these devices comes with its own indications, safety profile, and clinical efficacy. This document reviews and addresses only ISD without fusion or decompression.

Conclusions
ISD has been demonstrated to be effective in the treatment of LSS symptoms in a carefully designed trial, and there is evidence it maintains effectiveness in extended follow-up. It improves pain, function, quality of life, and decreases exposure to opioid medications when applied according to indications.

ISD has limited indications and specific contraindications, which support its utility and safety when followed. Clinical judgment of the physician and shared decision-making between physician and patient with a full discussion of risks and potential benefits must be undertaken. Offering ISD to patients who fall outside of the specific indications should be considered after careful deliberation, and only after discussion of the unknown effect on risk and benefit.

ISD appears remarkably safe if performed for appropriate patients by professionals trained in spine interventions. ISD should be performed by physicians with understanding of the radiographic and clinical presentation of lumbar stenosis, expertise in interventional or surgical treatments for the spine, interpretation of lumbar anatomy using advanced imaging and fluoroscopy, and specific training in the use of the ISD device

Any additional conclusions derived from the published literature are speculative at present and require further research. SIS encourages ongoing investigation of ISD technology to further examine its safety, effectiveness, and cost, and how to best apply it to improve the lives of patients. It is essential to continue to evaluate the device to determine how well ISD devices perform in the long term, the degree to which they allow avoidance of subsequent procedural intervention, decompression, and fusion, and how well they allow patients to return to meaningful activities. It will also be essential to examine the predictive factors for success and failure of ISD implantation and to determine which of the indications and exclusions for use of the device should be modified to best manage risk and potential benefits for patients, such as in patients with morbid obesity or severe stenosis. Specifically, though there has been inference that ISD results in less morbidity than surgical decompression with or without fusion, this has yet to be carefully studied. Additionally, it will be important to assess the effectiveness of ISD in direct comparison to interventions and procedures that may be offered to patients with spinal stenosis. There may also be subgroups of patients whose symptoms respond better than others – for example, central canal, subarticular, and foraminal stenosis may each have a different rate or degree of success – and improving patient selection could maximize effectiveness and minimize potential harm.

The undersigned societies appreciate the opportunity to provide these comments. The MPW societies would welcome the opportunity to work with Medicare Advantage health plans to establish a reasonable coverage policy that will eliminate inappropriate utilization and ensure appropriate access to ISD for Medicare patients. We offer our ongoing input and expertise in this matter. If you have any questions or wish to discuss any of our suggestions, please contact Sarah Cartagena, Director of Health Policy at the Spine Intervention Society, at scartagena@SpineIntervention.org.

Sincerely,

American Academy of Physical Medicine and Rehabilitation
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Spine Radiology
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology
Spine Intervention Society

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