Interlaminar/Interspinous Process Distraction Devices for Neurogenic Claudication or Lumbar Spinal Stenosis (CPT Codes 22867-22870)

July 2017

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Revised August 7, 2017

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Key Findings

- The authors of three good methodological quality systematic reviews with meta-analysis that evaluated interlaminar/interspinous process distraction devices (IPDs), compared to decompression surgery with or without spinal fusion, found no significant differences in terms of function, disability, or quality of life (Machado et al., 2016; Ren & Hu, 2016; Zhao et al., 2017).
- Findings on the effectiveness of IPDs for long-term pain or symptom severity (≥12 months) are conflicting. Among three good methodological quality systematic reviews evaluating IPDs compared to decompression surgery with or without spinal fusion, the authors of one observed no difference between IPD recipients and patients undergoing decompressive surgery; the authors of the other two reviews observed significantly increased pain and symptom severity for IPD recipients compared to decompressive surgery. Symptom severity was assessed using differing tools across studies, limiting comparisons of the systematic reviews.
- Among the three eligible systematic reviews comparing IPDs to decompression surgery with or without spinal fusion, IPDs were associated with a 2.5- to 4-fold increased risk of reoperation. Complications of IPDs include spinous process fracture, device dislocation or migration, and bruising. The risk of complication from IPD is approximately half that of decompression surgery, but the estimate is imprecise (risk ratio 0.54; 95% CI, 0.30 to 0.95).
- Data on IPDs compared to conservative therapy is limited. The single systematic review identified on the use of IPDs compared to conservative therapy found one study addressing this comparison (Zaina, Tomkins-Lane, Carragee, & Negrini, 2016).
- Clinical practice guidelines on this topic are not up-to-date (last published in 2013) and reported that there is insufficient evidence to support their use.
- Private insurers consider these devices experimental, investigational, or unproven.
- There is not a national coverage determination from Medicare on IPDs. Two local coverage determinations identified are not consistent. One provides explicit eligibility criteria for IPDs; the other does not.

Background

Clinical Overview

- The spine consists of 26 vertebrae that are generally divided into four regions: cervical (7), thoracic (12), lumbar (5), sacrum (1), and coccyx (1).
- Lumbar spinal stenosis is a condition in which the spinal canal narrows, often because of age-related changes, and the connective tissue of the spine sometimes thickens. Combined, these changes put pressure on the end of the spinal cord and nerves as they exit the lower spine. Individuals with these changes may experience back or leg pain. See Figures 1 through 3 for visual aids on spinal anatomy and lumbar spinal stenosis.
- In lumbar spinal stenosis, this pressure on the spinal cord and nerves is greater when standing upright. Thus, individuals with lumbar spinal stenosis experience leg pain that improves with sitting or forward bending of the spine (i.e., neurogenic claudication).
- Treatment options for lumbar spinal stenosis range from conservative measures (e.g., physical therapy, nonsteroidal anti-inflammatories, acupuncture, massage, manipulation, cognitive behavioral therapies) to invasive procedures including surgery.
- Surgical options include decompressing the nerve or connective tissue (i.e., laminectomy or ligamentectomy), and if the vertebrae move too much (i.e., spondylolisthesis), the procedure can include fusion of the two vertebrae by affixing them together with additional implanted components.
- IPDs are an alternative to more invasive surgical options. An IPD can be inserted between spinous processes to offload the joints of the spine that are putting pressure on the nerves.
- The use of an IPD avoids entering the spinal column and the ensuing risk of dura injury. However, IPD use comes with risk of damage to adjacent spinous processes (e.g., fracture), implant dislocation, and excess bone growth around the implant (i.e., heterotopic ossification).
- Available IPDs in the U.S. with Food and Drug Administration (FDA) approval include the following:
    - Coflex Interlaminar Technology (Medtronic) approved in 2012 for the following indication:

        > Adults with one or two level lumbar stenosis … with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. (FDA, 2012, p. 1)

    - Superion InterSpinous Spacer (VertiFlex) approved in 2015 for the same indication as Coflex (U.S. Food and Drug Administration, 2015).

- X-STOP (Medtronic) approved in 2005 for the following indication:

  > Patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with x-ray, magnetic resonance imaging (MRI), and/or computed tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X stop is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment (FDA, 2005, Approval Order Statement).

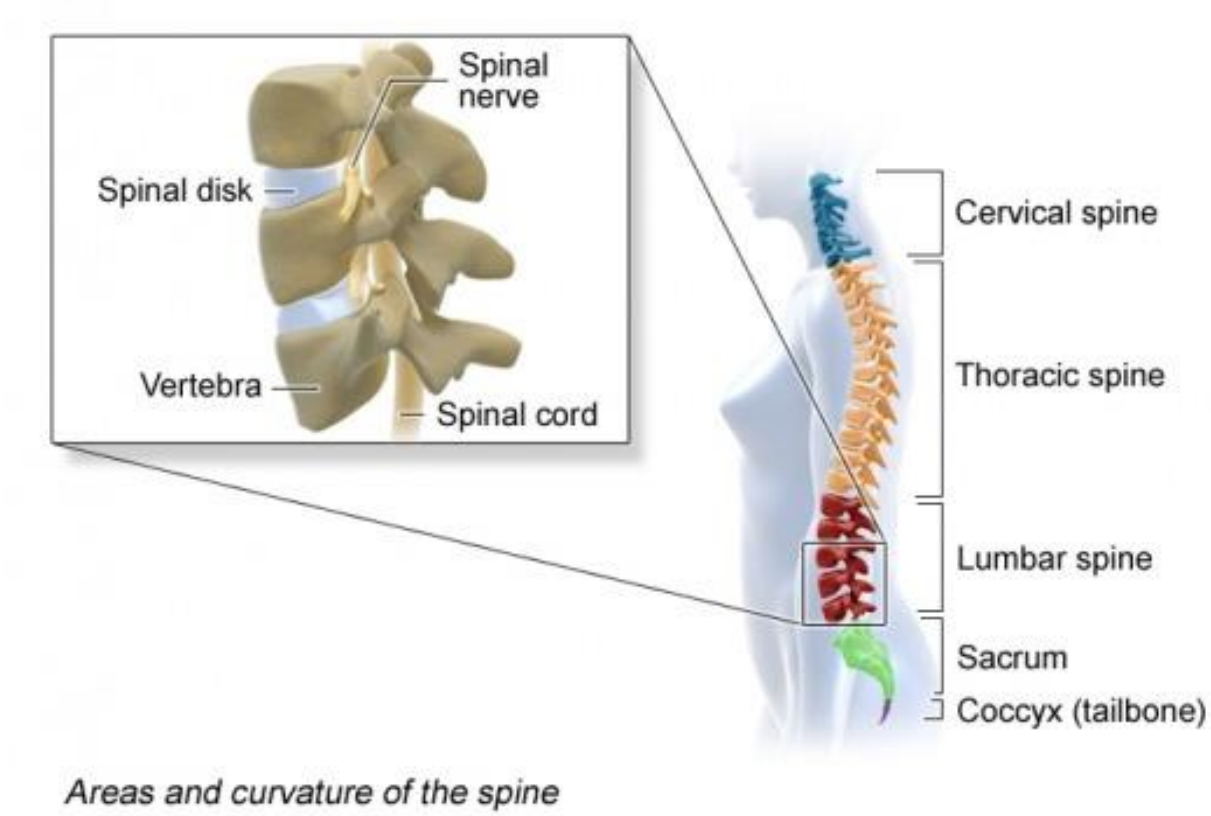
- The manufacturers of the DIAM spinal stabilization system, an H-shaped silicone and polyester device inserted between two spinous processes, applied for FDA approval in 2016 but the application was denied because of lack of clinical efficacy data (Mass Device, 2016).

- The Wallis implant from Abbot Spine, a titanium IPD, has been available in Europe since the mid-1980s (Stordeur, Gerkens, & Roberfroid, 2009). An RCT is registered at ClinicalTrials.gov, but no results have been reported since the study closed in 2014 (ClinicalTrials.gov, 2011).

- The evaluation of the effectiveness of IPDs includes assessments on function, quality of life, symptom severity, and disability. Commonly used tools include the Oswestry Disability Index, the SF-12 (for quality of life), the Visual Analog Scale (for pain scores), and the Zurich Claudication Questionnaire. All are validated tools for assessing symptoms in individuals with low back pain or lumbar spondylolisthesis (Stordeur et al., 2009).

