Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1422 – Minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles, of one or two lumbar motions

Applicant: **Medical Intelligence**

Date of MSAC consideration: **MSAC 69th Meeting, 6-7 April 2017**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

An application requesting two new Medicare Benefits Schedule (MBS) listings for minimally invasive lumbar decompression and dynamic stabilisation, using an interlaminar device (D+IL), with no rigid fixation to the vertebral pedicles for patients with lumbar spinal stenosis (LSS) or mild degenerative instability of one or two lumbar motion segments was received from LifeHealthcare Pty Ltd by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the comparative safety, clinical effectiveness and cost effectiveness, MSAC did not support public funding of the Coflex® Interlaminar Stabilization™ (Coflex®) device. MSAC considered that the evidence comparing use of the device with decompression and fusion, and with decompression alone, for LSS was too limited to support the listing and no evidence was presented comparing use of the device to other alternatives for mild degenerative instability alone.

MSAC noted that any resubmission would require high quality trial evidence that compared the benefits, harms and cost-effectiveness of using the device with decompression alone, and with decompression and fusion. Such a resubmission should also clarify the appropriate patient population who need 'stabilisation'.

Any resubmission would need to be considered by the Evaluation Sub-Committee (ESC).

MSAC requested that its advice regarding this MSAC application be provided to the Prostheses List Advisory Committee (PLAC).

3. Summary of consideration and rationale for MSAC's advice

MSAC considered a submission to include a service using the Coflex Interlaminar Stabilization device (hereafter the device) in the MBS. The proposed service involves use of

the device to stabilise the spine following decompression, without the need for fusion, in patients with lumbar spinal stenosis and mild degenerative instability of one or two lumbar motion segments.

MSAC noted that the submission only compared use of the device to decompression with fusion for people with lumbar spinal stenosis. MSAC noted that the PICO Sub-Committee (PASC) had asked that use of the device also be compared with decompression alone because of uncertainty about whether outcomes in people undergoing decompression and fusion were any better than outcomes in people undergoing decompression alone. Studies published around the time the protocol was written had compared decompression and fusion with decompression alone in people with lumbar spine stenosis (with or without spondylolisthesis). Two years post-surgery, these studies reported similar levels of disability due to back pain (Forsth P et al 2016; Ghogawala Z et al 2016).

MSAC questioned the applicant's claim that decompression and fusion, rather than decompression alone, was the appropriate comparator for use of the device. In addition to the two studies identified above, MSAC noted that a Cochrane review of spinal surgery for lumbar spinal stenosis was unable to identify any clear benefit of surgery compared to non-surgical treatment (Zaina F et al 2016).

MSAC noted that the submission did not provide a valid reason for failing to compare use of the device with decompression alone and as a result, the committee was unable to determine the relative safety and effectiveness of using the device compared with decompression alone.

With respect to the comparator of decompression and fusion, MSAC noted that the evidence to support listing of the device relied upon a single, low quality trial in people with moderate spinal stenosis with low back pain (>5/10) and with or without up to Meyerding grade I spondylolisthesis (the Investigational Device Exemption (IDE) trial).

MSAC had several concerns about the quality of the IDE trial including that the study was unblinded and that study outcomes may have been selectively reported. MSAC also noted that in the analysis of disability due to back pain five years post-surgery, 30% of patients were excluded from the analysis because they had had a secondary surgical procedure or epidural injection.

Given the uncertainty around clinical effectiveness, MSAC was unable to support the listing of the use of this device. MSAC requested this advice be provided to PLAC. MSAC noted that any resubmission required new high quality trial evidence comparing use of the device with decompression alone and comparing use of the device with decompression and fusion and for each of the indications requested (lumbar spinal stenosis with or without mild instability and mild instability alone).

Given MSAC's concerns as to whether decompression and fusion was any better than decompression alone, MSAC queried whether decompression and fusion should be funded on the MBS. MSAC suggested that a review of the current evidence for decompression and fusion in people with lumbar spine stenosis be undertaken. MSAC noted that the MBS Review of Spinal Surgery is currently reviewing available MBS items for spinal surgery. However, MSAC considered that an in-depth review of the evidence for decompression and fusion in this population was still warranted. MSAC noted that it would be helpful if the review considered utilisation and provider level data from the Department.

