



Australian Government

Department of Health

**MEDICAL SERVICES ADVISORY
COMMITTEE**

Final Protocol

for

Application 1422

**Minimally invasive, lumbar decompression and
dynamic stabilisation using an interlaminar device,
with no rigid fixation to the vertebral pedicles, for
one or two lumbar motion segments**

LifeHealthcare Pty Ltd

October 2016

Title of Application

Minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles, for one or two lumbar motion segments.

Purpose of application

Please indicate the rationale for the application and provide one abstract or systematic review that will provide background.

The indication

The proposed service 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/buttocks/groin pain, and who have undergone at least 6 months of non-operative treatment.

The Coflex® Interlaminar Stabilization™ device

The Coflex® Interlaminar Stabilization™ device is an interlaminar stabilization device intended to unload the facet joints, stabilize the motion segment, and maintain the direct neurological decompression. The device is compressible in extension, allows flexion, and is fixed to the lamina bone via a press-fit insertion. It is indicated to treat spinal stenosis with lowback pain and/or Grade 1 Meyerding spondylolisthesis or equivalent retrolisthesis at 1–2 lumbar levels from L1–5. It is made of titanium alloy and comes in five different sizes ranging from 8 to 16 mm in height in 2-mm increments.

Mode of delivery

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. In contrast, interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves.

The Coflex® Interlaminar Stabilization™ device is inserted through a small cut in the skin of the patient's back. The patient is placed on his/her stomach before the surgery allowing the surgeon to access the spine when the Coflex® Interlaminar Stabilization™ device is inserted during surgery. The surgery to implant the Coflex® Interlaminar Stabilization™ device typically lasts about one to two hours.

As part of the Coflex® Interlaminar Stabilization™ device surgery, the surgeon firstly removes part of the bone that is interfering with nerves, causing the patient's pain. This step is called a decompression procedure. Following this step, the spinous processes are prepared to fit the Coflex® Interlaminar Stabilization™ device. After preparation of the bones in the spine, the Coflex® Interlaminar Stabilization™ device is placed between two spinous processes and is positioned securely on the lamina bone in the back of the spine. This step uses a tool that is removed after the Coflex® Interlaminar Stabilization™ device is in place.

The Coflex® Interlaminar Stabilization™ device 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).

Abstract

14. Spine (Phila Pa 1976). 2013 Aug 15;38(18):1529-39.

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.

Davis RJ(1), Errico TJ, Bae H, Auerbach JD.

STUDY DESIGN: Prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial.

OBJECTIVE: To evaluate the safety and efficacy of Coflex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis.

SUMMARY OF BACKGROUND DATA: Long-term untoward sequelae of lumbar fusion for stenosis and degenerative spondylolisthesis have led to the search for motion-preserving, less-invasive alternatives. METHODS: Three hundred twenty-two patients (215 Coflex and 107 fusions) from 21 sites in the United States were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in Oswestry Disability Index, no reoperations, no major device-related complications, and no postoperative epidural injections.

RESULTS: Patient follow-up at minimum 2 years was 95.3% and 97.2% in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times ($P < 0.0001$), blood loss ($P < 0.0001$), and length of stay ($P < 0.0001$). There was a trend toward greater improvement in mean Oswestry Disability Index scores in the Coflex cohort ($P = 0.075$). Both groups demonstrated significant improvement from baseline in all visual analogue scale back and leg parameters. Patients taking Coflex experienced greater improvement in Short-Form 12 physical health outcomes ($P = 0.050$) and equivalent mental health outcomes. Coflex subjects experienced significant improvement in all Zurich Claudication Questionnaire outcomes measures compared with fusion (symptom severity [$P = 0.023$]; physical function [$P = 0.008$]; satisfaction [$P = 0.006$]). Based on the Food and Drug Administration composite for overall success, 66.2% of Coflex and 57.7% of fusions succeeded ($P = 0.999$), thus demonstrating noninferiority. The overall adverse event rate was similar between the groups, but Coflex had a higher reoperation rate (10.7% vs. 7.5%, $P = 0.426$). At 2 years, fusions exhibited increased angulation ($P = 0.002$) and a trend toward increased translation ($P = 0.083$) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion.

CONCLUSION: Coflex interlaminar stabilization is a safe and efficacious alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

LEVEL OF EVIDENCE: 1.