- In 2017, the Current Procedural Terminology (CPT) system added codes 22867 to 22870, which are used for the placement of an IPD:
  - 22867: Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
  - 22868: 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: Second level (list separately in addition to code for primary procedure)

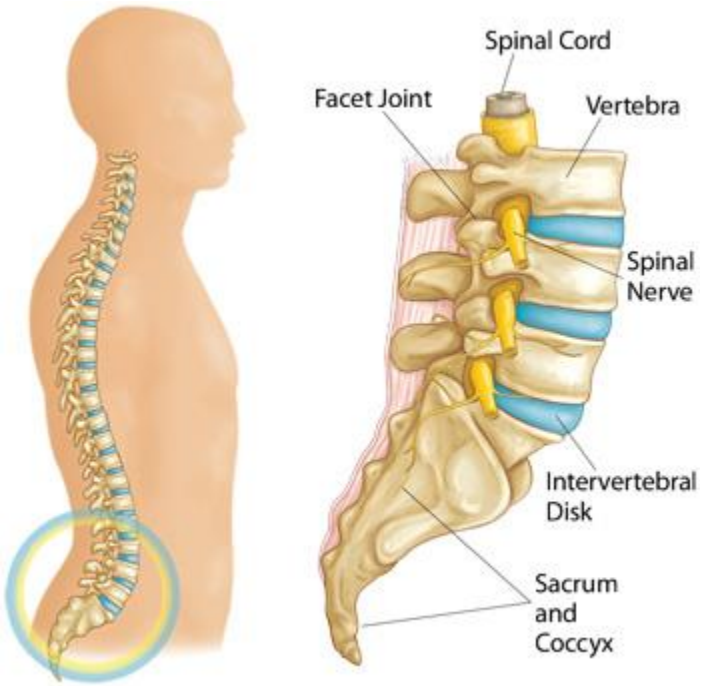
Figure 1. Spine Anatomy



Areas and curvature of the spine

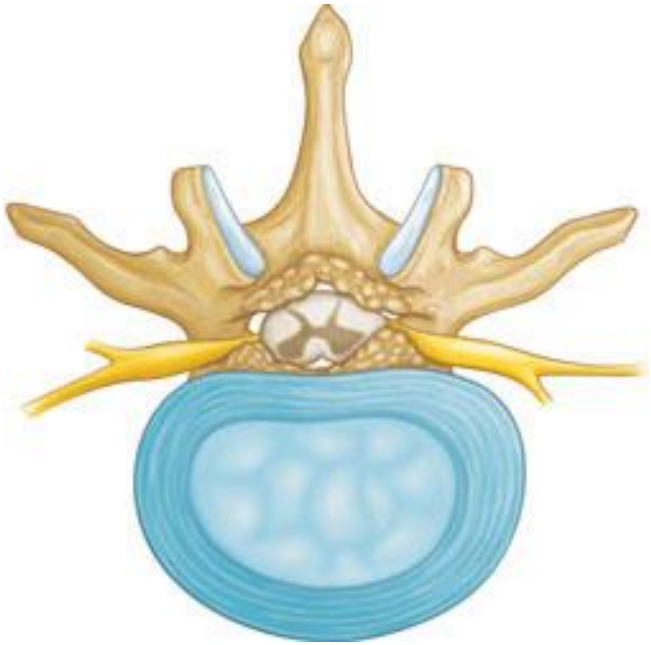
Source: https://www.informedhealth.org/how-does-the-spine-work.2375.en.html.

Figure 2. Lumbar Spine Anatomy



Source: http://orthoinfo.aaos.org/topic.cfm?topic=a00053

Figure 3. Vertebral Anatomy in Spinal Stenosis



Source: http://orthoinfo.aaos.org/topic.cfm?topic=A00329

Prevalence

Spinal stenosis in older adults is relatively common on imaging, with a prevalence of upwards of 80% among individuals 60 years or older (Machado et al., 2016). However, severe lumbar stenosis is present in only about 30% of individuals who present with symptoms and only approximately 17% of individuals with symptoms experience long-term neurogenic claudication (Machado et al., 2016).

PICO

Populations: Adults with lumbar spinal stenosis and neurogenic claudication, with or without spondylolisthesis

Intervention: Use of an IPD, over one or two spinal levels, without spinal fusion. The device can be placed after open decompression (CPT codes 22867 to 22868) or without open decompression (CPT codes 22869 to 22870).

Comparators: Spinal decompression laminectomy, spinal fusion, epidural corticosteroid injection with or without anesthetic, physical therapy

Efficacy and Effectiveness Outcomes: Recovery time, change in pain (at least one year from procedure), function, quality of life, proportion of patients who later need spinal fusion, cost and cost-effectiveness

Harm Outcomes: Harms, adverse events (e.g., infection, bleeding, rehospitalization, morbidity, mortality)

Methods

Center for Evidence-based Policy (Center) researchers searched Center core evidence and guidelines sources and Ovid MEDLINE for systematic reviews (with or without meta-analysis), cost or cost-effectiveness analyses, and technology assessments on interspinous implant use published within the last 10 years and clinical practice guidelines published within the last five years. To ensure that the most recent studies were included, Center researchers also searched Ovid MEDLINE through April 2017 for systematic reviews, individual studies (i.e., randomized controlled trials [RCTs], comparative observational studies, economic analyses) and clinical practice guidelines on the use of IPDs published after the search dates of the most recent included systematic reviews. Center researchers evaluated the methodological quality of systematic reviews with and without meta-analyses, RCTs, comparative observational studies, economic analyses, and clinical practice guidelines in this report using the quality assessment tools included with the New York State Department of Health dossier process (available on the New York State Department of Health website). Center researchers also searched Medicare, several state Medicaid programs, and private payer policies for coverage policies on the use of

IPDs for the treatment of adults with lumbar spinal stenosis. See Appendix A for a full list of payers searched.

Center researchers excluded systematic reviews if all of the included studies were also summarized by a more comprehensive systematic review, a systematic review of a higher methodological quality, and/or a more recently published systematic review. In addition, only patient-important outcomes have relevance for New York State Department of Health. For this report, outcomes excluded on this basis include surgical time and radiographic findings. Exclusion criteria were selected prior to review of the studies, and study methods were assessed prior to review of outcomes to eliminate bias. See Appendix A for a full description of methods.

Evidence Review

Findings

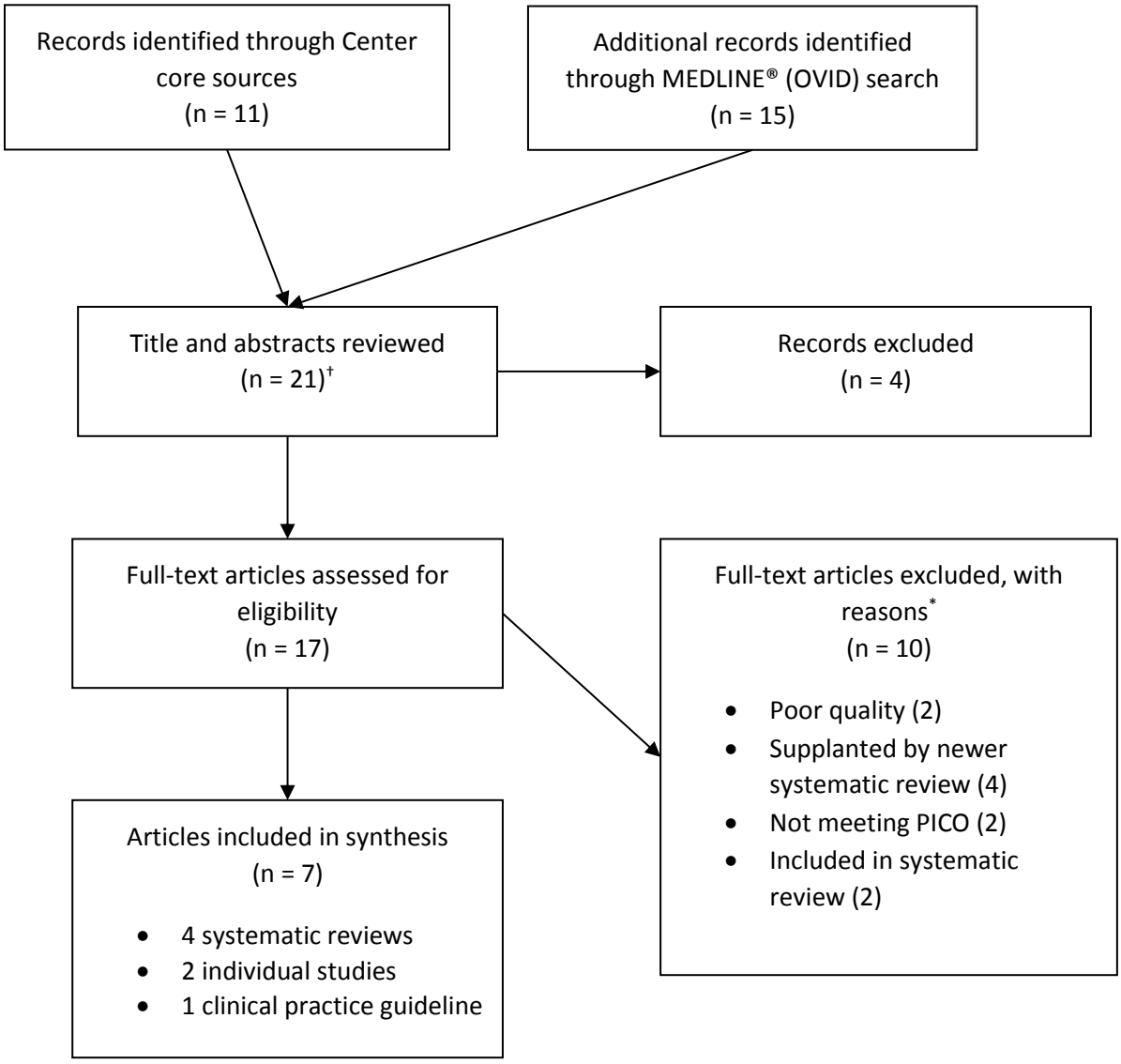
Center researchers identified four systematic reviews (Machado et al., 2016; Ren & Hu, 2016; Zaina et al., 2016; Zhao et al., 2017) and two RCTs (Huang, Chang, Zhang, Song, & Yu, 2015; Puzzilli et al., 2014) relevant to the effectiveness and/or harms of IPDs for lumbar spinal stenosis that met inclusion criteria. Two of the identified systematic reviews also included costs as an outcome (Machado et al., 2016; Zhao et al., 2017). Center researchers identified one clinical practice guideline (North American Spine Society, 2014). Figure 4 outlines the number of articles identified by each search and the total number of studies included in this evidence synthesis. The search strategies and list of studies reviewed in full with reasons for exclusion are in Appendices A and B, respectively.

