



Australian Government

Department of Health

MSAC Application 1661

Implantation of minimally invasive interspinous decompression spacers for moderate degenerative lumbar spinal stenosis

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation name: Boston Scientific

ABN: 45071 676 063

Business trading name: Boston Scientific Pty Ltd

Primary contact name: REDACTED

Alternative contact name: REDACTED

2. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

(b) If yes, are you listed on the Register of Lobbyists?

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Implantation of minimally invasive interspinous decompression spacers (IDSs) for moderate degenerative lumbar spinal stenosis (LSS).

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

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). NIC can lead to pain or discomfort that radiates to the lower leg, thigh, and/or buttocks while walking. Patients with more pronounced LSS may also develop lower extremity weakness, muscle cramping, numbness, imbalance, and difficulties controlling bowel and bladder function. The most common cause of LSS is the “wear and tear” that occurs with natural aging and osteoarthritis.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

IDSs were designed for the treatment of symptoms of intermittent NIC secondary to moderate degenerative LSS and are implanted by minimally invasive methods. When implanted between spinous processes of symptomatic level(s), IDSs stabilise and increase the interspinous distance and prevent the excessive dorsiflexion. There are a number of IDSs registered for use in Australia, including devices manufactured by Boston Scientific (Superion), REDACTED, REDACTED and REDACTED; however, all except Superion are used in addition to decompression surgery. Therefore, Superion is REDACTED currently registered IDS intended for use as an alternative to traditional decompression surgery (most often, laminectomy) with or without surgical fusion. The main advantages of an IDS relative to current approaches include providing equivalent effectiveness, significantly fewer and less serious risks and complications, and less hospitalisation time due to the minimally invasive implantation procedure.

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Not applicable

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

Not applicable

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
- No

(g) If yes, please advise:

Not applicable

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

Not applicable

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

Not applicable

(b) If yes, please list the relevant PBS item code(s):

Not applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

Not applicable

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Not applicable

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Protheses List?

- Yes
 No

(b) If yes, please provide the following information (where relevant):

Not applicable

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Protheses List Advisory Committee (PLAC)?

- Yes
 No

An application will be made to list Boston Scientific's Superior Indirect Decompression System on the Protheses List.

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

- Yes
 No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Not applicable

12. Please identify any single and / or multi-use consumables delivered as part of the service?

The Superior IDS system is a titanium implant designed to fit between the spinous process of the lumbar spine. It is composed of titanium 6Al-4V ELI alloy, and consists of a single component with deployable superior and inferior projections that engage the spinous processes to secure it in place dorsal to the lamina. The Superior IDS is provided sterile in sizes 8mm, 10mm, 12mm, 14mm, and 16mm. The Superior IDS is implanted by percutaneous means through a cannula inserted between adjacent spinous processes. Once inserted into the interspinous process space the Superior IDS is deployed, or opened, to provide distraction and restrict extension at the affected segment.

The Superior IDS system includes a set of proprietary instruments to deliver the Superior Implant minimally invasively. Instruments specifically designed for implanting the Superior Implant are sterile, single use disposable instruments consisting of a dilator assembly, a cannula assembly, an interspinous gauge, an inserter, a reamer, and a driver.

Single use consumables include:

- Lumbar interspinous decompression spacer(s), sterile

Multi-use consumables include:

- Superior Indirect Decompression Instrument Kit - Lumbar interspinous decompression instrument set, single-use

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

- ARTG ID 333162 - Boston Scientific Pty Ltd - Superior Indirect Decompression Instrument Kit - Lumbar interspinous decompression instrument set, single-use
- ARTG ID 334411 - Boston Scientific Pty Ltd - Lumbar interspinous decompression spacer, sterile

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III
 AIMD
 N/A

The Superior IDS System is Class IIb

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below)
 No

ARTG	TGA indication/purpose
ARTG ID 333162 - Boston Scientific Pty Ltd - Superior Indirect Decompression Instrument Kit - Lumbar interspinous decompression instrument set, single-use	The single-use manual instruments are employed to access the interspinous process space and to position the Superior implant
ARTG ID 334411 - Boston Scientific Pty Ltd - Lumbar interspinous decompression spacer, sterile	The intended use of the Superior Indirect Decompression System is to provide posterior stabilization of the lumbar spine, Levels L1 to L5, via a percutaneous/minimally invasive procedure.