PMID: 23680830 [PubMed - indexed for MEDLINE]

Population and medical condition eligible for the proposed medical services

Provide a description of the medical condition (or disease) relevant to the service.

Lumbar spinal stenosis (LSS) is a disabling medical condition in which narrowing of the spinal canal compresses the spinal cord and nerves causing a condition called neurogenic intermittent claudication (NIC).

The most common cause of lumbar spinal stenosis is the “wear and tear” that occurs with natural aging effects on the lower spine. Patients who have spinal stenosis are not able to walk for long periods of time. Symptoms include pain, numbness, tingling and weakness in the lower back, buttocks and legs, which are especially noticeable after walking and physical activity.

Define the proposed patient population that would benefit from the use of this service. This could include issues such as patient characteristics and /or specific circumstances that patients would have to satisfy in order to access the service.

Patients suitable for this modality should meet the following criteria:

- lumbar stenosis or mild degenerative instability – one or two lumbar motion segments.
- failure of conservative management for at least 6 months.*
- moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion (minimum Oswestry Disability Index (ODI) of 20 for 50 (40%), and visual analogue scale (VAS) back pain score of 50 for 100 or more).
- with or without low-grade spondylolisthesis (less than 50 percent slippage)

* Note that conservative management can include orthosis, rehabilitation, physical therapy, exercise, heat and cold, transcutaneous electrical nerve stimulation, ultrasounds, analgesics, nonsteroidal anti-inflammatory drugs, epidural steroids, and back bracing.

The Coflex® Interlaminar Stabilization™ device is contraindicated in patients with:

- Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle of greater than 25°).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection – systemic or local.
- Known allergy to titanium alloys or MR contrasting agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

Indicate if there is evidence for the population who would benefit from this service i.e. international evidence including inclusion / exclusion criteria. If appropriate provide a table summarising the population considered in the evidence.

The clinical evidence for this application is primarily based on a prospective, randomized, multicentre, FDA Investigational Device Exemption trial with 322 patients and two year follow-up.

Key Paper

- *Davis RJ, Errico TJ, Bae H, Auerbach JD. 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 (Phila Pa 1976). 2013 Aug 15;38(18):1529-39.*

Inclusion Criteria

1. Radiographical confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at 1 or 2 contiguous levels from L1–L5 that require surgical decompression. Moderate stenosis is defined as more than 25% reduction of the anteroposterior dimension compared with the next adjacent normal level, with nerve root crowding compared with the normal level, as determined by the investigator on CT Scan or MRI. The patient may have, but is not required to have for inclusion in the study:
 - a. Facet hypertrophy and subarticular recess stenosis at the affected level(s);
 - b. Foraminal stenosis at the affected level(s);
 - c. Up to grade I stable degenerative spondylolisthesis (Meyerding classification) or equivalent retrolisthesis as determined by flexion/ extension radiograph:
 - i. For single-level disease, there may be up to a grade I stable spondylolisthesis or equivalent retrolisthesis at the affected level as determined on flexion/extension films by the investigator.
 - ii. For 2-level disease, there may be up to a grade I stable spondylolisthesis or equivalent retrolisthesis at only 1 of the 2 contiguous affected levels, as determined on flexion/extension films by the investigator. Patients with up to grade I stable spondylolisthesis at 2 contiguous levels are excluded, but patients with up to grade I stable spondylolisthesis at 1 level and equivalent retrolisthesis at the adjacent level may be included.
 - d. Mild lumbar scoliosis (Cobb angle up to 25°).
2. Radiographical confirmation of the absence of angular or translatory instability of the spine at index or adjacent levels (instability as defined by White & Panjabi: Sagittal plane translation > 4.5 mm or 15% or sagittal plane rotation > 15 ° at L1–L2, L2–L3, and L3–L4; > 20 ° at L4–L5 based on standing flexion/extension radiographs).
3. VAS back pain score of at least 50 mm on a 100 mm scale.
4. Neurogenic claudication as defined by leg/buttocks or groin pain that can be relieved by flexion such as sitting in a chair.
5. Patient has undergone at least one epidural injection at any prior time point, and at least 6 months of prior conservative care without adequate and sustained symptom relief.
6. Age between 40 and 80 yr.