There was a high degree of overlap of included studies across identified systematic reviews. On full-text review, the systematic reviews by the National Institute for Health and Care Excellence (2010), Moojen, Arts, Bartels, Jacobs, and Peul (2011), and Stordeur et al. (2009) were excluded because they were supplanted by newer reviews. The reviews contained several subanalyses of a single RCT (Zucherman et al., 2004), which is included in a more up-to-date systematic review (Zaina et al., 2016). The reviews included other study designs that have a high risk of bias (e.g., case series, before-and-after studies).

Overview of Evidence Sources

Center researchers summarized the evidence as reported by the included systematic reviews. Center researchers did not review the methodological quality of eligible studies within the systematic reviews unless necessary for clarification of information reported in the systematic review. Table 1 provides an overview of findings from the included systematic reviews and additional individual studies.

Figure 4. Search Results



† Some duplication of articles between Center core source search results and MEDLINE® (Ovid) search results. *Detailed exclusion rationale provided in Appendix B.

Systematic Reviews

Machado et al. (2016)

Machado et al. (2016) conducted a good methodological quality systematic review and meta-analysis. The review included RCTs published through June 2016 of individuals with lumbar spinal stenosis. The meta-analysis evaluated the effectiveness and safety of IPDs, decompressive surgery, and IPDs compared to decompressive surgery with fusion. Outcomes were pain, disability, function, quality of life, blood loss, reoperation rate, and costs. The review authors used an extensive search strategy (e.g., multiple databases searched, comprehensive search strategy used, few to no limits on study publication date) and identified five articles that evaluated the comparative effectiveness and safety of IPDs.

Ren and Hu (2016)

Ren and Hu (2016) conducted a good methodological quality systematic review and meta-analysis. The review included RCTs and observational studies published through February 2016 of individuals with lumbar spinal stenosis. The meta-analysis evaluated the effectiveness and safety of IPDs compared to decompressive surgery. Outcomes were low back pain, leg pain, disability, complications, reoperation rates, and hospital stay. The review authors used an extensive search strategy (e.g., multiple databases searched, comprehensive search strategy used, few to no limits on study publication date) and identified eight articles that evaluated the comparative effectiveness and safety of IPDs.

Zaina et al. (2016)

Zaina et al. (2016) conducted a good methodological quality systematic review. The review included RCTs and quasi-randomized controlled studies published through February 2015 of individuals with lumbar spinal stenosis. The systematic review evaluated the effectiveness and safety of IPDs compared to nonsurgical options (e.g., exercise, manipulation, mobilization, physical therapy, medications, acupuncture, bracing, education, cognitive behavioral treatments). Outcomes were disability, function, pain, quality of life, walking capacity, side effects, complications, failure rates, and patient satisfaction. The review authors used an extensive search strategy (e.g., multiple databases searched, comprehensive search strategy used, few to no limits on study publication date) and identified one article that evaluated the comparative effectiveness and safety of IPDs.

Zhao et al. (2017)

Zhao et al. (2017) conducted a good methodological quality systematic review and meta-analysis. The review included RCTs published through August 8, 2016, involving individuals with lumbar spinal stenosis. The meta-analysis evaluated the effectiveness and safety of IPDs compared to decompressive surgery. Outcomes were pain, function, disability, reoperation rates, and costs. The review authors used an extensive search strategy (e.g., multiple databases

searched, comprehensive search strategy used, few to no limits on study publication date) and identified seven articles (from four RCTs) that evaluated the comparative effectiveness and safety of IPDs.

Individual Studies

Huang et al. (2015)

Huang et al. (2015) conducted a poor methodological quality RCT comparing the effectiveness of two IPDs (i.e., Rocker and X-STOP) in adults with lumbar spinal stenosis. The study enrolled 62 individuals from March 2011 to September 2012 in China. Although the study authors reported changes in disability scores from baseline to 24 months, the results were non-comparative. This study was included for data on complications only (e.g., death, spinous process fracture, device dislocation), and blood loss.

Puzzilli et al. (2014)

Puzzilli et al. (2014) conducted a poor methodological quality RCT evaluating the effectiveness of IPD compared to conservative therapy in adults with lumbar spinal stenosis and degenerative disc disease. The study enrolled 542 adults from 2005 to 2009 in Italy, Spain, and Germany. The study authors reported subcomponents of the Zurich Claudication Questionnaire (ZCQ), complications, and reoperation rates.

Quality and Limitations

Center researchers rated all four systematic reviews as having good methodological quality (Machado et al., 2016; Ren & Hu, 2016; Zaina et al., 2016; Zhao et al., 2017). All used extensive search strategies, evaluated and considered the quality of studies, and reported no or limited conflicts of interest for authors or funding bodies. Center researchers assessed the methodological quality of the systematic reviews and meta-analyses and not the individual studies within them. The individual studies included in the systematic reviews were assessed by the respective review authors. References to individual study quality are taken directly from the systematic reviews, and are not assessments made by Center researchers. The sole IPD vs. conservative therapy RCT—in Zaina et al. (2016)—was published in 2004; thus, the results might not be applicable to current conservative management strategies. The included systematic reviews frequently reported the available evidence on this topic to be unclear or at high risk of bias. The small number of studies available on this topic limited the ability to conduct formal estimates of publication bias (e.g., funnel plots).

Center researchers assessed the methodological quality of two RCTs that were not included in the systematic reviews using standard quality assessment methods (see Appendix A for further details). Of the two additional included RCTs, Center researchers rated both as poor methodological quality (Huang et al., 2015; Puzzilli et al., 2014). There are several biases across the individual RCTs. Baseline characteristics of participants were not provided (Puzzilli et al.,

2014), and blinding of study personnel or clinicians was not performed in either study, and thus individuals assessing participants' outcomes were aware of their intervention arm. Participants were not analyzed according to randomization, and there was high loss to follow-up in Puzzilli et al. (2014).

Summary of the Evidence

The evidence is summarized in the tables below by comparator and then by outcomes of effectiveness and harms. Individual study quality discussed in the context of included systematic reviews is taken directly from review authors and is not the Center's original assessment of the work. Table 1 provides a high-level summary of the evidence listed by systematic review and individual studies.

Table 1. Overview of Included Studies

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Meta-analyses: Interspinous Process Devices vs. Decompressive Surgery			
Machado et al. (2016) Search Dates Inception to 16 June 2016 Included Study Designs RCTs Methodological Quality Good	k = 3, n = 355 for IPD vs. DS k = 2, n = 382 for IPD vs. DS with fusion Full review 24 trials (39 total records) *SR authors' estimates of quality reported for each outcome in next column*	**Comparators** ***IPD vs. DS*** Outcomes *Pain intensity at ≥12 months (low-quality evidence)* MD -0.55 (95% CI, -8.08 to 6.99) p = 0.22 *Disability at ≥12 months (moderate quality evidence)* MD 1.25 (95% CI, -3.64 to 6.25) p = 0.13 *Function at ≥12 months (ZCQ subscale; moderate-quality evidence)* MD 0.00 (95% CI, -0.30 to 0.29) p = 0.26 *Quality of life at ≥12 months (moderate-quality evidence)* MD -0.05 (95% CI, -0.18 to 0.07) p = 0.48 *Perioperative blood loss (low-quality evidence)* MD 144.00 mL (95% CI, -209.74 mL to 497.74 mL) *Reoperation rate (high-quality evidence)* Risk ratio: 3.95 (95% CI, 2.12 to 7.37) increased risk of reoperation for IPD compared to DS	Two comparisons in this meta-analysis of IPD vs. DS and IPD vs. DS with fusion (see next page) Only 3 trials (355 participants) compared IPD (i.e., X-STOP or Coflex) to decompression. All included studies at risk of performance bias: none blinded study staff or care providers to treatment arm.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		Costs (moderate-quality evidence) Incremental cost for implant: $3,103.84 (95% CI, $2,141.14 to $4,066.55) **Comparators** ***IPD vs. DS with fusion*** Outcomes *Pain intensity ≥12 months (low-quality evidence)* MD 5.35 (95% CI, -1.18 to 11.88) p = 0.38 *Disability ≥12 months (low-quality evidence)* MD 5.72 (95% CI, 1.28 to 10.15) p = 0.50 *Quality of life ≥12 months (moderate-quality evidence)* MD -3.10 (95% CI, -6.30 to 0.10) p = 0.058 *Perioperative blood loss (moderate-quality evidence)* MD 238.90 mL (95% CI, 182.66 mL to 295.14 mL) p < 0.01 (i.e., greater blood loss for DS with fusion) *Reoperation rate (high-quality evidence)* RR 1.43 (95% CI, 0.66 to 3.09)* *Costs* No cost estimates for IPD vs. DS with fusion	