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

Not applicable

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

Not applicable

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

The evidence base for IDSs is expected to consist of randomised controlled trials (RCTs) in patients with LSS, with decompression or fusion and decompression as the main comparators. Evidence for long term efficacy outcomes is likely to be derived from an RCT of Superion compared to the X-Stop device, which has up to five years of efficacy data available.

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Moojen, 2015	Moojen WA, Arts MP, Jacobs WC, et al. IDS without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial. Eur Spine J 2015; 24:2295-305.	RCT of spinal bony decompression and an unnamed IDS in patients with NIC from LSS after failed conservative treatment. N=159	https://link.springer.com/article/10.1007%2Fs00586-014-3748-2	2015
2.	Stromqvist, 2013	Stromqvist BH, Berg S, Gerdhem P et al (2013) X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up. Spine 38:1436–1442.	RCT of indirect decompression by means of the X-Stop implant with conventional decompression in patients with NIC due to LSS. N=100	https://pubmed.ncbi.nlm.nih.gov/23403549/	2013
3.	Azzazi, 2010	Azzazi A, Elhawary Y (2010) Dynamic stabilization using X-stop versus transpedicular screw fixation in the treatment of lumbar canal stenosis; comparative study of the clinical outcome. Neurosurg Q 20:165–169	RCT to compare the clinical outcome of transpedicular screw fixation (spinal fusion) and dynamic stabilization using X-stop in patients with degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis. N=60	https://journals.lww.com/neurosurgery-quarterly/Abstract/2010/09000/Dynamic_Stabilization_Using_X_stop_Versus.9.aspx	2010

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Lonne, 2015	Lonne G, Johnsen LG, Rossvoll I, et al. Minimally invasive decompression versus x-stop in lumbar spinal stenosis: a randomized controlled multicenter study. Spine (Phila Pa 1976) 2015;40:77-85.	RCT to compare the effect of X-Stop with minimally invasive decompression (MID) in patients with NIC due to LSS in patients with symptoms of NIC within 250-m walking distance and 1- or 2-level LSS.	https://journals.lww.com/spinejournal/Abstract/2015/01150/Minimally_Invasive_Decompression_Versus_X_Stop_in.3.aspx	2015
5.	Patel et al. 2015a, 2015b, 2014; Nunley et al. 2018a, 2018b, 2017a, 2017b; Miller & Block 2012	SISS Study Prospective, randomised; Superion vs. X-Stop device	RCT of Superion and X-Stop in subjects suffering from symptoms of intermittent neurogenic claudication, secondary to a confirmed diagnosis of moderate degenerative lumbar spinal stenosis at one or two contiguous levels from L1 to L5 n=391	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4599047/	2015

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

*** If the publication is a follow-up to an initial publication, please advise.

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

Not applicable

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Boston Scientific is working with a number of professional bodies / consumer organisations /clinical experts to obtain clinical endorsement for Superior and will provide these details to the Department once they are available.

- 20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

See above

- 21. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

See above

- 22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

As noted previously, a number of manufacturers produce interspinous spacers; however, all except Superior require additional decompression surgery and are therefore not considered minimally invasive. As such, Superior is the only manufacturer of a device that would be considered eligible for implantation under the proposed MBS listing.

- 23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

See above. Boston Scientific will provide these details to the Department once they are available.

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

LSS is a common spinal disorder in the older population, and a clinical syndrome consisting of pain in the buttock or lower extremity, with or without low back pain and corresponding imaging findings of narrowing of spaces around neural and vascular elements in the lumbar spine. Spondylosis, or degenerative arthritis affecting the spine, is the most common cause of LSS and typically affects individuals over the age of 60 years.

LSS is a significant cause of disability, and its prevalence is expected to increase with the continued ageing of the population. The first symptoms of stenosis include bouts of low back pain. After a few months or years, this may progress to claudication. The pain may be radicular, following the classic neurologic pathways. This occurs as the spinal nerves or spinal cord become increasingly trapped in a smaller space within the canal. Most people with mild to moderate symptoms do not get worse (Djurasovic 2010); however, ongoing symptoms can have a substantial negative effect on general health-related quality of life (HRQoL) - especially in physical domains. A number of studies demonstrated that HRQoL is poorer in patients with LSS compared with healthy individuals without this condition and even compared with patients diagnosed with chronic back pain (Otani 2013; Saban 2007). Patients with LSS experience significantly lower job satisfaction than individuals without this condition (Sekiguchi 2015). In addition, about 20%–40% of the patients with LSS present clinically significant depressive symptoms (Levy 2002; Sinikallio 2006).