7. Oswestry Low Back Pain Disability Questionnaire score of at least 20/50 (40%).
8. Appropriate candidate for treatment using posterior surgical approach.
9. Psychosocially, mentally, and physically able to comply fully with this protocol, including adhering to scheduled visits, treatment plan, completing forms, and other study procedures.

Exclusion Criteria

- More than 2 vertebral levels requiring surgical decompression.
- Prior surgical procedure that resulted in translatory instability of the lumbar spine.
- More than 1 surgical procedure at any combination of lumbar levels.
- Prior fusion, implantation of a total disc replacement, complete laminectomy, or implantation of an interspinous process device at any lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumour (e.g. compression fracture).
- Severe facet hypertrophy that requires extensive bone removal that would cause instability.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle > 25 °).
- Disc herniation at any lumbar level requiring surgical intervention.
- Osteopenia: A screening questionnaire for osteopenia, SCORE (simple calculated osteoporosis risk estimation), will be used to screen patients who require a DEXA bone mineral density measurement. If DEXA is required, exclusion will be defined as a DEXA bone density measured T score of ≤ -1.0 (The World Health Organization definition of osteopenia).
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Pregnant or interested in becoming pregnant in the next 3 years.
- Known allergy to titanium, titanium alloys, or MR contrast agents.
- Active or chronic infection—systemic or local.
- Chronically taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g. steroids), not including a Medrol (Methylprednisolon) dose pack.
- History of significant peripheral neuropathy.
- Significant peripheral vascular disease (e.g. , with diminished dorsalis pedis or posterior tibial pulses).
- Unremitting back pain in any position.
- Uncontrolled diabetes.

- Known history of Paget disease, osteomalacia, or any other metabolic bone disease (excluding osteopenia, which is addressed earlier).
- Cauda equina syndrome, defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder (bladder retention or incontinence) dysfunction.
- Fixed and complete motor, sensory, or reflex deficit.
- Rheumatoid arthritis or other autoimmune diseases.
- Known or documented history of communicable disease, including AIDS, HIV, active hepatitis.
- Active malignancy: a patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless he/she has been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least 5 years. Patients with a primary bony tumour are excluded as well.

Provide details on the expected utilisation, if the service is to be publicly funded.

The expected utilisation of this service will be estimated based on:

- The current MBS claims for the treatment of spinal stenosis by the comparator - laminectomy plus posterolateral spinal fusion

MBS Item	Descriptor	Claims 2014/15
40330	SPINAL RHIZOLYSIS involving exposure of spinal nerve roots - for lateral recess, exit foraminal stenosis, adhesive radiculopathy or extensive epidural fibrosis, at 1 or more levels - with or without partial or total laminectomy (Anaes.) (Assist.) Fee: \$955.00 Benefit: 75% = \$716.25	22,563
40321	POSTERIOR SPINAL FUSION, not being a service to which items 40324 and 40327 apply (Anaes.) (Assist.) Fee: \$1,090.35 Benefit: 75% = \$817.80	248
48654	SPINAL FUSION (posterior interbody), with partial or total laminectomy, 1 level (Anaes.) (Assist.) Fee: \$1,082.70 Benefit: 75% = \$812.05	2,200
48657	SPINAL FUSION (posterior interbody), with partial or total laminectomy, more than 1 level (Anaes.) (Assist.) Fee: \$1,506.45 Benefit: 75% = \$1,129.85	980
48684	SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which any one of items 48642 to 48675 applies - 1 or 2 levels (Anaes.) (Assist.) Fee: \$941.45 Benefit: 75% = \$706.10	6,290
48687	SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which items 48642 to 48675 apply - 3 or 4 levels (Anaes.) (Assist.) Fee: \$1,317.80 Benefit: 75% = \$988.35	1,164
48690	SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which items 48642 to 48675 apply - more than 4 levels (Anaes.) (Assist.) Fee: \$1,506.45 Benefit: 75% = \$1,129.85	384

Intervention – proposed medical service

Provide a description of the proposed medical service.

The Coflex® Interlaminar Stabilization™ device 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).

If the service is for investigative purposes, describe the technical specification of the health technology and any reference or “evidentiary” standard that has been established.

This service is not for investigative purposes.