MSAC foreshadowed that if there was insufficient evidence for decompression and fusion in lumbar spinal stenosis then a wider review including decompression and/or fusion for other conditions may be recommended.

4. Background

In May 2007, MSAC considered application 1099, 'Lumbar Non-fusion Posterior Stabilisation Devices', which assessed the safety, effectiveness and cost-effectiveness for a pedicle screw device (Dynesys) and interspinous spacer devices (Coflex, the X STOP, the Wallis and the DIAM) compared with laminectomy with and without conventional spinal fusion. At that time, MSAC recommended that there was insufficient evidence to recommend a change in the public funding arrangements for the devices. Although there were no studies on Coflex at the time, it was the view of the assessment report that data from one device could be reasonably extrapolated to the others.

5. Prerequisites to implementation of any funding advice

The Coflex® Interlaminar Stabilization™ device (Coflex) is TGA registered under ARTG 151022 Class IIb.

An application to the PLAC is required for the device to be listed on the Prostheses List. The proposed service is limited to specialist referral, to either an orthopaedic surgeon or neurosurgeon that has undergone hands-on training with the devices.

6. Proposal for public funding

The proposed MBS item descriptors are summarised in Table 1 and Table 2.

Table 1 Proposed MBS item descriptor for one lumbar motion segment

Category 3 – THERAPEUTIC PROCEDURES
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. 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 per cent slippage). (Anaes.) (Assist.) Explanatory 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. 3) Low-grade spondylolisthesis, Grade 1, is when 25% or less of vertebral body has slipped forward.^
Fee: $1,082.70 75% = $812.05

Table 2 Proposed MBS item descriptor for two lumbar motion segments

Category 3 – THERAPEUTIC PROCEDURES
48xxy Posterior, interlaminar, non-fusion, dynamic stabilisation following decompression using an interlaminar device, with no rigid fixation to the vertebral pedicles, implantation between the spinous processes* of two lumbar motion segments. 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 per cent slippage). (Anaes.) (Assist.) Explanatory 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. 3) Low-grade spondylolisthesis, Grade 1, is when 25% or less of vertebral body has slipped forward.^
Fee: $1,506.45 Benefit: 75% = $1,129.85

7. Summary of Public Consultation Feedback/Consumer Issues

PASC received one response from an organisation.

Issues raised in the response were:

- The intervention should include other non-fusion posterior stabilization devices.
- The comparator should include decompression without fusion.