A systematic review in general and clinical populations (Jensen 2020), based on an analysis of 55 study samples, reported the mean prevalence of LSS in the general population was 11% (95% CI 4–18%) based on clinical diagnosis. In Australia, decompression rates for LSS increased from 2003 to 2013, and the fastest increasing surgical procedure was complex fusion.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

There have been two previous applications to the MSAC for IDSs. In 2007, a contracted assessment (MSAC Application 1099) assessed the safety, effectiveness, and cost-effectiveness for a pedicle screw device (Dynesys) and IDSs (Coflex, the X STOP, the Wallis and the DIAM) compared with laminectomy with and without conventional spinal fusion. A more recent applicant developed assessment report (ADAR) in 2017 (MSAC Application 1422) looked specifically at the safety, effectiveness, and cost-effectiveness of using the Coflex interlaminar stabilisation device in combination with decompression. Both of the previous applications were rejected by MSAC due to poor evidence for clinical efficacy.

The population broadly targeted in the proposed submission consists of patients with moderate degenerative LSS. The population proposed for treatment in a future MSAC application for Superior would be broadly similar to that included in the previous MSAC submission for Coflex (1422), that is:

- 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.
- With or without low-grade spondylolisthesis.

These criteria are similar to the Australian indication for Superion, which is as follows:

"skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion IDS [Superion] is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superion IDS may be implanted at one or two adjacent lumbar levels in patients in whom operative treatment is indicated at no more than two levels, from L1 to L5".

Identifying individuals with moderate degenerative LSS is challenging and often relies on the assessment of the individual's symptoms and physical examination findings. NIC represents the key symptomatic aspect of LSS, defined as intermittent pain radiating to the buttocks, thighs and/or lower legs that is typically provoked by standing, walking and/or lumbar extension, and relieved with sitting, lying down or lumbar flexion. In individuals with history and physical examination findings consistent with LSS, magnetic resonance imaging (MRI), X-ray and/or computed tomography (CT) are suggested as appropriate tests to confirm the presence of moderate degenerative LSS (e.g., evidence of thickened ligamentum flavum).

The presence of a narrowed spinal canal on radiographic imaging is not a sufficient criterion to diagnose LSS, and a correlation between narrowing of the spinal canal and clinical symptoms of spinal stenosis has not been demonstrated yet. Therefore, LSS is mainly a clinical diagnosis supported by consistent radiological findings. The Superion Instructions for Use defines moderate degenerative LSS as follows:

- 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
 - Evidence of thecal sac and/or cauda equina compression
 - Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements
 - Evidence of hypertrophic facets with canal encroachment
- AND Associated with the following clinical signs:
 - Presents with moderately impaired Physical Function (PF) defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire (ZCQ)
 - Ability to sit for 50 minutes without pain and to walk 50 feet or more.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

In Australia, the appropriate treatment for moderate generative LSS is determined following an appointment with a consultant pain specialist, neurosurgeon or orthopaedic surgeon based on the individual needs of the patient. Once diagnosed, patients with moderate degenerative LSS are required to first undergo 6 months of conservative management, which may include any of the following: orthosis, rehabilitation, physical therapy, exercise, heat and cold, transcutaneous electrical nerve stimulation, ultrasounds, analgesics, nonsteroidal anti-inflammatory drugs, epidural steroids, and back bracing. This approach is consistent with evidence-based clinical practice guidelines, which generally recommend conservative care for patients with moderate degenerative LSS, and surgical or invasive options where this approach is unsuccessful (Kreiner 2013).