Indicate whether the service includes a registered trademark with characteristics that distinguish it from any other similar health technology.

This service includes the use of a registered trademarked device, the Coflex® Interlaminar Stabilization™ device supplied in Australia by LifeHealthcare Pty Ltd. Other similar technologies, interspinous rather than interlaminar devices (available in Australia) include the X STOP, the Wallis and the DIAM and have not been included.

Interspinous versus interlaminar spacers

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. There are three interspinous spacers (X STOP, Wallis, DIAM) registered for use in Australia.

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. There is one interlaminar spacer (the Coflex® Interlaminar Stabilization™ device) registered for use in Australia.

Indicate the proposed setting in which the proposed medical service will be delivered and include detail for each of the following as relevant: inpatient private hospital, inpatient public hospital, outpatient clinic, emergency department, consulting rooms, day surgery centre, residential aged care facility, patient’s home, laboratory. Where the proposed medical service will be provided in more than one setting, describe the rationale related to each.

The proposed setting for the delivery of this service is an operating theatre with the patient classified as an inpatient in either a private or public hospital. The in-patient status is determined by the need for a general anaesthetic.

Describe how the service is delivered in the clinical setting. This could include details such as frequency of use (per year), duration of use, limitations or restrictions on the medical service or provider, referral arrangements, professional experience required (e.g.: qualifications, training, accreditation etc.), healthcare resources, access issues (e.g.: demographics, facilities, equipment, location etc.).

Details of the delivery of this services include:

- The proposed service is performed by an Orthopaedic Surgeon or a Neurosurgeon.
- It is intended that the proposed service will only be performed once.
- The proposed service can be performed in any hospital that currently offers the comparator.

Co-dependent information (if not a co-dependent application go to Section 6)

Please provide detail of the co-dependent nature of this service as applicable.

This is a co-dependent service only in as much as it requires an application for the listing of the Coflex® Interlaminar Stabilization™ device on the Prostheses List.

Comparator – clinical claim for the proposed medical service

Please provide details of how the proposed service is expected to be used, for example is it to replace or substitute a current practice; in addition to, or to augment current practice.

It is intended that this service will be provided as an alternative to the current practice of open posterior spinal nerve decompression with lumbar fusion using pedicle screw instrumentation with autograph.

As per the 'clinical management algorithm – including proposed service' the alternative comparator of decompression alone will also be examined.

Additionally, the current indications for recommending decompression alone versus decompression and lumbar fusion in patients eligible for surgery due to failed conservative management, citing clinical guidelines if available or RCTs comparing these procedures, will be reviewed.

Expected health outcomes relating to the medical service

Identify the expected patient-relevant health outcomes if the service is recommended for public funding, including primary effectiveness (improvement in function, relief of pain) and secondary effectiveness (length of hospital stays, time to return to daily activities).

Primary outcome measures - effectiveness

- improvement of at least 15 points in ODI (ODI-15) compared with baseline; and
- no lumbar epidural steroid injection at any postoperative time point.

Primary outcome measures – safety

- no reoperations, revisions, removals, or supplemental fixation; and
- no major device-related complications, including but not limited to permanent new or increasing sensory or motor deficit.

Secondary outcome measures

- Visual Analogue Scale (VAS)
- Short-form 12 (SF-12)
- Zurich Claudication Questionnaire (ZCQ)
- Narcotic Usage
- Radiologic Assessment

Process/resource measures

- Procedure time
- Length of hospital stay
- Blood loss

Describe any potential risks to the patient.

Data has demonstrated that spinous process fractures can occur with an interlaminar stabilization device implantation. Potential predictors for spinous process fractures include:

- Over-decompression during surgery leading to instability in the spine,
- Resection of the spinous process to ≤ 14 mm,
- Height of the spinous process ≤ 23 mm pre-operatively,
- Osteopenia or osteoporosis, and
- “Kissing” spinous processes.

Risks associated with an interlaminar stabilization device, including the Coflex® Interlaminar Stabilization™ device, include: implant malposition or incorrect orientation; allergies to implant materials; possible wear debris, implantation at the wrong spinal level; fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery; the implant may loosen, deform, break, fatigue, or move, which may necessitate another surgery to correct the problem; and instruments also may break or malfunction in use, which may cause damage to the operative site or adjacent structures.