8. Proposed intervention's place in clinical management

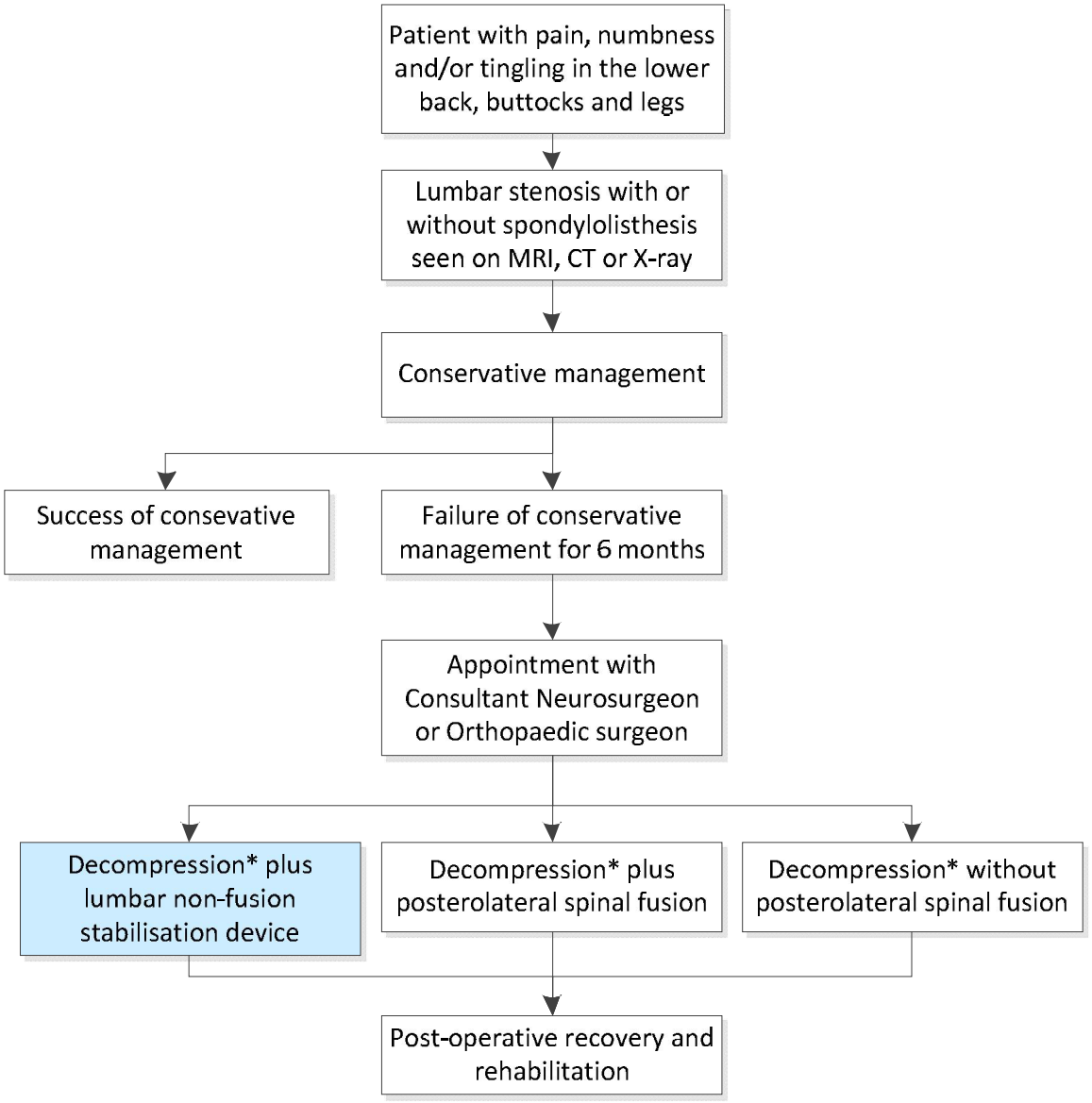
The proposed medical service involves minimally invasive, lumbar decompression and dynamic stabilisation using an interlaminar device, with no rigid fixation to the vertebral pedicles.

The intervention is proposed for patients:

- with LSS or mild degenerative instability – one or more lumbar motion segments;
- who have failed conservative management for six or more months;
- with moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion; and
- with or without low-grade spondylolisthesis.

The proposed clinical management algorithm is shown in Figure 1.

Figure 1 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.

9. Comparator

The comparator reported in the assessment report is open posterior spinal nerve decompression with lumbar fusion using pedicle screw instrumentation (D+PS) with autograft. Decompression without posterior spinal fusion was nominated as a comparator in the protocol, but was omitted from the assessment report.

The assessment report provided the following explanations for excluding decompression without fusion as a comparator.

1. The population included in the key prospective, randomized, multicentre, head-to-head clinical trial were patients with moderate to severe stenosis at one or two levels with up to Grade I spondylolisthesis and, very importantly, who had back pain with severity of at least 50 of 100. This tends to be the population where fusion is more likely to be performed rather than decompression alone. The study was designed to evaluate the Coflex device as a fusion alternative in such patients and not as a

decompression add-on in patients for whom the surgeon thinks decompression alone can adequately address the patient's symptoms."

2. Uncertainty of the most effective treatment between decompression alone vs. fusion vs. instrumented fusion, in patients with lumbar stenosis and back pain of greater severity than leg pain.
3. In symptomatic spinal stenosis without spondylolisthesis, decompression alone is the treatment of choice, but in spinal stenosis with degenerative spondylolisthesis of significance, fusion improves outcome.
4. According to Ghogawala et al (2016) "patients with degenerative grade I spondylolisthesis, the addition of lumbar spinal fusion to laminectomy was associated with slightly greater but clinically meaningful improvement in overall physical health-related quality of life than laminectomy alone."