In patients for whom conservative care is unsuccessful, the available treatment options are decompression with or without fusion surgery or fusion surgery alone. Decompression can be conducted with laminectomy, partial laminectomy, or spinous process osteotomy, depending on the nature of the pathology. The most common treatment option is usually compression without fusion surgery; however, some patients will receive both interventions together, and others will undergo surgical fusion after the failure of decompression. Additionally, it was noted in MSAC Application 1099 that in Australia, fusion surgery is only occasionally performed without prior decompression. The Lumbar Spinal Stenosis

Consensus Group Guidelines for Minimally Invasive Spine Treatment (MIST Guidelines) contain a consensus recommendation for the use of IDSs to treat LSS. The guideline proposes that if IDS efficacy is at least equivalent to that of laminectomy, the less-invasive IDS procedure, with its lower risk and complication rate, is the preferable treatment option (Deer 2019).

The current clinical management algorithm for the treatment of moderate degenerative LSS is summarised in Attachment X.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

While IDSs differ in their exact design, they can be broadly described as implants that fit between the spinous processes of the lumbar spine. The process for implanting an IDS such as Superior is minimally invasive and is generally undertaken in a day surgery setting (without the need for hospital admission) under local anaesthesia with conscious sedation. IDS placement may be performed by interventional pain physicians sufficiently adept at implantable device procedures (e.g., spinal cord stimulators), and does not require the services of an orthopaedic surgeon or neurosurgeon.

The placement of the Superior IDS is generally via a midline approach through a cannula roughly 12 mm in diameter. The implant is positioned between adjacent spinous processes dorsal to the lamina, and the cannula is removed. Excepting only the initial skin incision to place the cannula, no tissue is dissected or resected, and the implant is positioned dorsal to the neural elements. In the event of treatment failure, the implant may be removed in the same minimally invasive manner in which it was implanted. To note, the placement of IDSs may differ in clinical practice but the proposed MBS listing is limited to those that are implanted using a minimally invasive approach. Any differences between Superior and other IDSs in terms of the implantation procedure will be explored in the ADAR.

The TGA approved indication states that the Superior IDS may be implanted at one or two adjacent lumbar levels in patients in whom operative treatment is indicated at no more than two levels, from L1 to L5. Therefore, a proportion of patients with evidence of stenosis at more than just one level may require the implantation of two devices. Based on the current utilisation of one and two-level laminectomies (MBS items 51011 and 51012), it is expected that approximately 31% of patients treated with IDSs will be implanted at two levels.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

Superior is the only registered device that is indicated for placement without decompression surgery. The proposed medical service is for the implantation of any minimally invasive IDS that meets the item descriptor, not restricted to Superior.

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

The implantation of an IDS is less invasive and associated with fewer complications than traditional approaches to the management of LSS (e.g. decompression surgery). Therefore, the use of an IDS would result in a change to the manner in which patients with moderate degenerative LSS are managed.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

In terms of procedure complexity and resources, implantation of an IDS is clinically similar to laminectomy. Therefore, the necessary capabilities to perform IDS implantation are already established at the relevant clinics and institutions.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

IDS percutaneous implantation is commonly provided under local anaesthesia with conscious sedation. An anaesthetist may be required to provide the appropriate level of sedation.

32. If applicable, advise which health professionals will primarily deliver the proposed service:

Pain Specialists will primarily perform this procedure(>85%), with orthopaedic, spine, and neurosurgeons being a smaller group of treating physicians.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not applicable

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Not applicable

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

No further training would be required.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

37. Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

Not applicable.

38. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

- 39. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):**

Patients only become candidates for surgical treatment when they have exhausted non-operative treatments without pain relief. Surgery is suitable for a small number of patients who are psychologically healthy and who have the source of their pain verified through the use of clinical assessment, plain radiography, MRI and discography where appropriate. Surgical options currently available for treating symptomatic LSS include spinal decompression with or without fusion surgery. Accordingly, in MSAC Application 1099, these two procedures were the main comparators for non-fusion devices.

Decompression surgery

The aim of decompression is to alleviate pain caused by compression of a nerve. The procedure involves removal of a portion of bone over the nerve root and/or disc material under the nerve root to provide more space for the nerve.

In a laminectomy, a 5–15-cm incision is made in the back, and the muscles are dissected off the lamina. The lamina is then removed, and the facet joints are trimmed to create more room for the nerve roots.

For compression of a nerve by a disc, microdiscectomy may be considered to alleviate symptoms. This involves a small (approximately 3 cm) incision in the midline of the low back. The back muscles are moved to allow the surgeon access to the nerve (possibly with the removal of some facet joint). The nerve root is then moved to the side and the disc material is removed. Almost all of the joints, muscles and ligaments are left intact.