Specify the type of economic evaluation.

The economic evaluation will be a cost-effectiveness / cost-utility analysis.

Fee for the proposed medical service

Explain the type of funding proposed for this service.

As a service rendered in an in-patient setting, the type of funding proposed for this service is a fee for the providers.

Please indicate the direct cost of any equipment or resources that are used with the service relevant to this application, as appropriate.

The incremental (in addition to those used in a partial laminectomy) direct equipment costs associated with this service are:

- The cost of the Coflex® Interlaminar Stabilization™ implanted prosthesis.

Provide details of the proposed fee.

As with all new MBS Items, the proposed fee for this service will be based on the time taken, the degree of difficulty and the expertise required to perform the service and will be in line with the MBS fee for ‘similar’ services.

MBS Item 48xxx

Posterior, interlaminar, non-fusion, dynamic stabilization following decompression using an interlaminar device, with no rigid fixation to the vertebral pedicles, implantation between the spinous processes of one lumbar motion segment. (Anaes.) (Assist.)

For patients:

- with lumbar spinal stenosis or mild degenerative instability– one or two lumbar motion segments;
- who have failed conservative management for ≥ 6 months;
- with moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion; and
- with or without low-grade spondylolisthesis (less than 50 percent slippage).

Fee: \$1,082.70 Benefit: 75% = \$812.05

Notes

- 1) Conservative management can include included orthosis, rehabilitation, physical therapy, exercise, heat and cold, transcutaneous electrical nerve stimulation, ultrasounds, analgesics, nonsteroidal anti-inflammatory drugs, and epidural steroids.
- 2) Moderately severe functional impairment with symptoms exacerbated in extension as measured by the following criteria:
 - minimum Oswestry Disability Index (ODI) of 20 for 50 (40%), and
 - visual analogue scale (VAS) back pain score of 50 for 100 or more.

MBS Item 48xxx

Posterior, interlaminar, non-fusion, dynamic stabilization following decompression using an interlaminar device, with no rigid fixation to the vertebral pedicles, implantation between the spinous processes of two lumbar motion segments. (Anaes.) (Assist.)

For patients:

- with lumbar spinal stenosis or mild degenerative instability– one or two lumbar motion segments;
- who have failed conservative management for ≥ 6 months;
- with moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion; and
- with or without low-grade spondylolisthesis (less than 50 percent slippage).