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Ren and Hu (2016) Search Dates Inception to February 2016 Included Study Designs RCTs, observational studies Methodological Quality Good	k = 8 n = 834 adults with lumbar spinal stenosis *SR's quality assessment of individual studies:* Moderate to high for comparative cohorts; high for RCTs	Comparators IPD vs. DS Pooled Data Outcomes *Low back pain score at follow-up* WMD 0.68 (95% CI, 0.12 to 1.24) p = .02 *Leg pain score at follow-up* WMD 0.46 (95% CI, -0.77 to 1.69) p = .009 *ODI Score at follow-up* WMD 0.00 (95% CI, -12.47 to 12.48) p = 1.00 Harms *Complications* RR 0.54 (95 % CI, 0.30 to 0.95) *Reoperation* RR 2.48 (95% CI, 1.71 to 3.61) *Hospital stay* WMD -1.49 (95% CI, -2.94 to -0.04) p < 0.01 When meta-analysis was restricted to only RCTs, no statistically significant differences in leg pain score, ODI	Follow-up ranged from 18 to 51 months across included studies. A positive WMD equates to a higher (worse) pain score. IPD recipients reported higher pain scores than DS at follow-up in both analyses. Implants used in included studies: Aperius, X-STOP, Coflex

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		score, complications, or hospital stay duration were observed *Low back pain score* WMD 0.62 (95% CI, 0.05 to 1.20) p = 0.03 *Reoperation* RR 3.18 (95% CI, 1.89 to 5.35)	
Zhao et al. (2017) Search Dates Inception to August 8, 2016 Included Study Designs RCTs Methodological Quality Good	k = 4 RCTs (7 articles) Total n = 400 *SR's quality assessment of individual studies:* high risk of bias	Comparators IPD vs. DS *Low back pain at 2 years (VAS)* MD 9.65 (95% CI, 0.78 to 18.51) *Function using ZCQ at 2 years* Synthesized analysis not performed. Of three studies reporting this outcome, none observed statistically significant differences. *ODI* Synthesized analysis not performed. Of two studies reporting this outcome, contradictory estimates were observed. One study observed decreased disability estimate for IPD group compared to DS; the other observed no difference. *Reoperation*	Different devices used in each of the included studies. Small sample sizes for specific outcomes limited analysis.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
		28.8% IPD vs. 9.4% DS RR 2.91 (95% CI, 1.72 to 4.92) *Costs* Synthesized analysis not performed. Of two studies reporting this outcome, both observed greater costs for IPD compared to DS without improved quality of life.	
Systematic Review without Meta-analysis: Interspinous Process Devices vs. Conservative Therapy			
Zaina et al. (2016) Search Dates Inception to February 11, 2015 Included Study Designs RCTs, quasi-randomized controlled studies Methodological Quality Good	k = 5 (10 articles) Total n = 643 participants SR authors' estimates of quality reported for each outcome in next column	Comparators IPD vs. nonsurgical options (e.g., exercise, manipulation, mobilization, physical therapy, drugs, acupuncture, bracing ,education, cognitive behavioral treatments) Narrative Summary "Low quality evidence favoring the interspinous spacer at six weeks, six months, and one year for symptom severity and physical function." *Complications* 21/191 (11%) of IPD recipients experienced side effects ranging from spinous process fracture, coronary ischemia, respiratory distress, hematoma, or death due to pulmonary edema.	Only a single RCT compared IPD (with X-STOP) to usual care (n = 191) at high risk of bias. Comparison group received epidural steroid injection, nonsteroidal anti-inflammatories, analgesics, physical therapy. All participants required to have completed ≥6 months of non-operative therapy.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Randomized Controlled Trials			
Huang et al. (2015) Study time frame 2011 to 2012 Location China Methodological quality Poor	n = 62	Comparators Rocker vs. X-STOP *Death* 1 individual in Rocker group, reason not given but reported as not related to study. *Complications* 1 spinous process fracture, 2 device migrations requiring replacement, 1 device dislocation requiring revision surgery, 1 dural rupture *Blood loss* 111 mL ±71 Rocker vs. 138 mL ±68 X-STOP (p = 0.429)	Single site with single team of surgeons performing all procedures. Discectomy was also performed if indicated for individuals with lateral recess stenosis; 61% of participants underwent discectomy in addition to IPD. This limits ability to determine impact of IPD alone. Loss to follow up: 12.5% Rocker group, 10% X-STOP group. 16% of study sample with a BMI ≥30 may limit generalizability to U.S. population.
Puzzilli et al. (2014) Study timeframe 2005 to 2009 Location Italy, Spain, Germany	n = 542 (422 underwent surgery vs. 120 conservative therapy) Adults with positional	Comparators IPD (X-STOP) vs. conservative therapy Patients meeting ZCQ "success" at 1 year *Symptom severity* 84% vs. 41% (p < .05)	ZCQ success defined as a "15 point improvement in normalized scores, along with a patient satisfaction score of less than 2.5." Baseline characteristics not fully reported.

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Methodological quality Poor	claudication, 6-month conservative therapy failure	*Physical function* 78% vs. 39% (p < .05) *Patient satisfaction* 81% vs. 40% (p < .05) *Complications* 25 (5%) intra-operative, 47 (11.1%) postoperative 16 spinous process fractures, 9 CSF leaks, 18 device dislocations with subsequent laminectomy/spinal fusion in 16 cases, another IPD used in remaining 2 *Reoperation or need for surgery* 24 out of 422 in surgery group (5.7%) due to worsening neurological symptoms 20 out of 120 in conservative group were reported to need surgery due to worsening of neurological symptoms (16.6%, unclear what timeframe)	Concern for selection bias because surgical group was 3 times larger than conservative therapy group despite report of 1:1 randomization scheme. After 24 months, conservative group stopped because of "poor clinical results" of physical and medical therapy. No further details provided. Staff not blinded. High loss to follow-up (11% at 1 year).

Abbreviations. CI: confidence interval; CSF: cerebrospinal fluid; DS: decompressive surgery; IPD: interspinous process device; MD: mean difference; ODI: Oswestry disability index; RCT: randomized controlled trial; RR: risk ratio; SD: standard deviation; SR: systematic review; WMD: weighted mean difference; VAS: visual analog scale; ZCQ: Zurich Claudication Questionnaire. Notes: a indicates assessed by review authors. In this instance, decompressive surgery was compared to IPD; Center researchers entered study data into OpenEpi (Dean, Sullivan, & Soe) and recalculated effect sizes to reflect IPD vs. decompressive surgery.*

Effectiveness Outcome #1: Pain or Symptom Severity (at ≥ 1 year)

Systematic Reviews

IPDs vs. conservative therapy

A systematic review (identifying a single RCT) provides evidence on the effectiveness of IPDs compared to conservative therapy for change in symptom severity (Zaina et al., 2016). The authors reported significantly improved symptom severity at one year for IPDs compared to conservative therapy using the ZCQ (specific data not reported). The authors rated the quality of the body of evidence as low.

IPDs vs. decompressive surgery (with or without fusion)

Three systematic reviews provide evidence on the effectiveness of IPDs compared to decompressive surgery for pain or symptom severity at a follow-up period of at least one year (Machado et al., 2016; Ren & Hu, 2016; Zhao et al., 2017). In one review, pain intensity was not significantly different for patients who received IPD compared to decompressive surgery or decompressive surgery with fusion (Machado et al., 2016). Two reviews found significantly higher back pain or leg pain among IPD recipients. The Ren & Hu meta-analysis of eight studies (n = 834) found significantly higher back pain and leg pain intensity among IPD recipients (Ren & Hu, 2016). However, when Ren & Hu (2016) limited their analysis to only RCTs (k = 3, n = 326), there were no significant differences across groups for leg pain, and back pain remained significantly greater for IPD recipients (WMD 0.62 (95% CI, 0.05 to 1.20)). In their meta-analysis (k = 4 RCTs, n = 400), Zhao and colleagues also observed greater pain in the IPD recipient group compared to DS for back pain at two years (9.65 points greater for IPD compared to DS (95% CI, 0.78 to 18.51)) (Zhao et al., 2017).

Individual Studies

IPDs vs. conservative therapy

Puzzilli et al. (2014) observed that a significantly greater proportion of patients reported improvement in symptom severity in the IPD group compared to the conservative treatment group. Center researchers identified potential selection bias in this study, given the greater number of individuals in the IPD group compared to conservative therapy (n = 422 surgery, n = 120 conservative therapy) despite reports of using a 1:1 randomization scheme (Puzzilli et al., 2014).

Effectiveness Outcome #2: Disability or Function (at ≥ 1 year)

Systematic Reviews

IPDs vs. conservative therapy

A systematic review (identifying a single RCT) provided evidence on the effectiveness of IPDs compared to conservative therapy for change in physical function (Zaina et al., 2016). The

authors reported significant improvements in physical function at one year for IPDs compared to conservative therapy using the ZCQ (specific data not reported). The authors rated the quality of the body of evidence as low.

IPDs vs. decompressive surgery (with or without fusion)

None of the three systematic reviews found statistically significant changes in function for recipients of IPDs compared to decompressive surgery (Machado et al., 2016; Ren & Hu, 2016; Zhao et al., 2017).

