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Interspinous Fixation (Fusion) Devices

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Disclaimer

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Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Interspinous fixation (fusion) devices, **are considered experimental, investigational and/or unproven** for any indication, including but not limited to use:

- In combination with interbody fusion, or
- Alone for decompression in individuals with spinal stenosis.

EXCEPTION: Clinical input has identified potential exceptions where the devices might be considered medically necessary, such as individuals with small pedicles where pedicle screws could not be safely placed.

NOTE 1: The Coflex Interlaminar Stabilization Device, referred to in SUR712.029 (Interspinous Distraction (Spacers) and Interlaminar Stabilization Device), is different from the coflex-IF® device addressed in this policy.

NOTE 2: The name of the specific fixation device used for the procedure should be included in the clinical documentation.

Policy Guidelines

None.

Description

Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

Background
Contemporary models of interspinous fixation devices have evolved from spinous process wiring with bone blocks and early device designs (e.g., Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. They are intended as an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed under direct visualization or percutaneously. Use of an interspinous fixation devices in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for stand-alone use.

For use in combination with fusion, it has been proposed that interspinous fixation devices are less invasive and present fewer risks than pedicle or facet screws. While biomechanics studies have indicated that interspinous fixation devices may be similar to pedicle screw-rod constructs in limiting the range of flexion and extension, they may be less effective than bilateral pedicle screw-rod fixation for limiting axial rotation and lateral bending. (1) There is a potential for a negative impact on the interbody cage and bone graft due to focal kyphosis resulting from the interspinous fixation devices. There is also a potential for spinous process fracture.

Unlike interspinous fixation devices, interspinous distraction devices (spacers) are used alone for decompression and are typically not fixed to the spinous process. In addition, interspinous distraction devices have been designed for dynamic stabilization, whereas interspinous fixation devices are rigid. However, interspinous fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, interspinous fixation devices could be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If interspinous fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

Regulatory Status
The following interspinous fixation devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. This list may not be exhaustive.

- Aerial™ Interspinous Fixation (Globus Medical Inc.)
- Affix™ (NuVasive)
- Aileron™ (Life Spine)
- Aspen™ (Lanx, acquired by BioMet)
- Axle™ (X-Spine)
- BacFuse® (Pioneer Surgical)
- BridgePoint™ (Alphatec Spine)
- coflex-IF® (Paradigm Spine)
- Inspan™ (Spine Frontier)
- InterBRIDGE® Interspinous Posterior Fixation System (LDR Spine)
- Minuteman™ (Spinal Simplicity)
- Octave™ (Life Spine)
- PrimaLOK™ (OsteoMed Spine)
- Spire™ (Medtronic)
- SP-Fix™ (Globus)
- SP-Link™ System (Medical Designs LLC)
- ZIP® MIS Interspinous Fusion System (Aurora Spine).

Food and Drug Administration product code: PEK.

Interspinous fixation devices are intended for use as an adjunct to interbody fusion. For example, the indication for the coflex-IF® implant is as:

> "a posterior, nonpedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies – with up to Grade 1 spondylolisthesis."

A number of interspinous plate systems have also been cleared for marketing by the Food and Drug Administration.

Use of an interspinous fixation devices for a stand-alone procedure is considered off-label.

Rationale

This policy was originally created in February 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed though January 16, 2023.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality

of life, and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical uses of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Interspinous Fixation Device With Fusion

Clinical Context and Therapy Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals who are undergoing spinal fusion.

The question addressed in this medical policy is: Does the use of interspinous fixation improve the net health outcome in individuals who are undergoing spinal fusion?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing spinal fusion.

Interventions

The therapy being considered is interspinous fixation devices with interbody fusion.

Comparators

The following practice is currently being used for individuals who are undergoing spinal fusion: interspinous fixation devices with pedicle screw construct.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A systematic review by Lopez et al. (2017) evaluated the literature on lumbar spinous process fixation and fusion devices. (2) Reviewers included both interspinous plates and fixation devices and excluded dynamic devices such as the X-Stop. Fifteen articles met inclusion and exclusion criteria, including 4 comparative studies (level III evidence), 2 case series (level IV evidence), and 9 in vitro biomechanics studies (level V evidence). Two of the nonrandomized studies compared interspinous fixation devices with pedicle screws in patients undergoing interbody fusion and 2 included interspinous fixation devices alone or pedicle screws plus an interspinous fixation devices in patients undergoing interbody fusion. Use of an interspinous fixation device decreased surgical time and blood loss compared with pedicle screws. No study showed that interspinous fixation devices reduced the hospital length of stay compared with pedicle screw implantation.