Fee: \$1,506.45 Benefit: 75% = \$1,129.85

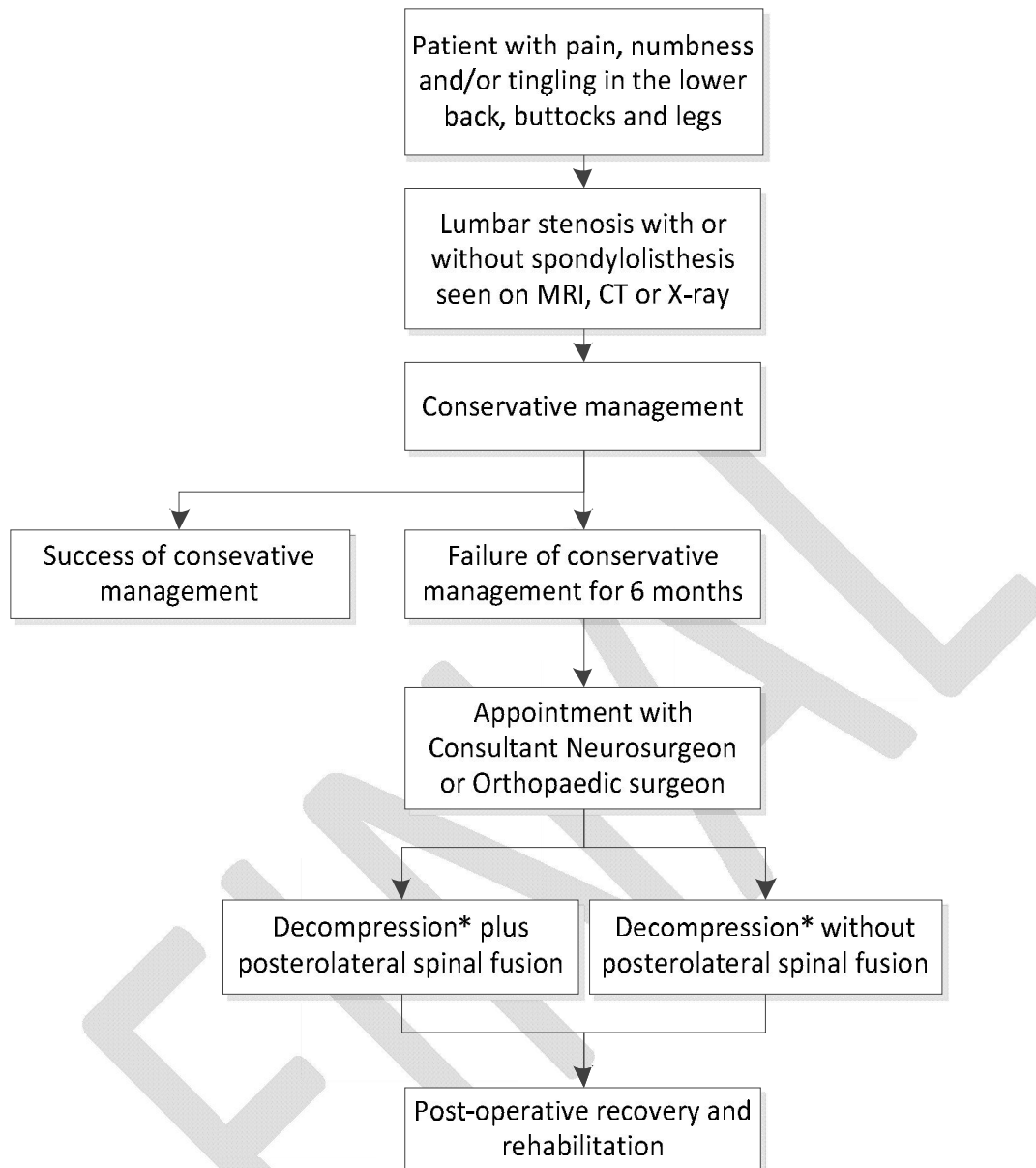
Notes

- 1) Conservative management can include included orthosis, rehabilitation, physical therapy, exercise, heat and cold, transcutaneous electrical nerve stimulation, ultrasounds, analgesics, nonsteroidal anti-inflammatory drugs, and epidural steroids.
- 2) Moderately severe functional impairment with symptoms exacerbated in extension as measured by the following criteria:
 - minimum Oswestry Disability Index (ODI) of 20 for 50 (40%), and
 - visual analogue scale (VAS) back pain score of 50 for 100 or more.

Clinical Management Algorithm - clinical place for the proposed intervention

Provide a clinical management algorithm (e.g.: flowchart) explaining the current approach (see (6) Comparator section) to management and any downstream services (aftercare) of the eligible population/s in the absence of public funding for the service proposed preferably with reference to existing clinical practice guidelines.