Two systematic reviews found no significant differences between recipients of IPDs compared to decompressive surgery in disability (mean difference -0.55; 95% CI, -8.08 to 6.99; mean difference 0.00; 95% CI, -12.47 to 12.48) (Machado et al., 2016; Ren & Hu, 2016). One systematic review reported contradictory results from the two studies using the Oswestry disability index (where higher scores convey greater disability) included in their review; one study observed no significant difference (IPDs 14.3 vs. DS 18.4; $p > 0.05$) and the other study observed a significant decrease in disability (IPDs 26.5 vs. DS 34.5 $p < .01$) for the IPD group (Zhao et al., 2017).

Individual Studies

IPD vs. IPD

Huang et al. (2015) reported overall improvements in disability scoring for both the Rocker and X-STOP groups. This RCT did not include a comparator to conservative therapy or decompressive therapy; thus, the effectiveness of IPDs alone are unknown.

Effectiveness Outcome #3: Quality of Life (at ≥ 1 year)

Systematic Reviews

IPD vs. conservative therapy

The single systematic review addressing IPD compared to conservative therapy did not identify any studies reporting quality of life outcomes (Zaina et al., 2016).

IPD vs. decompressive surgery with or without fusion

A single systematic review, Machado et al. (2016), observed no significant change in quality of life for IPD vs. decompressive surgery with or without fusion (MD -0.05; 95% CI, -0.18 to 0.07).

Individual Studies

Neither of the identified individual studies reported on quality of life outcomes (Huang et al., 2015; Puzzilli et al., 2014).

Effectiveness Outcome #4: Hospital Stay

Systematic Reviews

IPD vs. decompressive surgery without fusion

A single systematic review reported on differences in hospital stay for IPD compared to decompressive surgery without fusion and observed a significantly shorter hospital stay for IPD recipients (weighted mean difference -1.49 days; 95% CI, -2.94 to -0.04) (Ren & Hu, 2016).

Harms Outcome #1: Perioperative Blood Loss

Systematic Reviews

IPD vs. decompressive surgery with or without fusion

A single systematic review reported outcomes on perioperative blood loss (Machado et al., 2016). The authors observed that blood loss was not significantly different for IPD and decompression recipients; patients who underwent decompression with fusion experienced significantly greater blood loss than those undergoing IPD placement alone (mean difference 238 mL [95% CI, 182.66 to 295.14]; approximately 8 to 10 ounces).

Individual Studies

IPD vs. IPD

Blood loss was not significantly different for both IPD groups in Huang et al. (2015).

Harms Outcome #2: Need for Repeat Surgery

Systematic Reviews

IPD vs. decompressive surgery with or without fusion

The risk of reoperation was 2.5 to 4 times significantly greater for patients who underwent IPD placement compared to decompression surgery without fusion in all three systematic reviews:

- Risk ratio (RR) 3.95; 95% CI, 2.12 to 7.37 (Machado et al., 2016)
- RR 2.48; 95% CI, 1.71 to 3.61 (Ren & Hu, 2016)
- RR 2.91; 95% CI, 1.72 to 4.92 (Zhao et al., 2017)

The observed risk of reoperation was, on average, greater for patients who underwent IPD compared to decompression with fusion, but the finding was not statistically significant (RR 1.4; 95% CI, 0.66 to 3.09) (Machado et al., 2016).

Individual Studies

IPD vs. conservative therapy

Puzzilli et al. (2014) reported that 24 out of 422 individuals (5.7%) in the IPD group required reoperation. In the conservative group, 20 out of 120 were reported to need surgery due to worsening of neurological symptoms (16.6%).

Harms Outcome #3: Complications

Systematic Reviews

IPD vs. decompressive surgery without fusion

A single systematic review with meta-analysis observed a 46% decreased risk of complications for IPD compared to decompressive surgery without fusion (RR 0.54; 95 %CI, 0.30 to 0.95).

Individual Studies

Reports of complications were reported in both individual studies (Huang et al., 2015; Puzzilli et al., 2014) and included spinous process fractures, cerebrospinal fluid leaks, device dislocations requiring subsequent laminectomy/spinal fusion, and death (reported to not be related to IPD placement but not otherwise characterized). Puzzilli et al. (2014) reported that 5% of patients in the IPD group experienced an interoperative complication and 11.1% experienced a postoperative complication.

Costs

Two systematic reviews providing effectiveness evidence also included costs as an outcome (Machado et al., 2016; Zhao et al., 2017). As mentioned above, the systematic reviews were both rated as having good methodological quality. Table 2 provides study details for the included economic studies. The systematic review by Machado et al. (2016) reported that the incremental cost (difference in total costs) for IPD compared to DS was $3,103.84 greater (95% CI, $2,141.14 to $4,066.55). The authors did not find any cost estimates comparing IPD to decompression surgery with fusion (Machado et al., 2016). Zhao et al. (2017) identified two studies that provided cost estimates on IPDs compared to decompressive surgery, and in-narrative text reported greater costs for IPDs compared to DS without improved quality of life.

Table 2. Economic Studies

Citation, Study Details	Population (n)	Study Summary and Findings	Comments
Systematic Reviews			
Machado et al. (2016) Search Dates Inception to June 2016 Included Study Designs Economic studies Methodological Quality Good	k = 2 total n = 240 *SR's quality assessment of individual studies:* Fair-quality evidence	Comparators IPD vs. DS Outcomes Incremental cost for an implant $3,1013.84 (95% CI, $2,141.14 to $4,066.55) The SR did not identify any cost estimates on IPD vs. DS with fusion.	The authors noted the cost estimates to be imprecise. One of the individual studies funded by industry could lead to biased estimates of cost.
Zhao et al. (2017) Search Dates Inception to June 2016 Included Study Designs Economic studies Methodological Quality Good	k = 2 total n = not reported *SR's quality assessment of individual studies:* Good	Comparators IPD vs. DS Outcomes *Initial treatment costs** $6,155.59 vs. $3,148.98 p < 0.01 *Total societal costs** $18,099.77 vs. $14,492.36 p < 0.01	Original studies conducted in Netherlands and Norway, and so might not reflect U.S. costs.

*Abbreviations. IPD: interlaminar/interspinous process distraction devices; DS: decompressive surgery; SR: systematic review. Notes: *Costs converted from 2013 euros to U.S. dollars using www.x-rates.com.*

Clinical Practice Guidelines

Center researchers identified one fair methodological quality clinical practice guideline that addresses the use of IPDs for neurogenic claudication or lumbar spinal stenosis. Table 3 provides a summary of recommendations from the North American Spine Society. The strength of underlying evidence noted in the table for guideline recommendations is an assessment by guideline authors and not Center researchers.

The guideline is based on a 2013 review of the literature, and thus does not include the most recent evidence available. One guideline author received significant research support from an IPD manufacturer.

Table 3. Summary of Clinical Practice Guidelines' Recommendations for the Use of IPDs

Citation, Methodological Quality	Recommendation (Evidence Rating)
North American Spine Society (2014, p.13) Methodological Quality Fair	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: Insufficient Evidence*

*Note. *Determined by guideline authors.*

Payer Policies

Center researchers searched for coverage policies on IPDs for the treatment of lumbar spinal stenosis from Aetna, Anthem, Blue Shield of Northeastern New York, Capital District Physicians' Health Plan, Centers for Medicare and Medicaid Services (CMS), Cigna, Emblem Health, Empire Blue Cross Blue Shield (BCBS), Excellus BCBS, Tufts Health Plan, UnitedHealthcare, and nine state Medicaid programs (CA, FL, MA, NJ, NY, OR, PA, TX, and WA).

A search of the CMS website identified two local coverage determinations (LCDs); Medicare policies are discussed in detail below. Of the 10 private payers searched, seven payers (Aetna, Anthem, Blue Shield of Northeastern New York, Cigna, Empire BCBS, Excellus BCBS, and UnitedHealthcare) do not cover IPDs for enrollees, although Blue Shield of Northeastern New York does cover IPDs for Medicare advantage members. No publicly available coverage policies were identified for the Capital District Physicians' Health Plan and the Tufts Health Plan. Emblem Health covers IPDs under certain conditions, as described below. Center researchers were not able to identify coverage policies for IPDs in any of the nine state Medicaid programs searched.

Medicare Coverage Policies

National Coverage Determination

No national coverage determination on IPDs identified through the current search.

Local Coverage Determinations

Center researchers identified two Medicare LCDs pertaining to IPDs. The first LCD (L34006) was issued in January 2017 by First Coast Service Options, Inc. and covers the jurisdictions of Florida, Puerto Rico, and the U.S. Virgin Islands (First Coast Service Options Inc., 2017). This LCD refers to IPDs as interspinous process decompression and covers the procedure for individuals meeting the following criteria:

- Aged 50 or older suffering from (intermittent neurogenic claudication) secondary to a *confirmed* diagnosis of lumbar spinal stenosis.
- With moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain; and
- Patients who have undergone at least 6 months of non-operative treatment (First Coast Service Options Inc., 2017, p. 2).