Randomized Controlled Trials

Subsequent to the systematic review by Lopez et al. (2017), 2 small RCTs (total N = 149) have been published on individuals with single-level lumbar degenerative diseases undergoing spinal fusion who receive an interspinous fixation device with interbody fusion as alternatives to pedicle screw and rod constructs (Table 1). (3, 4) The first was a single-center study by Huang et al. (2017) that randomized 46 individuals to either an unknown type of interspinous fixation devices or pedicle screws and followed them for 24 months. (3) The second was a multicenter study by Panchal et al. (2018) that randomized 103 individuals to either the Aspen MIS Fusion System or pedicle screws and followed them for 12 months. (4) Compared to the pedicle screw control groups (Table 2), similar or better fusion, disability, and quality of life outcomes were observed for the interspinous fixation device groups. Comparative complications rates were mixed across studies, but comparative treatment effects were not calculated. In the study by Panchal et al. (2018), revisions were numerically lower in the interspinous fixation device group, but comparative treatment effects were not calculated. Interpretation of these findings is limited by important weaknesses, however. In the RCT by Panchal et al. (2018), weaknesses included insufficient follow-up duration, lack of control for selection bias, and data incompleteness (Tables 3 and 4). In the RCT by Huang et al. (2017), weaknesses include unclear blinding of outcome assessors and potential use of a device that is not commercially available in the United States. Larger, longer-term, and more rigorous multicenter RCTs are needed to confirm these findings.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Huang et al. (2017) (3)	China	1	2013-2014	Single-level lumbar degenerative diseases, including lumbar disc herniation, lumbar spinal stenosis, or lumbar degenerative spondylolisthesis	PLIF+ISF, N=23	PLIF+pedicle screws, N=23
Panchal et al. (2018) (4)	United States	9	NR	Single-level lumbar degenerative disc disease and/or spondylolisthesis (grade ≤ 2)	ALIF or LLIF +ISPF, N=66	ALIF or LLIF + pedicle screws, N=37

ALIF: anterior lateral lumbar interbody fusion; ISF: interspinous fastener (Wego, Weihai, China); ISPF: interspinous process fixation; LLIF: lateral lumbar interbody fusion; NR: not reported; PLIF: posterior lumbar interbody fusion; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results

Study	Fusion	Disability	Quality of Life	Revisions	Overall Compli-cations
Huang et al. (2017) (3)	**43**	**43**	**N/A**	**N/A**	**43**
Outcome definition	24-mo: radiograph/CT-scan	% of patients achieved MCID on ODI[1]	N/A	N/A	
PLIF+ISP	17 (77%)/15 (68%)	33 (77%) overall[2]	NR	NR	2 (9%)
PLIF+pedicle screws	17 (81%)/16 (76%)		NR	NR	1 (5%)
p-value	1.000/0.736	NR	N/A	N/A	NR
Panchal et al. (2018) (4)	**88**	**88**	**88**	**88**	**88**
Outcome definition	12-mo radiographic fusion based on BSF-3/BSF-2/BSF-1 (95% CI)	ODI mean improvements ± SD at 12 mo	SF-36 physical component mean improvement ± SD at 12 mo	Required secondary surgical inter-vention	Rated as device-related / NOT device-related

ALIF or LLIF +ISPF	45.5% (32.7%–59.6%)/45.5% (32.7%–59.6%) /9.1% (0.0%–23.2%)	25.97±4.23	10.87±2.79	1 (1.5%)	5 (7.5%) / 14 (21.2%)
ALIF or LLIF + pedicle screws	50% (33.3%–67.8%)/50% (3.3%–67.8%)/0% (0.0%–17.8%)	22.38±5.84	9.10±3.89	4 (10.8%)	6 (16.2%) / 7 (18.9%)
p-value	0.33	<0.01	≥0.22	NR	NR

ALIF: anterior lateral lumbar interbody fusion; BSF criteria: Brantigan, Stelfee, Fraser criteria: BSF-1, radiographic pseudoarthrosis with loss of intervertebral height with lucency around the implant; BSF-2, radiographic locked pseudoarthrosis with lucency within the cage but solid bone growth into the cage from each vertebral endplate; and BSF-3, radiographic fusion with bony bridges in at least half of the fusion area; CI: confidence interval; CT: Computed Tomography; ISF: interspinous fastener (Wego, Weihai, China); ISPF: interspinous process fixation; LLIF: lateral lumbar interbody fusion; MCID: minimally important clinical difference; N/A: not available; NR: not reported; ODI: Oswetry Disability Index; PLIF: posterior lumbar interbody fusion; mo: month; RCT: randomized controlled trial; SD: standard deviation; SF-36: 36-Item Short Form Health Survey.

[1] MCID was prespecified as an 8-point difference.

[2] Did not stratify by group.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Huang et al. (2017) (3)		2. Version used unclear			
Panchal et al. (2018) (4)					1. Not sufficient duration for benefit; 2. Not sufficient duration for harms

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Huang et al. (2017) (3)	3. Allocation concealment unclear; "using closed envelopes"	3. Blinding unclear	1. Not registered			
Panchal et al. (2018) (4)	4. Inadequate control for selection bias: More males (53% vs. 30%), on sick leave (23% vs. 5%) and with degenerative disk disease (55% vs. 43%)			1. High loss to follow-up or missing data (excluded 13% vs. 21% from 12-mo analysis); 6. Not intent to treat analysis (per protocol for noninferiority trials)		

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 3. Blinding unclear

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated

Section Summary: Interspinous Fixation Device With Fusion

The evidence for use of an interspinous fixation device with interbody fusion for those undergoing spinal fusion consists of a systematic review of nonrandomized comparative studies and case series and 2 small RCTs. The randomized trials found comparable benefits for

interspinous fixation device with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation).