10. Comparative safety

The assessment report concluded that the D+IL group performed as well as the D+PS group on safety. The assessment report stated that upon further examination, it appeared that some of the D+IL revision surgeries could be explained as "learning curve" issues such as wound closure problems, poor surgical planning resulting in under treatment requiring additional surgery at the index and adjacent levels within days to a few months postoperatively, or poor patient selection resulting in ineffective treatment within two years. These three categories accounted for more than half of revisions in the D+IL group. In comparison, these three categories resulted in only 32% of revisions in the D+PS group. Focusing on the categories of durability and sustainability, the D+PS group had a 6.5% rate of device-related failure requiring revision and 5.6% late-term ineffective treatment revisions thereby an effective 12.1% revision rate. In comparison, the D+IL group had a 2.8% rate of device-related revisions and a 4.2% late-term ineffective treatment revisions resulting in an effective 7% revision rate with regard to durability and sustainability during 5-year follow-up.

The critique noted there was a high rate of losses to follow-up (up to 30%) reported in the IDE trial. Further surgery or Oswestry Disability Index was considered an endpoint of the study and therefore these participants were excluded from the analysis of patient-reported outcomes. Comparative safety outcomes were not evaluated by either the studies provided or the submission. Reoperation, revisions and removals of the devices were inconsistently reported and therefore associated with a high risk of bias. Claims regarding the comparative safety outcomes were subject to a high degree of uncertainty.

11. Comparative effectiveness

The assessment report concluded that the results of the key clinical trial, with 5-year follow-up, Musacchio et al (2016) support that DL+IL is an effective and sustainable treatment option for moderate to severe spinal stenosis. D+IL produces outcomes similar or superior D+PS. One and two levels yield equally good results compared to D+PS. Two level D+IL procedures had a significantly lower rate of revision than D+PS procedures.

The submission selectively presented effectiveness data from one Randomised Control Trrial (the IDE trial). The clinical cut-off criteria reported in the IDE trial were not adequately defined, and may not be clinically relevant. Results from the IDE trials also lacked transparency, and was subject to a high risk of bias. Based on this, the critique suggested that the comparative effectiveness and safety profile of the Coflex® device is subject to high risk of bias, and point estimates are subject to substantial uncertainty.

The critique also identified significant issues and biases in the primary and secondary outcomes. The definition of the primary endpoint (i.e. CCS) was not appropriately supported with clinical justifications and was reported inconsistently across the (five) publications from the IDE trial. Secondary outcomes were also selectively reported and lacked transparency.

Clinical Claim

Based on studies reported by Davis et al (2013) and Musacchio et al (2016), the assessment report claimed the intervention, in comparison to decompression plus fusion, has:

- non-inferior clinical outcomes, as measured by Oswestry Disability Index (ODI) scores (minimum 15 points), visual analogue scale (VAS) scores, short form-12 (SF-12) scores, and Zurich Claudication Questionnaire (ZCQ) scores;
- superior short term outcomes related to shorter operative times, reduced blood loss and reduced hospital length of stay; and
- non-inferior reoperation/revision rates.

12. Economic evaluation

The assessment report presented a cost-minimisation analysis, based on the five-year results reported by Musacchio et al (2016), and the two-year results reported by Davis et al (2013). Health outcomes are assumed to be the same for the intervention and comparator. No measure of the final health outcome from a patient perspective, such as QALYs is relevant.

Estimated health care resource costs in the assessment report were presented in disaggregated form. Costs were estimated for Level 1 and Level 2 patients then combined using a weighting of 64% for Level 1 and 36% Level 2 procedures.

D+IL was estimated to have a lower cost for both patient levels. The combined cost saving without the inclusion of re-operation was $3,702.10. The assessment report included sensitivity scenarios which involved increasing the proposed MBS fee to match that for the replaced MBS services, increasing the cost of the Coflex device from $5,000 to $5,823.53, changing the ratio of Level 1 and 2 procedures to 50:50, and increasing the average length of stay for D+IL by 1.29 days.

In addition to those sensitivity analyses presented in the submission, scenarios were included in the critique for:

- inclusion of re-operation rate of 16.3% 5-year cumulative re-operation rate for D + IL and D + PS was 17.8% using appropriate discounting;
- an accommodation cost saving of 50% of $1,100 per day;
- no savings assumed for operating costs; and
- the costs of D+IL compared to decompression surgery alone.