Patients with the following conditions would be excluded from coverage of the procedure:

- Allergic to titanium or titanium alloy
- Spinal anatomy or disease that would prevent implant of the device or cause the device to be unstable *in situ,* such as significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4); an ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis
- Significant scoliosis (Cobb angle greater than 25 degrees)
- Cauda equine syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normal in the presence of one or more fragility fractures
- Active systemic infection or infection localized at the site of implantation
- Body mass index (BMI) > 40 kg/m^2 (First Coast Service Options Inc., 2017, pp. 1-2)

The LCD further states that diagnosis of lumbar spinal stenosis should be confirmed by radiological tests such as a CT scan, MRI, or a myelogram and that the patient should not have previously received a laminotomy or laminectomy at the same level of spine targeted by the intervention (First Coast Service Options Inc., 2017, pp. 4-5).

The second LCD (L35942) was issued by Cahaba Government Benefit Administrators, LLC, in February 2017 and covers Alabama, Georgia, and Tennessee (Cahaba Government Benefit Administrators LLC, 2017). Titled "Surgery: Fusion for Degenerative Joint Disease of the Lumbar Spine," the LCD primarily addresses spinal fusion procedures for individuals with an ICD-10 diagnostic code of spondylolysis (i.e., a defect in the connection between vertebrae) and does not provide any specific criteria for coverage or exclusion from coverage for IPDs (Cahaba Government Benefit Administrators LLC, 2017). The LCD does include the four codes discussed in this review (CPT codes 22867-22870) without any further information (Cahaba Government Benefit Administrators LLC, 2017).

Private Payer Policies

As noted above, seven of the 10 private payers searched do not cover IPDs for their general populations and consider the procedure investigational and not medically necessary. Specific language used by each private payer is included in the Table 4 and 5 below. Center researchers were not able to identify coverage policies for Capital District Physicians' Health Plan and Tufts Health Plan.

Emblem Health does cover IPDs with the same criteria used by First Coast Service Options, Inc. [LCD (L34006), discussed above], although Emblem Health does not have a BMI requirement. Blue Shield of Northeastern New York covers IPDs for its Medicare Advantage members under criteria similar to Emblem Health's.

Medicaid Policies

Center researchers did not identify Medicaid coverage policies for IPDs for the nine states searched.

Summary of Payer Policies

Table 4 and Table 5 provide a comparison of the four coverage policies identified, including indications for coverage and coverage limitations: the two Medicare LCDs, Emblem Health, and Blue Shield of Northeastern New York's Medicare Advantage coverage. Table 6 includes the language used by the seven private payer policies that do not cover IPDs.

Table 4. Indications for Coverage of IPDs

Payer	Indications for Coverage			
	≥ age 50 with symptoms of intermittent neurogenic claudication	Confirmed diagnosis of lumbar spinal stenosis (radiological reports)	Moderately impaired function with relief from symptoms with flexion	≥ 6 months of failed non-operative treatment*
Medicare				
LCD (L34006) *(effective 1/1/2017)*	√	√	√	√
LCD (L35942) *(effective 2/17/2017)*	*No specific coverage criteria identified.*			
Private Payers				
Emblem Health *(last review 5/27/2016)*	√	√	√	√
Blue Shield of Northeastern New York (for Medicare Advantage members only) *(last review 7/2016)*	√	√	√	√

Note. *Non-operative treatment includes nonsteroidal anti-inflammatory medications, analgesics, oral and epidural steroids, rest, physical therapy, and bracing.*

Table 5: Limitations and Exclusions of Coverage

Payer	Limitations and Exclusions of Coverage						
	Allergy to titanium or titanium alloy	Spinal anatomy or disease that would prevent implementation of device[1]	Significant scoliosis (Cobb angle >25 degrees)	Cauda Equina Syndrome	Diagnosis of Severe Osteoporosis[2]	Active systemic infection or infection localized at the implantation site	Body mass index (BMI) >40 kg/m^2
Medicare							
LCD (L34006) *(effective 1/1/2017)*	√	√	√	√	√	√	√
LCD (L35942) *(effective 2/17/2017)*	*No information on coverage limitations or exclusions identified.*						
Private Payers							
Emblem Health *(last review 5/27/2016)*	√	√	√	√	√	√	---
Blue Shield of Northeastern New York (for Medicare Advantage members only) *(last review 7/2016)*	*No information on coverage limitations or exclusions identified.*						

Note. [1]Defined as isthmic spondylolisthesis or degenerative spondylolisthesis >1.0 (on a 1 to 4 scale); ankylosed segment at the affected level(s); acute fracture of the spinous process or pars interarticularis. [2]Defined as bone mineral density from DEXA scan or some comparable study in the spine or hip that is >2.5 standard deviations below the mean of adult normal in the presence of ≥1 fragility fracture.

Table 6: Payers without Coverage Policies

Payer	Policy Language
Private Payers	
Aetna (*last review 12/2016*)	"Considered experimental and investigational"
Anthem (*last review 11/2016*)	"Investigational and not medically necessary"
BSNENY (*last review 7/2016*)	"Investigational" (commercial policy; see Medicare Advantage coverage policy in Tables 4 and 5 above)
CDPHP	*Coverage policy not publicly available.*
Cigna (*effective 4/15/2017*)	"Experimental, investigational or unproven"
Empire BCBS (*last review 11/2016*)	"Investigational and not medically necessary"
Excellus BCBS (*last review 6/2016*)	"Have not been proven to be medically effective and are considered investigational for all indications"
Tufts Health Plan	*No coverage criteria identified.*
UnitedHealthcare (*effective 4/1/2017*)	"Unproven"
State Medicaid	
California	*No coverage criteria identified.*
Florida	*No coverage criteria identified.*
Massachusetts	*No coverage criteria identified.*
New Jersey	*No coverage criteria identified.*
New York	*No coverage criteria identified.*
Oregon	*No coverage criteria identified.*
Pennsylvania	*No coverage criteria identified.*
Texas	*No coverage criteria identified.*
Washington	*No coverage criteria identified.*

Abbreviations. BCBS: Blue Cross Blue Shield; BSNENY: Blue Shield Northeastern New York; CDPHP: Capital District Physicians' Health Plan.

Conclusions

Lumbar spinal stenosis is a common degenerative condition that causes pain in the legs, which can limit function and quality of life. Treatment options range from conservative efforts to invasive surgeries; IPDs offer a less invasive surgical option than decompression with or without spinal fusion. Compared to spinal decompression with or without spinal fusion, systematic reviews with and without meta-analyses have consistently demonstrated no significant change in pain, function, or disability scores with a consistently increased risk of need for reoperation in patients undergoing IPD placement. Complications of IPD placement have been reported in 5% to 16% of individuals and include but are not limited to spinous process fracture, device dislocation, cerebral spinal fluid leak, and complications of general anesthesia (e.g., cardiac ischemia, respiratory distress). Low methodological quality evidence from a single RCT, identified in a good methodological quality systematic review, demonstrated improved pain, function, and disability for IPDs compared to conservative therapy. Clinical practice guidelines do not make a recommendation on the use of IPDs, but are not up to date. Current coverage policies place IPDs as investigational in the majority of private policies identified. No state Medicaid policies were identified in this report.

Strength of Evidence

The Center uses the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group approach to enhance consistency in grading the strength of evidence. RCTs are initially categorized as having high strength of evidence and observational studies are categorized as having low strength of evidence. The strength rating is downgraded based on limitations including inconsistency of results, uncertainty of directness of measurement or population, imprecise or sparse data, and high probability of reporting bias. The grade is increased from low for evidence from observational studies if there is a strong association (i.e., significant relative risk of >2 or <0.5 with no plausible confounders in two or more observational studies), a very strong association (i.e., significant relative risk of >5 or <0.2 based on direct evidence with no major threats to validity), or a dose-response gradient. The grade is also increased if all plausible confounders would have reduced the effect (GRADE Working Group, 2004). Tables 7 and 8 provide an overview of the strength of evidence by outcome and associated rationale for the strength of evidence rating.

Table 7. Strength of Evidence for IPDs Compared to Conservative Therapy: Effectiveness, Harms, and Cost-Effectiveness

Outcome	Strength of Evidence Assessment	Rationale
Effectiveness		
Symptom severity	Low	A single SR identified a single RCT addressing this comparison, which reported significant improvements for IPD compared to conservative therapies for these outcomes. • Downgraded one level for study risk of bias • Downgraded one level for indirectness
Function		
Disability		
Quality of life	Unknown	The current search did not identify any evidence on this outcome
Harms		
Bleeding	Unknown	The current search did not identify any evidence on this outcome.
Reoperation	Very low	The single individual study that reported on this outcome provided non-comparative data on risk of reoperation. • Downgraded one level for study risk of bias
Electing to have surgery after conservative therapy course	Very low	The single individual study that reported on this outcome provided non-comparative data on risk of electing to have surgery after conservative therapy. • Downgraded one level for study risk of bias
Complications	Moderate	A single SR and 2 individual studies reported greater complications for IPD recipients than patients who underwent conservative therapy. • Downgraded one level for study risk of bias
Costs		
Costs or cost-effectiveness	Unknown	The current search did not identify any evidence on this outcome.