Interspinous Fixation Device as a Stand-Alone

Clinical Context and Therapy Purpose

The purpose of interspinous fixation devices is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with spinal stenosis and/or spondylolisthesis.

The question addressed in this medical policy is: Does the use of interspinous fixation alone improve the net health outcome in individuals who have spinal stenosis and/or spondylolisthesis?

The following PICO was used to select literature to inform this policy.

Population

The relevant population of interest is individuals who have spinal stenosis and/or spondylolisthesis.

Intervention

The therapy being considered is an interspinous fixation device alone.

Comparator

The following practice is currently being used to treat spinal stenosis and/or spondylolisthesis: decompression.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Case Series

Sclafani et al. (2014) reported on an industry-sponsored, retrospective series of the polyaxial PrimaLOK interspinous fusion device. (5) Thirty-four patients were implanted with the interspinous fixation devices alone, 16 patients received the PrimaLOK plus an interbody cage, and 3 patients received the PrimaLOK plus pedicle screw instrumentation and an interbody cage. Evaluation at 6 weeks found no cases of fracture or device migration, although there were 4 cases of hardware removal and 2 cases of reoperation for adjacent-level disease during follow-up. At a mean 22 months after the index surgery, the average pain score had improved from 7.2 to 4.5 on a 10-point scale (method of collection, e.g., visual analog scale, were not specified). There was a statistically significant improvement in pain score for patients with degenerative disc disease with lumbar stenosis (2.8, n=25, $p<0.001$) and spondylolisthesis (4.6, n=6, p=0.01), but not for patients with lumbar disc herniation (2.2, n=10, $p>0.05$).

Section Summary: Interspinous Fixation Devices as a Stand-Alone

There is a lack of evidence (only a retrospective series) on the efficacy of interspinous fixation devices as a stand-alone procedure for those who have spinal stenosis and/or spondylolisthesis. Randomized controlled trials are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression.

Summary of Evidence

For individuals who are undergoing spinal fusion who receive an interspinous fixation devices with interbody fusion, the evidence includes a systematic review of nonrandomized comparative studies and case series and 2 small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The randomized trials found comparable benefits for interspinous fixation devices with interbody fusion for those undergoing spinal fusion compared with interbody fusion with pedicle screws, but the comparative safety was less clear. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Additionally, the RCTs had important methodological and relevancy weaknesses that limited their interpretation. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of interspinous fixation devices compared with the established standard (pedicle screw with rod fixation). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal stenosis and/or spondylolisthesis who receive an interspinous fixation device alone, the evidence includes a retrospective series. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There is a lack of evidence on the efficacy of interspinous fixation devices as a stand-alone procedure. RCTs are needed that evaluate health outcomes following use of interspinous fixation devices as a stand-alone for decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
Clinical input was received from 3 physician specialty societies (2 reviewers) and 2 academic medical centers while this policy was under review in 2012. The input was mixed. Some indications where the devices might be medically necessary were noted, such as patients with small pedicles where pedicle screws could not be safely placed.

Practice Guidelines and Position Statements
North American Spine Society
In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. (6) The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that "No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

Ongoing and Unpublished Clinical Trials
Some currently unpublished and ongoing trials that might influence this medical policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01455805[a]	Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease With the Minuteman Interspinous Interlaminar Fusion Implant Versus Surgical Decompression	50	Mar 2024
Unpublished			
NCT01560273[a]	A Multi-Center Prospective Study Evaluation Aspen Spinous Process Fixation System for Use in Posterolateral Fusion (PLF) in Patients With Spondylolisthesis	25	Sep 2015 (terminated)
NCT01549366[a]	System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)	64	Jan 2016 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22840, 22853, 22854, 22859, 22899
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
11/15/2024	Reviewed. No changes.
12/15/2023	Document updated with literature review. Coverage unchanged. No new references added.
12/01/2022	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. References 3 and 4 were added, reference 6 was revised. Other references were removed.
08/01/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged
09/01/2017	Document updated with literature review. Coverage unchanged.
02/01/2017	Coverage section changed to include the following: NOTE: Clinical input has identified potential exceptions where the devices might be considered medically necessary, such as patients with small pedicles where pedicle screws could not be safely placed. NOTE: The name of the specific fixation device used for the procedure should be included in the clinical documentation.
09/01/2016	Reviewed. No changes.
02/01/2016	New medical document. Interspinous fixation (fusion) devices are considered experimental, investigational and/or unproven for any indication, including but not limited to use: In combination with interbody fusion, or alone for decompression in patients with spinal stenosis.