Current clinical management algorithm - existing clinical practice

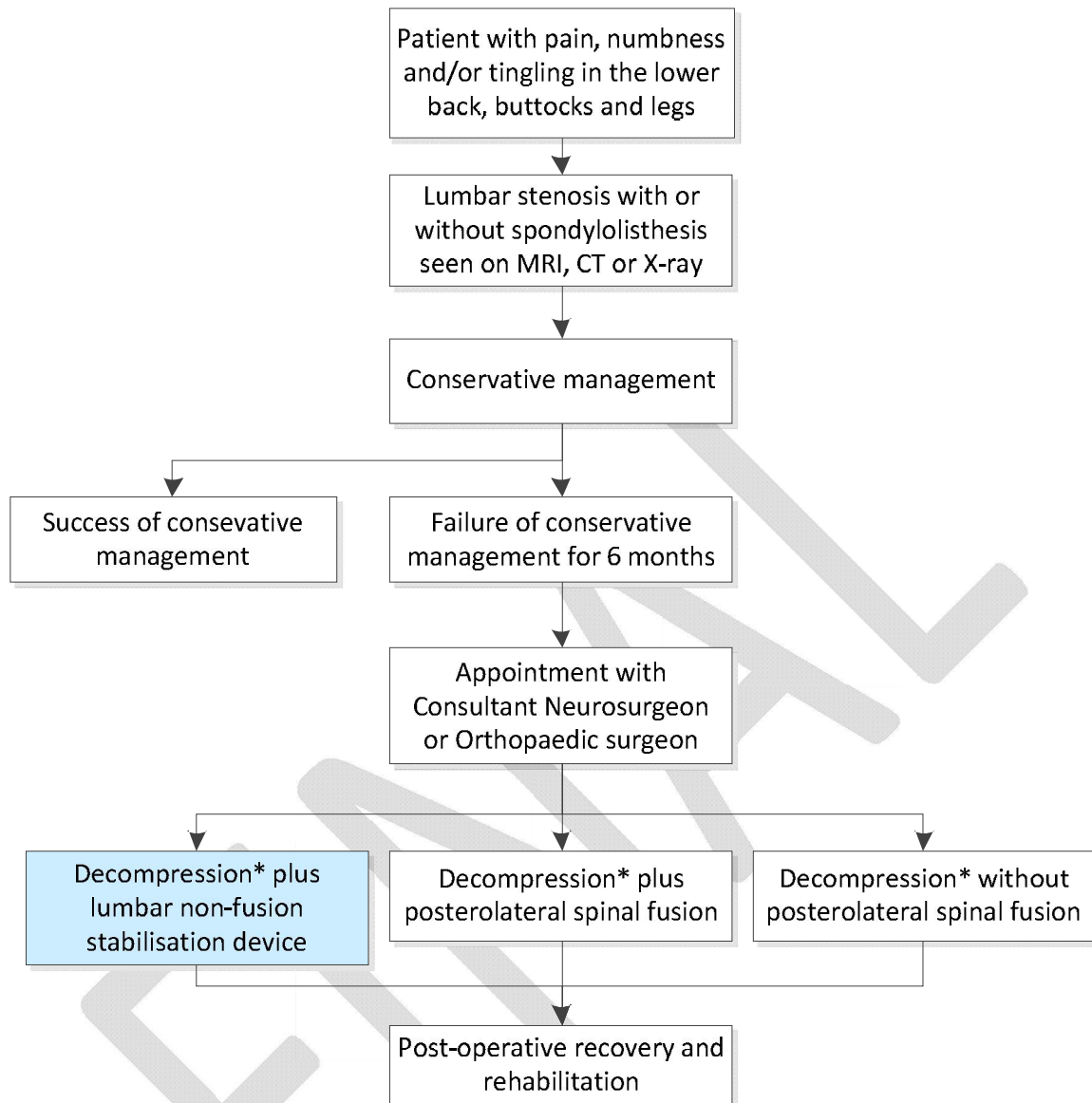


*Decompression can be conducted with laminectomy, partial laminectomy, or spinous process osteotomy, depending on the nature of the pathology.

MRI = magnetic resonance imaging. CT = computed tomography.

Provide a clinical management algorithm (e.g.: flowchart) explaining the expected management and any downstream services (aftercare) of the eligible population/s if public funding is recommended for the service proposed.

Clinical management algorithm – including proposed service



*Decompression can be conducted with laminectomy, partial laminectomy, or spinous process osteotomy, depending on the nature of the pathology.

MRI = magnetic resonance imaging. CT = computed tomography.

Regulatory Information

Please provide details of the regulatory status. Noting that regulatory listing must be finalised before MSAC consideration.

The details of registration (including certificates) of all medical devices and capital equipment used as part of this service were supplied in the original MSAC Application document.

- The Coflex® Interlaminar Stabilization™ device is TGA registration under ARTG 151022 Class IIb.
- The TGA-approved intended purpose is: Device intended for permanent implantation between the spinous processes of 1 or 2 lumbar motion segments and controls segmental motion in cases of lumbar stenosis or mild degenerative instability.

Decision analytic

Provide a summary of the PICO as well as the health care resource of the comparison/s that will be assessed, define the research questions and inform the analysis of evidence for consideration by MSAC

Key Research Question

- For patients with spinal stenosis, who have failed six months of conservative treatment, is partial laminectomy and Coflex interlaminar stabilization at least as safe, effective and cost-effective as the current Gold Standard, laminectomy and posterolateral spinal fusion?