Table 8. Strength of Evidence for IPDs Compared to Decompressive Therapy with or without Fusion: Effectiveness, Harms, and Cost-Effectiveness

Outcome	Strength of Evidence Assessment	Rationale
Effectiveness		
Symptom Severity	Moderate	Effectiveness of IPDs are inconsistent across SRs of good methodological quality. Estimates of effectiveness range from not significantly different to significantly greater pain for IPD recipients. • Downgraded one level for inconsistency
Function	High	IPDs are not significantly different compared to DS with or without fusion across multiple high methodological quality systematic reviews.
Quality of life	High	IPDs are not significantly different compared to DS with or without fusion across multiple high methodological quality systematic reviews.
Disability	High	IPDs are not significantly different compared to DS with or without fusion across multiple high methodological quality systematic reviews.
Harms		
Bleeding	High	IPD group experienced similar amounts of bleeding to DS. IPD group experienced less perioperative bleeding than DS with fusion; the clinical significance of this is not clear.
Reoperation	High	IPDs consistently demonstrate increased risk of reoperation compared to DS with or without fusion across good methodological quality systematic reviews.
Complications	Moderate	A single SR reported reduced risk of complication for IPD compared to DS, but the estimate was imprecise. • Downgraded one level for imprecision
Costs		
Incremental cost-effectiveness ratio	Moderate	IPDs reported as having increased costs without significant improvement in quality-adjusted life-years. • Downgraded for risk of bias.

References

Cahaba Government Benefit Administrators LLC. (2017). *Local coverage determination (LCD): Surgery: Fusion for degenerative joint disease of the lumbar spine (L35942)*. Retrieved from https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35942&ver=10&Cntrctr=275&CntrctrSelected=275*1&name=+(06302%2c+MAC+-+Part+B)&s=18&DocType=Future&LCntrctr=All&bc=AgIAAAAAAAAA%3d%3d&

Campbell Collaboration. (2017). *For researchers*. Retrieved from https://www.campbellcollaboration.org/research-resources.html

ClinicalTrials.gov. (2011). *Wallis stablization system for low back pain*. Retrieved from https://clinicaltrials.gov/ct2/show/NCT00484458

Cochrane. (2017). *Cochrane handbook for systematic reviews of interventions*. Retrieved from http://training.cochrane.org/handbook

Davis, R. J., Errico, T. J., Bae, H., & Auerbach, J. D. (2013). Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: Two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. *Spine, 38*(18), 1529-1539. doi: https://dx.doi.org/10.1097/BRS.0b013e31829a6d0a

Dean, A., Sullivan, K., & Soe, M. *OpenEpi: Open source epidemiologic statistics for public health*. Retrieved from http://www.openepi.com/TwobyTwo/TwobyTwo.htm

First Coast Service Options Inc. (2017). Local coverage determination (LCD): Interspinous process decompression (L34006).

GRADE Working Group. (2004). Grading quality of evidence and strength of recommendations. *British Medical Journal, 328*, 1-8.

Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., & Schünemann, H. J. (2008). GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ, 336*(7650), 924-926. doi: 10.1136/bmj.39489.470347.AD

Hong, P., Liu, Y., & Li, H. (2015). Comparison of the efficacy and safety between interspinous process distraction device and open decompression surgery in treating lumbar spinal stenosis: a meta analysis. *Journal of Investigative Surgery, 28*(1), 40-49. doi: 10.3109/08941939.2014.932474

Huang, W., Chang, Z., Zhang, J., Song, R., & Yu, X. (2015). Interspinous process stabilization with Rocker via unilateral approach versus X-Stop via bilateral approach for lumbar spinal stenosis: A comparative study. *BMC Musculoskeletal Disorders, 16*(1), 328.

Machado, G. C., Ferreira, P. H., Yoo, R. I., Harris, I. A., Pinheiro, M. B., Koes, B. W., . . . Ferreira, M. L. (2016). Surgical options for lumbar spinal stenosis. *Cochrane Database of Systematic Reviews,* (11). Retrieved from http://onlinelibrary.wiley.com/store/10.1002/14651858.CD012421/asset/CD012421.pdf?v=1&t=j2huyg2m&s=686db3e9de15c19ddad9b1ec0002cd17de44f787 doi:10.1002/14651858.CD012421

Mass Device. (2016). Retrieved from http://www.massdevice.com/fda-panel-votes-against-medtronics-diam-spine-stabilization-system/

Moojen, W. A., Arts, M. P., Bartels, R. H. M. A., Jacobs, W. C. H., & Peul, W. C. (2011). Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: A systematic review and meta-analysis. *European Spine Journal, 20*(10), 1596-1606. doi: https://dx.doi.org/10.1007/s00586-011-1873-8

National Institute for Health and Care Excellence. (2009). *Developing NICE guidelines: The manual*. London: NICE. Retrieved from https://www.nice.org.uk/proxy/?sourceUrl=http%3a%2f%2fwww.nice.org.uk%2fmedia%2f095%2fFE%2fDeveloping_NICE_guidelines_manual_draft_for_consultation.pdf.

National Institute for Health and Care Excellence. (2010). *Interventional procedure overview of interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication*. Retrieved from https://www.nice.org.uk/guidance/ipg365/evidence/overview-495587773

North American Spine Society. (2014). *Evidence-based clinical guidelines for multidisciplinary spine care*. Retrieved from https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf

Preferred Reporting Items for Systematic Reviews and Meta-Analyses. (2015). *PRISMA statement*. Retrieved from http://www.prisma-statement.org/Default.aspx

Puzzilli, F., Gazzeri, R., Galarza, M., Neroni, M., Panagiotopoulos, K., Bolognini, A., . . . Alfieri, A. (2014). Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: A multicenter study with a minimum 3-year follow-up. *Clinical Neurology & Neurosurgery, 124*, 166-174. doi: https://dx.doi.org/10.1016/j.clineuro.2014.07.004

Ren, S., & Hu, Y. (2016). Stand-alone interspinous spacers versus decompressive surgery in lumbar spinal stenosis: A systematic review and meta-analysis. *Inernational Journal of Clinical and Experimental Medicine, 9*(7), 13359-13371.

Scottish Intercollegiate Guidelines Network. (2009). *Critical appraisal: Notes and checklists*. Retrieved from http://www.sign.ac.uk/methodology/checklists.html

Staats, P. S., & Benyamin, R. M. (2016). MiDAS ENCORE: Randomized controlled clinical trial report of 6-month results. *Pain physician, 19*(2), 25-38.

Stordeur, S., Gerkens, S., & Roberfroid, D. (2009). *Interspinous implants and pedicle screws for dynamic stabilization of lumbar spine: Rapid assessment*. Belgian Health Care Knowledge Centre. Retrieved from https://kce.fgov.be/sites/default/files/page_documents/d20091027346.pdf.

U.S. Food and Drug Administration. (2005). *Premarket approval: X Stop interspinous process decompression system*. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P040001

U.S. Food and Drug Administration. (2012). *Summary of safety and effectivness data: Coflex interlaminar technology*. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf

U.S. Food and Drug Administration. (2015). *Premarket approval letter: Superion interspinous spacer*. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140004a.pdf

Vertos Medical. (2016). *A formal request for a national coverage determination (NCD) on percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS)*. Retrieved from https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id284.pdf

Wu, A.-M., Zhou, Y., Li, Q.-L., Wu, X.-L., Jin, Y.-L., Luo, P., . . . Wang, X.-Y. (2014). Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: A systematic review and meta-analysis. *PLoS One, 9*(5), e97142.

Yaghoubi, M., Moradi-Lakeh, M., Moradi-Joo, M., Rahimi-Movaghar, V., Zamani, N., & Naghibzadeh-Tahami, A. (2016). The cost effectiveness of dynamic and static interspinous spacer for lumbar spinal stenosis compared with laminectomy. *Medical Journal of the Islamic Republic of Iran, 30*, 339.

Zaina, F., Tomkins-Lane, C., Carragee, E., & Negrini, S. (2016). Surgical versus non-surgical treatment for lumbar spinal stenosis. *Cochrane Database of Systematic Reviews*(1). doi: 10.1002/14651858.CD010264.pub2

Zhao, X.-W., Ma, J.-X., Ma, X.-L., Li, F., He, W.-W., Jiang, X., . . . Lu, B. (2017). Interspinous process devices (IPD) alone versus decompression surgery for lumbar spinal stenosis (LSS): A systematic review and meta-analysis of randomized controlled trials. *International Journal Of Surgery, 39*, 57-64. doi: https://dx.doi.org/10.1016/j.ijsu.2017.01.074

Zucherman, J. F., Hsu, K. Y., Hartjen, C. A., Mehalic, T. F., Implicito, D. A., Martin, M. J., . . . Ozuna, R. M. (2004). A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. *European Spine Journal, 13*(1), 22-31. doi: 10.1007/s00586-003-0581-4

Appendix A. Methods

General Search Strategy

Evidence

A full search of Center's core clinical evidence primary sources was conducted to identify systematic reviews, meta-analyses, and technology assessments using the search terms *(interspinous or interlaminar) and (stabiliz* or distract*) and (device* or spacer* or implant*)*. Searches of core sources were limited to sources published after 2007. Center researchers also searched the MEDLINE® (Ovid) database for relevant systematic reviews, meta-analyses, and technology assessments, and for individual studies published after the search dates of the identified systematic reviews, and cost-effectiveness studies published after 2007.

