Anthem

Medical Policy

Subject: Implanted Devices for Spinal Stenosis
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Description/Scope

This document addresses devices for the treatment of spinal stenosis. Spinal stenosis is a narrowing of the spinal canal diameter in the cervical or lumbar areas and can result in compression of the nerve roots or spinal cord. Interspinous process spacer devices are constructed to widen or open the foramen, allowing the spinal nerves to pass through more freely.

Note: Please see the following related documents for other treatments of stenosis of the spine:

- SURG.00071 Percutaneous and Endoscopic Spinal Surgery
- SURG.00075 Intervertebral Stabilization Devices
- SURG.00134 Interspinous Process Fixation Devices

Position Statement

Investigational and Not Medically Necessary:

Implanted devices for treatment of spinal stenosis are considered **investigational and not medically necessary.**

Rationale

Interspinous process devices versus laminectomy

In a 2013 prospective, multicenter, double-blind randomized, controlled trial (RCT), Moojen and colleagues compared the surgical outcomes of individuals with lumbar spinal stenosis who underwent either implantation of an interspinous process device (n=80) or spinal bony decompression (n=79). The study assessed neurogenic claudication as the primary outcome using the Zurich Claudication Questionnaire score. At 8 weeks, 63% of individuals in the interspinous process device implantation group and 72% of individuals in the decompression group had a successful recovery (odds ratio [OR] 0.73; p=0.44). At 52 weeks, 66% of those in the interspinous process device implantation group and 69% of those in the decompression group (OR 0.90; p=0.77) reported good results. While there was no significant difference between the groups in terms of long- and short-term surgical outcomes, there was a significant difference between the groups in terms of those undergoing late reoperation due to absence of recovery. In the interspinous process device implantation group, 29% (21/73) of individuals underwent reoperation compared to 8% (6/72) of individuals in the decompression group (p<0.001). The study did report shorter surgery times for the interspinous process device implantation group, but this did not translate into significantly fewer less direct complications or shorter hospital stays.

Machado and colleagues performed a systematic review and meta-analysis comparing the efficacy of several surgical options to treat lumbar spinal stenosis (2015). Of the 17 randomized clinical trials included in this study, two trials compared laminectomy/laminotomies to interspinous process spacer devices (n=259). The authors reported no difference in pain reduction (moderate quality evidence). The authors also reported no difference in long-term pain, or short- or long-term disability between the groups (low quality evidence). In addition, two studies compared decompression plus fusion to interspinous process spacer devices (n=382). There was no difference in pain reduction between the groups, the interspinous spacer group did report slightly superior long-term disability outcomes (low quality evidence). The reoperation rates showed mixed results, interspinous spacers had a significantly higher rate when compared to decompression alone (34/123, 28% versus 9/122, 7%; p<0.001), but not significantly higher when compared to decompression plus fusion (23/215, 11% versus 8/107, 7%; p=0.36). There was no significant difference in adverse events. The authors noted that as interspinous spacers are associated with higher revision surgeries, safety of interspinous spacers in the management of individuals with lumbar spinal stenosis is questionable.

An updated systematic review by Machado and colleagues (2017) included three studies which compared interspinous process spacer devices to conventional decompression. The authors noted no studies directly compared spacers with decompression surgery but were based on indirect comparisons. A total of 355 individuals were included in studies for the coflex and X-stop devices. The authors concluded that while surgery using the interspinous spacer devices resulted in less blood loss and shorter hospital stays when compared to fusion, use of the devices did not lead to improved outcomes when compared to decompression. In addition, interspinous spacer devices were associated with higher reoperation rates.

Wu and colleagues published a systematic review and meta-analysis of two RCTs and three non-randomized prospective studies with 12 to 24 months of clinical results (2014). A total of 208 individuals received an interspinous spacer (IS) and 217 individuals received traditional decompressive surgery (TDS). Pooled analysis of four of the studies found no significant difference between the IS and TDS groups in the areas of low back pain or leg pain. In addition, there was no significant difference in Oswestry disability index (ODI) or the Roland disability questionnaire (RDQ) between the groups in the two studies which reported this outcome. There was no significant difference in complication rates between IS and TDS groups in any of the five studies. The researchers noted the incidence of reoperation was significantly lower in the TDS group (11/160, 6.9%) compared to the IS group (37/161, 23.0%) in the three studies reporting this result.