Key Evidence

The key evidence for the submission will be from a prospective, randomized, multicentre, FDA Investigational Device Exemption trial with 322 patients and two year follow-up. Some of the papers reporting the details of this trial are:

Davis RJ, Errico TJ, Bae H, Auerbach JD. 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 (Phila Pa 1976)*. 2013 Aug 15;38(18):1529-39.

Davis R, Auerbach JD, Bae H, Errico TJ. Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: clinical article. *J Neurosurg Spine*. 2013 Aug;19(2):174-84.

Bae HW, Laurysen C, Maislin G, Leary S, Musacchio MJ Jr. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. *Int J Spine Surg*. 2015 May 11;9:15.

Bae HW, Davis RJ, Laurysen C, Leary S, Maislin G, Musacchio M Jr. Three-Year Follow-up of the Prospective, Randomized, Controlled Trial of Coflex Interlaminar Stabilization vs Instrumented Fusion in Patients With Lumbar Stenosis. *Neurosurgery*. 2016 Apr 4.

Musacchio MJ, Laurysen C, Davis RJ, Bae HW, Pelozza JH, Guyer RD, Zigler JE, Ohnmeiss DD, Leary S. Evaluation of Decompression and Interlaminar Stabilization Compared with Decompression

and Fusion for the Treatment of Lumbar Spinal Stenosis: 5-year Follow-up of a Prospective, Randomized, Controlled Trial. *Int J Spine Surg.* 2016 Jan 26;10:6.

These key papers will be supplemented by the results of literature searches in Medline, Embase and the Cochrane Library.

Details of the key trial will also be sourced from such documents as “Instructions for Use: coflex® Interlaminar Technology”.

PICO

- Patients:
- with lumbar spinal stenosis or mild degenerative instability;
 - who have failed conservative management for ≥ 6 months;
 - with moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion (indicative of neurogenic claudication); and
 - with or without low-grade spondylolisthesis.
- Intervention: Minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles, implantation between the spinous processes of one or two lumbar motion segments
- Comparator: Open posterior spinal nerve decompression with lumbar fusion using pedicle screw instrumentation with autograph. Open decompression will also be evaluated as a comparator.
- Outcomes: Composite Clinical Success (CCS) made up from:
- Difference in the Oswestry Low Back Pain Disability Index (ODI-15) at 60 months compared with baseline;
 - Reoperations, revisions, removals, or supplemental fixation;
 - Major device-related complications, including but not limited to permanent new or increasing sensory or motor deficit at 60 months;
 - Narcotic usage;
 - Lumbar epidural steroid injection at any postoperative time point;
 - Spinous process fractures;
 - Other quality of life measures.

Note: In the prospective, randomized, multicentre, Food and Drug Administration Investigational device exemption trial, overall FDA success criteria or composite clinical success (CCS) required a patient to meet the following 4 end points: 1) improvement of at least 15 points in ODI (ODI-15) at 60 months compared with baseline; 2) no reoperations, revisions, removals, or supplemental fixation; 3) no major device-related complications, including but not limited to permanent new or increasing sensory or motor deficit at 60 months; and 4) no lumbar epidural steroid injection at any postoperative time point. (*Davis et al 2013*)

Healthcare resources

Provide a list of the health care resources whose utilisation is likely to be impacted should the proposed intervention be made available as requested whether the utilisation of the resource will be impacted due to differences in outcomes or due to availability of the proposed intervention itself.

It is anticipated that the main change in resources use will result from the replacement of laminectomy and posterolateral spinal fusion with partial laminectomy and Coflex interlaminar stabilization.

Surgeon/ operating time: Approximately 55 minutes less compared to the comparator.

Prostheses: Coflex® Interlaminar Stabilization™ device versus posterior pedicle screw fixation system used for fusion.

All fees will be determined as part of the submission and in consultation with the relevant clinicians (Craft Groups and colleges).

Questions for public funding

Please list questions relating to the safety, effectiveness and cost-effectiveness of the service / intervention relevant to this application, for example:

- Which health / medical professionals provide the service
- Are there training and qualification requirements
- Are there accreditation requirements

Service Provider

- (i) Orthopaedic Surgeon; or
- (ii) Neurosurgeon

Training and Qualification Requirements

The coflex® Interlaminar Technology should only be used by surgeons who are experienced and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the coflex® Interlaminar Technology should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.