The core sources searched included the following:

Agency for Healthcare Research and Quality (AHRQ)

BMJ Clinical Evidence

Cochrane Library (Wiley Interscience)

National Institute for Health and Care Excellence (NICE)

PubMed Health

Tufts Cost-Effectiveness Analysis Registry

Veterans Administration Evidence-based Synthesis Program (ESP)

Washington State Health Technology Assessment Program

Clinical Practice Guidelines

Center researchers conducted a full search of Center clinical practice guidelines primary sources to identify clinical practice guidelines using the terms *Interspinous* or *interlaminar*. Searches were limited to sources published within the last five years.

The guideline sources included the following:

Australian Government National Health and Medical Research Council (NHMRC)

Centers for Disease Control and Prevention (CDC) – Community Preventive Services

Institute for Clinical Systems Improvement (ICSI)

National Guidelines Clearinghouse

National Institute for Health and Care Excellence (NICE)

Scottish Intercollegiate Guidelines Network (SIGN)

United States Preventive Services Task Force (USPSTF)

Veterans Administration/Department of Defense (VA/DOD)

North American Spine Society

American Society of Interventional Pain Physicians

American College of Rheumatology

Coverage Policies

Center researchers searched for policies on the coverage of IPDs for the treatment of lumbar spinal stenosis from Aetna, Anthem, Blue Shield of Northeastern New York, Capital District Physicians' Health Plan, Centers for Medicare and Medicaid Services, Cigna, Emblem Health, Empire BCBS, Excellus BCBS, Tufts Health Plan, UnitedHealthcare, and nine state Medicaid programs (CA, FL, MA, NJ, NY, OR, PA, TX, WA).

General Exclusion Criteria

Staff members excluded studies that were not systematic reviews, meta-analyses, or technology assessments, in addition to individual studies (as applicable by topic) that were published before 2007 or published in a language other than English. A systematic review containing individual studies published earlier or of lower methodological quality was excluded when a newer or higher methodological quality review was identified.

Quality Assessment

Center researchers assessed the methodological quality of the included studies using standard instruments developed and adapted by the Center that are modifications of the systems in use by the Campbell Collaboration, Cochrane, the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA), the National Institute for Health and Care Excellence (NICE), and the Scottish Intercollegiate Guidelines Network (SIGN) (Campbell Collaboration, 2017; Cochrane, 2017; Guyatt et al., 2008; NICE, 2009; PRISMA, 2015; SIGN, 2009).Two Center researchers independently rated all studies. In cases where there was not agreement about the quality of a study, consensus was reached through discussion.

Each rater assigned the study a rating of good, fair, or poor, based on its adherence to recommended methods and potential for biases. In brief, good-quality systematic reviews include a clearly-focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., RCTs) and assess study quality, and assessments of heterogeneity to determine if a meta-analysis would be appropriate. Good-quality RCTs include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Good-quality systematic reviews and RCTs also have low potential for bias from conflicts of interest and funding source(s). Fair-quality systematic reviews and RCTs

have incomplete information about methods that might mask important limitations. Poor-quality systematic reviews and RCTs have clear flaws that could introduce significant bias.

Ovid MEDLINE Search

Lumbar spinal stenosis MEDLINE search:
Database: Ovid MEDLINE <1946 to April Week 4 2017>

Search Strategy, lumbar spinal stenosis:

1 ((interspinous or interlaminar) and (stabiliz* or distract*) and (device* or spacer* or implant*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

2 limit 1 to (english language and humans)

3 limit 2 to yr="2013 -Current"

4 stenosis, lumbar.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

5 spinal stenosis.mp. or Spinal Stenosis/

6 4 or 5

7 3 and 6

8 limit 7 to (clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or guideline or meta analysis or practice guideline or randomized controlled trial or systematic reviews)

Claudication MEDLINE® search:
Database: Ovid MEDLINE(R) <1946 to May Week 2 2017>

Search Strategy:

1 ((interspinous or interlaminar) and (stabiliz* or distract*) and (device* or spacer* or implant*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

2 neurogenic claudication.mp.

3 Intermittent Claudication/ or claudication.mp.

4 2 or 3

5 1 and 4

6 limit 5 to (english language and humans)

7 limit 6 to (clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or guideline or meta analysis or practice guideline or randomized controlled trial or systematic reviews)

Appendix B. Articles Selected for Full-Text Review Inclusion/Exclusion Rationale

Citation	Exclusion Rationale
Davis, Errico, Bae, and Auerbach (2013)	Included in Machado et al. (2016)
Hong, Liu, and Li (2015)	Supplanted by higher quality SR
Moojen et al. (2011)	Supplanted by higher quality SR
National Institute for Health and Care Excellence (2010)	Supplanted by newer SR
Staats and Benyamin (2016)	Excluded: wrong intervention
Stordeur et al. (2009)	Supplanted by newer SR
Vertos Medical (2016)	Excluded: wrong intervention
Wu et al. (2014)	Supplanted by newer SR
Yaghoubi et al. (2016)	Supplanted by higher-quality SR, cost estimates without methods
Zucherman et al. (2004)	Included in Zaina et al. (2016)

Abbreviations. SR: systematic review.

References Excluded (on Full-Text Review)

Davis, R. J., Errico, T. J., Bae, H., & Auerbach, J. D. (2013). Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: Two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. *Spine, 38*(18), 1529-1539. doi: https://dx.doi.org/10.1097/BRS.0b013e31829a6d0a

Hong, P., Liu, Y., & Li, H. (2015). Comparison of the efficacy and safety between interspinous process distraction device and open decompression surgery in treating lumbar spinal stenosis: A meta-analysis. *Journal of Investigative Surgery, 28*(1), 40-49. doi: 10.3109/08941939.2014.932474

Moojen, W. A., Arts, M. P., Bartels, R. H. M. A., Jacobs, W. C. H., & Peul, W. C. (2011). Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: A systematic review and meta-analysis. *European Spine Journal, 20*(10), 1596-1606. doi: https://dx.doi.org/10.1007/s00586-011-1873-8

National Institute for Health and Care Excellence. (2010). I*nterventional procedure overview of interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication.* Retrieved from https://www.nice.org.uk/guidance/ipg365/evidence/overview-495587773

Staats, P. S., & Benyamin, R. M. (2016). MiDAS ENCORE: Randomized controlled clinical trial report of 6-month results. *Pain Physician, 19*(2), 25-38.

Stordeur, S., Gerkens, S., & Roberfroid, D. (2009). Interspinous implants and pedicle screws for dynamic stabilization of lumbar spine: Rapid assessment. *Belgian Health Care Knowledge Centre*. Retrieved from https://kce.fgov.be/sites/default/files/page_documents/d20091027346.pdf

Vertos Medical. (2016). *A formal request for a national coverage determination (NCD) on percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS).* Retrieved from https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id284.pdf

Wu, A.-M., Zhou, Y., Li, Q.-L., Wu, X.-L., Jin, Y.-L., Luo, P., . . . Wang, X.-Y. (2014). Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: A systematic review and meta-analysis. *PLoS One, 9*(5), e97142.

Yaghoubi, M., Moradi-Lakeh, M., Moradi-Joo, M., Rahimi-Movaghar, V., Zamani, N., & Naghibzadeh-Tahami, A. (2016). The cost effectiveness of dynamic and static interspinous spacer for lumbar spinal stenosis compared with laminectomy. *Medical Journal of the Islamic Republic of Iran, 30*, 339.

Zucherman, J. F., Hsu, K. Y., Hartjen, C. A., Mehalic, T. F., Implicito, D. A., Martin, M. J., . . . Ozuna, R. M. (2004). A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. *European Spine Journal, 13*(1), 22-31. doi: https://dx.doi.org/10.1007/s00586-003-0581-4

Appendix C. List of Ongoing Trials

Trial	Status	Intervention
Feasibility Study of NL-Prow Interspinous Spacer to Treat Lumbar Spinal Stenosis	Unknown	Device: NL-Prow interspinous spacer implant
Investigating Superion™ In Spinal Stenosis	Completed	Device: Superion™ Interspinous Spacer Device: X-STOP® IPD® Device
Intermittent Neurogenic Claudication Treatment With APERIUS® (INCA)	Completed	Device: Aperius® Percutaneous Interspinous Spacer
A Study of the In-Space Device for Treatment of Moderate Spinal Stenosis (In-Space)	Terminated	Device: Interspinous Spacer device Device: Interspinous Process Distraction Device
Study on the Treatment of Degenerative Lumbar Spine Stenosis With a Percutaneous Interspinous Implant	Terminated	Procedure: Spacer Other: physiotherapy
Condition of Approval Study (COAST)	Terminated	Device: X-STOP PEEK
Study Evaluating the Safety and Effectiveness of the FLEXUS(TM) Interspinous Spacer	Terminated	Device: FLEXUS(TM) Interspinous Spacer Device: XSTOP® Interspinous Spacer
Long-Term Outcomes for Lumbar Spinal Stenosis Patients Treated With X STOP®	Completed	Device: X STOP® Interspinous Process Decompression System
DIAM™ Spinal Stabilization System vs. Decompression, Formerly vs. Posterolateral Fusion	Terminated	Procedure: Single-Level Posterior Decompression Device: DIAM Spinal Stabilization Device: Fusion

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Suggested citation: Ray, M. K., Thielke, A., Carson, S., Leof, A., King, V., & Harrod, C. S. (2017). *Interlaminar/interspinous process distraction devices for neurogenic claudication or lumbar spinal stenosis (CPT codes 22867-22870)*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Conflict of Interest Disclosures: No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

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