Several other systematic reviews and meta-analyses have been published. Overall, the studies reported similar results between IS devices and TDS, with the exception of higher reoperation rates in the IS groups in those that reported this outcome. At this time, additional studies are needed to further evaluate the IS device compared to the gold standard treatment of TDS (Cai, 2016; Hong, 2015; Machado, 2015).

The North American Spinal Society (NASS) has two clinical guidelines that address the use of interspinous spacers in the treatment of degenerative lumbar spondylolisthesis and degenerative lumbar spinal stenosis. The NASS clinical guidelines note there is insufficient and conflicting evidence to make a recommendation for or against use of these devices for either of these conditions. In addition to the clinical guidelines, NASS also published coverage policy recommendation for interspinous devices without fusion (2014). This recommendation includes several circumstances in which static interspinous distraction devices might be appropriate. This particular recommendation did not include dynamic devices, such as coflex.

Overall, the evidence and recommendations do not support that implanted interspinous spacers result in equivalent outcomes when compared with the gold standard of standard decompression surgery. Additional studies are needed to evaluate reoperation rates and long-term results of these devices.

The coflex® Interlaminar Technology (Paradigm Spine, New York, NY)

In October 2012, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) granted pre-market approval (P110008) for commercial distribution of the coflex Interlaminar Technology implant. According to the FDA approval letter, the device is:

> Indicated for use in one or two level lumbar stenosis from L1–L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

Davis and colleagues (2013a) discussed the data from a clinical study to establish a reasonable assurance of the safety and effectiveness of the coflex device (IDE #G060059). A total of 322 participants were enrolled in the multi-center study (215 with coflex implantation and 107 fusion recipients). Surgeons were blinded prior to the participants being randomized and the participants were blinded until after surgery. The control group consisted of individuals who underwent posterolateral fusion with autograft bone and pedicle screw fixation following surgical decompression (D+PS). The treatment group underwent decompression and interlaminar stabilization with the coflex device (D+ILS). Participants had radiographic confirmation of moderate lumbar stenosis with narrowing of the central spinal canal at one or two contiguous levels from L1-L5 that required surgical decompression. A subset of participants with spinal stenosis had up to grade I degenerative spondylolisthesis.

Participants were scheduled to return for follow-up examinations at 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months postoperatively. Evaluations were carried out using the ODI, Zurich Claudication Questionnaire (ZCQ), SF-12, back and leg pain via visual analog scale (VAS). A neurological assessment was conducted during the preoperative visit and at all postoperative visits. Radiographic evaluation was performed at each time point. Adverse events and complications were recorded at all visits. With the exception of wound complications, the coflex implant was found to have a reasonable assurance of safety and to be at least as safe as the control treatment. The numerical difference of wound complications between coflex 14.0% (30/215) and control 8.4% (9/107) was 5.6%. The rate of secondary surgery (revisions and reoperations) for coflex was higher than the control group at 24 months. The study noted the presence of additional spinous process fractures in a number of participants identified by the core laboratory and not by the investigator surgeons in both the coflex and the fusion control groups. At 24 months, these fractures were asymptomatic and the evaluation of the CCS, ODI, and ZCQ endpoints for these participants did not demonstrate the clinical significance of these spinous process fractures. The long-term significance of these fractures is not known. Analysis of participant demographic and baseline data demonstrated the treatment groups to be comparable. Mean surgery time was longer for the spinal fusion group than for the coflex group. Blood loss was greater for the control group by 238.9 ml, as was length of hospital stay by 1.3 days. The results of this study suggest that the coflex interlaminar device is comparable to fusion, at least in the short term.