The overall cost minimisation results of D+PS compared to D+ ILS remains unchanged over the sensitivity analysis scenarios presented, except for the comparison with decompression only. D+IL is the lower cost intervention when compared to D+PS.

13. Financial/budgetary impacts

An epidemiological approach was adopted in the assessment report. The key issue for financial analysis was associated with costing the comparator (D+PS) and the proposed procedure (D+IL). It was concluded that any costing would be an underestimate, since the proposed procedure (D+IL) is less costly.

The following table gives the net effect of the replacement of the currently listed procedure D+PS with the proposed procedure D+ILS for the first five years of listing. As shown in the following table, it is estimated that there will be a saving, resulting from the listing of D+ILS, of $936,079 in the fifth year of listing.

Table 3 Five year net savings of decompression and interlaminar stabilisation (D+IL) to Medicare

Year	1	2	3	4	5
Year	2017/18	2018/19	2019/20	2020/21	2021/22
Savings – 1 level	$79,044	$191,516	$344,033	$510,129	$628,173
Savings – 2 levels	$38,744	$93,874	$168,631	$250,046	$307,906
Savings - total	$117,788	$285,390	$512,664	$760,175	$936,079

14. Key issues from ESC for MSAC

ESC considered that the evidence presented to inform any decision about including a medical service using the Coflex® device on the MBS was limited and of poor quality.

ESC noted that the original protocol included two comparators; decompression alone and decompression with fusion. ESC noted that the submission did not compare the device to decompression alone and did not provide a valid reason for failing to do so. ESC noted that as a result of this omission, it was not possible to determine the relative safety and effectiveness of the device to decompression alone.

ESC also noted that the protocol had requested a review of the current indications for recommending decompression alone versus decompression and fusion in patients eligible for surgery due to failed conservative management, citing clinical guidelines if available or randomised controlled trials (RCTs) comparing these procedures. ESC noted that this had not been done.

ESC noted further issues with the submission including:

- issues in the design and reporting of the only RCT presented in the submission — the IDE trial comparing the device to decompression with fusion. ESC considered this study to be at high risk of bias. Shortcomings included inadequate description of the primary outcome (composite clinical success), limited and selective outcome reporting, unclear statistical methods and a high rate of loss to follow-up (up to 30%);
- uncertainty about the proposed population for the device due to a lack of clarity around the indications for its use and concerns about the applicability of the evidence base;
- uncertainty around the numbers of patients who would be eligible for the device instead of decompression alone; and
- uncertainty as to whether all available evidence for the device had been presented due to an inappropriate literature searching technique.

Bearing all of this uncertainty in mind, ESC noted that when compared with decompression and fusion, use of the device was cost saving. However, when compared to decompression alone, ESC considered that use of the device would increase health costs.

ESC noted the applicant's argument that the device differed from other similar devices because it is implanted between the lamina and spinous processes (interlaminar) rather than between the spinous processes only (interspinous). However, ESC noted that in a previous application (Application 1099: Lumbar Non-fusion Posterior Stabilisation Devices) the Coflex device was considered to be similar to interspinous devices. ESC also noted that clinical expert feedback suggested the terms interlaminar and interspinous are interchangeable in the context of non-fusion surgery.

ESC noted that the applicant had not followed the MSAC technical guidelines when compiling the submission and, as a result, the methodology and analysis was not transparent and introduced further uncertainty into the decision making process.

ESC noted consumer concerns regarding the limited evidence presented for this device.

15. Other significant factors

Nil

16. Applicant's comments on MSAC's Public Summary Document

As the title of the Application clearly indicated (lumbar decompression and dynamic stabilisation), the Application did not include decompression alone as a comparator. This was also made clear by the proposed MBS Item descriptors. A detailed literature search and review, carried out as part of the submission, clearly showed that there was no high level evidence to support decompression alone as a comparator. The Public Summary stated that MSAC had several concerns about the quality of the IDE trial including that the study was unblinded and that study outcomes may have been selectively reported. There are numerous reports on the difficulty of blinding a surgical procedure. Additionally, the use of the word 'may' is of some concern to the sponsor.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website:
visit the MSAC website