Musacchio and colleagues (2015) reported on the 5-year outcomes of the Davis (2013a) study. Results were evaluated based upon a composite score which included four components: (1) at least 15-point improvement in the ODI (ODI-15) at 60 months compared with baseline; (2) no reoperations, revisions, removals, or supplemental fixation; (3) no major device-related complications such as permanent new or increasing sensory or motor deficit at 60 months; and (4) no lumbar epidural steroid injections within the post-operative period. At 5 years, there was no significant difference in the success rate between the D+ILS group and the D+PS group (50.3% versus 44%; p>0.35). Specifically, at 60 months, there was no significant difference in the cumulative reoperation/revision rates between D+ILS and D+PS (35/215 [16.3%] versus 19/107 [17.8%]; p>0.90). It is notable that this study did not include a “decompression only” group for comparison. In addition, Grade I spondylolisthesis was present in 99/215 (46.0%) of those in the coflex group and in 51/107 (47.7%) of those in the fusion group. A limitation of the study is the un-blinding of the subjects postoperatively, creating the potential for expectation bias.

Davis and colleagues (2013b) reported the findings of another study which evaluated a subset of the participants in the IDE trial described above (Davis 2013a). This study evaluated only the subset of individuals from this overall cohort with both lumbar spinal stenosis and Grade 1 spondylolisthesis (99 in the coflex group and 51 in the fusion group.) At a minimum of 24 months, individual follow-up was 94.9% and 94.1% in the coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age of the participants was 63 and 65 years in the coflex and fusion groups, respectively. Subjects in the coflex group experienced shorter operative times (an average of 53.3 fewer minutes) than those in the fusion group. The estimated blood loss was lower for the coflex cohort (106.2 versus 335.5 ml), and the average hospital length of stay was reduced by 1 day in the coflex group. The reoperation rate was higher in the coflex cohort (14 [14.1%] of 99) compared with fusion (3 [5.9%] of 51, p=0.18), although this difference was not statistically significant. The rate of severe adverse events that were probably or definitely related to the implant was 9.1% in the coflex arm and 7.8% in the fusion arm. Wound-related problems were seen in 14.1% of coflex cohort compared with 13.7% in the fusion cohort. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS leg and VAS back, with no significant group differences. However, coflex demonstrated significantly greater ZCQ satisfaction at 2 years. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while coflex showed no significant radiographic changes at the operative or index levels.

Bae and colleagues (2017) performed a 3-year follow-up analysis of the Davis (2013a) RCT. At 36 months, 91% (195/215) of the coflex group and 88% (94/107) of the fusion group were included in the analysis. The initial efficacy endpoints (composite scores) were modified for use at 36 months. At 36 months. 62.2% of the individuals in the coflex group compared to 48.9% of the individuals in the fusion group reported composite clinical success scores (difference = 13.3%; 95% confidence interval [CI], 1.1%-25.5%; p=0.03). There are several limitations in this study including the limited follow-up period and the heterogeneous mix of individuals including those without listhesis for which fusion/stabilization is an unproven procedure. The authors noted that an RCT comparing decompression and stabilization with coflex device to decompression alone will be underway in the near future.

In a prospective, randomized multicenter study, Schmidt and associates (2018) reported on the 2-year results of a study comparing treatment with decompression with interlaminar stabilization with the coflex device (D+ILS) to decompression alone (DA) in individuals with moderate to severe lumbar spinal stenosis at one or two adjacent levels. A total of 115 individuals were randomized to each arm. A composite clinical success (CCS) measure consisted of four components: ODI improvement > 15 points, survivorship with no secondary surgeries or lumbar injections, maintenance or improvement of neurological symptoms, and no device- or procedure-related severe AEs. The CCS is a binary outcome measure and all components must be achieved in order for the endpoint to be met. At 24 months follow-up, the D+ILS group reported significant superior CCS scores compared to the DA group (58.4% versus 41.7%; p=0.017 respectively). At 24 months, there were no significant differences between the groups in the patient-reported outcomes: the ODI scores, VAS back and neck pain scores and the Zürich Claudication Questionnaire. There were no significant

differences in patient-reported outcomes between the groups. There were no significant differences in the primary outcome measures between the groups. However, when the secondary measure outcome of subsequent epidural injections (4.5% in the D+ILS group versus 14.8% in the DA group) was included in the CCS, the result became significant. In a review of this study, NASS (2018) noted:

> Overall, the results of this study on a strict evidence-based medicine level can be summarized as not finding a significant difference in the primary outcome measure(s). However, when considering the significant difference in subsequent epidural injections, which is a secondary outcome measure, the composite clinical success score becomes different.

Du and colleagues (2020) reported on a small group of individuals who underwent interlaminar decompression and Coflex implantation to treat symptomatic lumbar spinal stenosis (LSS) and completed follow-up for at least 8 years. A total of 73 individuals underwent the initial surgery and 56 individuals completed all follow-up with an average follow-up time of 107.6 ± 13.3 months. At the last follow-up, the VAS scores for leg pain, back pain and ODI were significantly improved over baseline scores. During the course of follow-up, 19.6% (10/56) reported complications and 10.7% (6/56) required a secondary surgery. While the results were promising, larger studies directly comparing decompression with Coflex device and decompression alone are needed.

In 2018, NASS published a coverage recommendation regarding the use of lumbar interspinous devices with decompression, noting that an interspinous device, the coflex device, may be used in conjunction with laminectomy. This recommendation is based upon studies comparing the coflex device/laminectomy to laminectomy alone or to fusion. The cited studies have several limitations, including short follow-up periods, a lack of clear data which directly addresses whether the coflex device provides additional benefit, or have been discussed earlier in this document.

Superion® Indirect Decompression System (Boston Scientific, Marlborough, ME)

In May 2015, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) granted pre-market approval (P140004) for commercial distribution of the Superion ISS. The approval was contingent upon post approval follow-up data submission for safety and efficacy at 2 and 5 years. Superion is the only non-fusion interspinous distraction device currently available in the U.S. (Guyer, 2016).

The FDA-approved indications for Superion ISS are for the treatment of neurogenic intermittent claudication symptoms caused by moderate degenerative lumbar spinal stenosis with or without Grade 1 spondylolisthesis, who have failed at least 6 months of conservative treatment. The device is approved to be implanted at one or two adjacent levels. The Superion Post-Approval Clinical Evaluation and Review (SPACER) trial has been identified as the lead PMA post approval study.

A 2014 prospective, multicenter, randomized, controlled trial by Patel and colleagues evaluated surgical outcomes for individuals who received either the Superion ISS or the X-STOP implant. A total of 250 individuals with moderate lumbar spinal stenosis were followed for a minimum of 2 years post implant. While the reported indicators of successful outcomes between the groups were comparable, the study did not include a comparison to decompression surgery, the current standard surgical treatment.

The 5-year clinical outcomes of a randomized controlled U.S. FDA noninferiority trial in individuals with moderate lumbar spinal stenosis were reported by Nunley and colleagues (2017). While the original trial compared the Superion to the X STOP device, the analysis was restricted to the Superion trial arm. A total of 73% (88/121) of the living individuals who received the spacer device participated in the 5-year clinical outcomes assessment. Outcomes were assessed using the ZCQ, leg and back pain severity by VAS, and the ODI. The authors reported success rates in all areas of assessment, 84% reported clinical success in at least two of the three ZCQ domains, 80% leg pain VAS scores, 65% back pain VAS scores and 65% for ODI scores. There remains a lack of studies which compare interspinous spacers to standard treatments, such as decompression surgery.

Tekmyster and associates (2019) reported on the data captured in a post-market registry of individuals who had the Superion device placed to treat LSS associated with neurogenic claudication. The reported data included leg and back pain VAS scores and participant satisfaction at 3 weeks, 6 and 12 months. Respondents reported an overall 60% improvement in leg pain and 48% overall improvement in back pain. Scores for participant satisfaction with treatment at 3 weeks, 6 and 12 months were 89%, 80% and 80% respectively. This observational study was limited by the low response rate and limited follow-up. The number of responders varied from 291 to 1542 out of a possible 2090 eligible individuals. In addition, the results of this study do not address concerns about long-term outcomes and clinical outcomes compared to standard decompression.

Overall, there is a lack of evidence to support that interspinous spacer devices are as safe and effective as the gold standard of decompression. Surrogate radiologic endpoint outcomes, such as improvements in spinal canal and neuroforaminal narrowing are improved following surgery. However, the studies do not show that the use of interspinous spacer devices improves clinical outcomes such as pain and function. There appears to be some concerns that the devices are not as effective as surgical decompression and lead to higher rates of reoperation.

X STOP® (Medtronic Inc., Minneapolis, MN)

The U.S. Food and Drug Administration (FDA) granted premarket approval (PMA) for the X STOP interspinous implant in November 2005. The approval was contingent upon post approval follow-up data submission for safety and efficacy at 2 and 5 years. The Condition of Approval Study (COAST), a prospective Phase IV 5-year post approval study of the X STOP device has been completed; however results have not been published. In 2015, Medtronic noted "...study costs outweigh business benefits for marketing X-STOP in US." and removed the device from the U.S. market.

Facet Replacement Devices

Facet replacement devices or facet arthroplasty is proposed as an alternative to fusion when individuals undergo decompression to treat spinal stenosis and spondylolisthesis. There are several devices currently being evaluated, although no devices have received FDA approval. The Total Facet Arthroplasty System™ (TFAS) (Facet Solutions, Inc., Hopkinton, MA) is no longer being moved forward to seek FDA approval. The Total Posterior Spine System (TOPS™) (Premia Spine Ltd., Philadelphia, PA) has been approved in Europe and is undergoing review in the US. A randomized trial (NCT03012776) is currently being conducted to assess the safety and effectiveness of TOPS.

Background/Overview

Spinal stenosis or narrowing of the spinal canal may cause neurogenic intermittent claudication, a syndrome that individuals may experience as progressive pain, numbness, and weakness of the legs while standing or walking. Currently, spinal stenosis can be treated by laminectomy, a surgical procedure performed to increase the space between interspinous structures and to reduce neural compression. The risks associated with laminectomy are nerve damage, vertebral instability, and return of symptoms at another level of the spine. Neurogenic intermittent claudication (NIC) secondary to LSS is a bio-mechanical, posture-dependent condition in which

symptoms such as lower limb tingling, pain, and numbness are typically exacerbated in extension and relieved in flexion. The central canal, lateral recess or intervertebral foramen are the usual sources of stenotic changes and nerve impingement (Truumees, 2005). Spinal stenosis is a progressive disease and while decompression surgery is used to treat the symptoms of spinal stenosis, symptoms can recur (Schmidt, 2018).

Decompression, with or without fusion, is currently the gold standard for the surgical treatment of stenosis. The placement of an interspinous spacer device following decompression has been proposed as an alternative to fusion. The device is meant to provide segmental stability while avoiding limitations associated with fusion, such as motion limitation or adjacent segment degeneration. The coflex device is the only device with FDA PMA approval for this use. The use of stand-alone interspinous distraction devices are also proposed as an alternative to decompression. At present, the Superion device is the only FDA approved non-fusion interspinous distraction device available.

Definitions

Foramen: Space between adjacent vertebrae through which the nerve root exits at each level in the spine.

Investigational Device Exemption (IDE): Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA.

Laminectomy: Also known as decompression. A surgical procedure for treating spinal stenosis by relieving pressure on the spinal cord. The lamina of the vertebra is removed or trimmed to widen the spinal canal and create more space for the spinal nerves.

Neurogenic**:** Originating in the nervous system.

Neurogenic claudication: Symptoms of leg pain (and occasionally weakness) on walking or standing, relieved by sitting or spinal flexion, related to neural compression, usually spinal stenosis.

Premarket Approval (PMA): The most stringent type of device marketing application required by the FDA. A PMA is an application submitted to the FDA to request clearance to market or to continue marketing of a Class III medical device. Class III medical devices are those devices that present significant risk to the individual and/or require significant scientific review of the safety and effectiveness of the medical device prior to commercial introduction. Frequently the FDA requires follow-up studies for these devices.

Spondylolysis: A condition where there is a defect in a specific region of the spinal column. This region of the spinal column, called the pars interarticularis, connects adjacent vertebrae in the spine.

Vertebrae: Bones that make up the spinal column, which surround and protect the spinal cord.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
HCPCS	
C1821	Interspinous process distraction device (implantable)
ICD-10 Procedure	
0RH008Z-0RH048Z	Insertion of spacer into occipital-cervical joint [by approach; includes codes 0RH008Z, 0RH038Z, 0RH048Z]
0RH108Z-0RH148Z	Insertion of spacer into cervical vertebral joint [by approach; includes codes 0RH108Z, 0RH138Z, 0RH148Z]
0RH408Z-0RH448Z	Insertion of spacer into cervicothoracic vertebral joint [by approach; includes codes 0RH408Z, 0RH438Z, 0RH448Z]
0RH608Z-0RH648Z	Insertion of spacer into thoracic vertebral joint [by approach; includes codes 0RH608Z, 0RH638Z, 0RH648Z]
0RHA08Z-0RHA48Z	Insertion of spacer into thoracolumbar vertebral joint [by approach; includes codes 0RHA08Z, 0RHA38Z, 0RHA48Z]
0RH00DZ-0RH04DZ	Insertion of facet replacement spinal stabilization device into occipital-cervical joint [by approach; includes codes 0RH00DZ, 0RH03DZ, 0RH04DZ]
0RH10DZ-0RH14DZ	Insertion of facet replacement spinal stabilization device into cervical vertebral joint [by approach; includes codes 0RH10DZ, 0RH13DZ, 0RH14DZ]
0RH40DZ-0RH44DZ	Insertion of facet replacement spinal stabilization device into cervicothoracic vertebral joint [by approach; includes codes 0RH40DZ, 0RH43DZ, 0RH44DZ]
0RH60DZ-0RH64DZ	Insertion of facet replacement spinal stabilization device into thoracic vertebral joint [by approach; includes codes 0RH60DZ, 0RH63DZ, 0RH64DZ]
0RHA0DZ-0RHA4DZ	Insertion of facet replacement spinal stabilization device into thoracolumbar vertebral joint [by approach; includes codes 0RHA0DZ, 0RHA3DZ, 0RHA4DZ]

0SH008Z-0SH048Z	Insertion of spacer into lumbar vertebral joint [by approach; includes codes 0SH008Z, 0SH038Z, 0SH048Z]
0SH308Z-0SH348Z	Insertion of spacer into lumbosacral joint [by approach; includes codes 0SH308Z, 0SH338Z, 0SH348Z]
0SH508Z-0SH548Z	Insertion of spacer into sacrococcygeal joint [by approach; includes codes 0SH508Z, 0SH538Z, 0SH548Z]
0SH608Z-0SH648Z	Insertion of spacer into coccygeal joint [by approach; includes codes 0SH608Z, 0SH638Z, 0SH648Z]
0SH00DZ-0SH04DZ	Insertion of facet replacement spinal stabilization device into lumbar vertebral joint [by approach; includes codes 0SH00DZ, 0SH03DZ, 0SH04DZ]
0SH30DZ-0SH34DZ	Insertion of facet replacement spinal stabilization device into lumbosacral joint [by approach; includes codes 0SH30DZ, 0SH33DZ, 0SH34DZ]

ICD-10 Diagnosis

All diagnoses

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.

Reviewed	08/11/2022	MPTAC review. Updated Description, Rationale, Background, Definitions and References sections. Added Websites for Additional Information section.
Reviewed	08/12/2021	MPTAC review. Updated Rationale and References section.
Reviewed	08/13/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	08/22/2019	MPTAC review. Updated References section.
Reviewed	09/13/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Coding section updated.
Reviewed	11/03/2016	MPTAC review. Description, Rationale and References sections updated. Updated Coding section with 01/01/2017 CPT changes.
Reviewed	11/05/2015	MPTAC review. Description, Rationale and References sections updated. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Rationale and References updated.
Reviewed	11/14/2013	MPTAC review. Rationale and References updated.
Reviewed	05/09/2013	MPTAC review. Rationale and References updated.
Reviewed	05/10/2012	MPTAC review. Rationale and References updated.
Reviewed	05/19/2011	MPTAC review. Rationale and References updated.
Reviewed	05/13/2010	MPTAC review.
Revised	05/21/2009	MPTAC review. Position statement revised to address implanted devices for the treatment of spinal stenosis. Title changed to *Implanted Devices for Spinal Stenosis*. Rationale and References updated. Coding updated to include 07/01/2009 CPT changes.
Revised	08/28/2008	MPTAC review. Position statement reworded, Rationale and References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. References updated.
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes.
New	09/14/2006	MPTAC initial document development. Split from SURG.00055, Implanted Spinal Devices for Chronic Back Pain or Radiculopathy to address interspinous vertebral devices in a separate document.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.