Fusion surgery

The aim of fusion surgery is to use a bone graft to fuse the vertebrae superior and inferior to a disc. Bone grafts can be either autologous (harvested from the patient’s own pelvic bone) or an allograft (from a bone bank). Recently, bone morphogenetic protein products have also been used. There are a number of different methods of performing fusion surgery, including anterior or posterior lumbar intervertebral body fusion and posterolateral fusion. Instrumentation is used to facilitate the fusion by providing stability. There are three types of spinal instrumentation: pedicle screws, anterior interbody cages, and posterior lumbar cages

For spines with segmental instability or potential post-operative instability after decompression, fusion surgery may be used in addition to decompression. It was noted in MSAC Application 1099 that in Australia, fusion surgery is only occasionally performed without prior decompression, and fusion surgery alone was therefore excluded from the economic evaluation.

Proposed comparator

In Australia, patients with moderate degenerative LSS who have failed conservative management are most often treated with surgical decompression; however there appears to be increasing use of spinal fusion in addition to decompression. A recent Australian study by Machado (2017) reported that the proportion of LSS patients receiving fusion surgery is 19% compared to 81% for decompression (Machado 2017; Table 1). On this basis, the proposed comparator for IDS is a weighted comparator consisting of decompression with or without fusion surgery. This is consistent with the approach taken in MSAC Application 1099.

- 40. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?**

- Yes (please list all relevant MBS item numbers below)
 No

The relevant MBS item numbers of decompression are MBS items 51011 (one segment) and 51012 (two segments) based on its TGA-approved indication. For patients who require posterolateral spinal fusion without instrumentation in combination with a decompression procedure, MBS items 51031 (one segment) and 51032 (two segments) may be selected. For posterolateral spinal fusion with instrumentation, an

additional item can be selected from MBS items 51020 (simple fixation), 51021 (one segment) and 51022 (2 segments), as described below.

Decompression
<p>51011</p> <p>Spinal decompression or exposure via partial or total laminectomy, partial vertebrectomy or posterior spinal release, one motion segment, not being a service associated with a service to which item 51012, 51013, 51014 or 51015 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,458.45 Benefit: 75% = \$1,093.85</p>
<p>51012</p> <p>Spinal decompression or exposure via partial or total laminectomy, partial vertebrectomy or posterior spinal release, 2 motion segments, not being a service associated with a service to which item 51011, 51013, 51014 or 51015 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,944.40 Benefit: 75% = \$1,458.30</p>
Spinal fusion
<p>51031</p> <p>Spine, posterior and/or posterolateral bone graft to, one motion segment, not being a service associated with a service to which item 51032, 51033, 51034, 51035 or 51036 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$956.50 Benefit: 75% = \$717.40</p>
<p>51032</p> <p>Spine, posterior and/or posterolateral bone graft to, 2 motion segments, not being a service associated with a service to which item 51031, 51033, 51034, 51035 or 51036 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,147.85 Benefit: 75% = \$860.90</p>
Instrumentation
<p>51020</p> <p>Simple fixation of part of one vertebra (not motion segment) including pars interarticularis, spinous process or pedicle, or simple interspinous wiring between 2 adjacent vertebral levels, not being a service associated with:</p> <p>(a) interspinous dynamic stabilisation devices; or (b) a service to which item 51021, 51022, 51023, 51024, 51025 or 51026 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.) Fee: \$777.70 Benefit: 75% = \$583.30</p>

51021

Fixation of motion segment with vertebral body screw, pedicle screw or hook instrumentation including sublaminar tapes or wires, one motion segment, not being a service associated with a service to which item 51020, 51022, 51023, 51024, 51025 or 51026 applies

Multiple Operation Rule

(Anaes.) (Assist.)

Fee: \$1,301.70 Benefit: 75% = \$976.30

51022

Fixation of motion segment with vertebral body screw, pedicle screw or hook instrumentation including sublaminar tapes or wires, 2 motion segments, not being a service associated with a service to which item 51020, 51021, 51023, 51024, 51025 or 51026 applies

Multiple Operation Rule

(Anaes.) (Assist.)

Fee: \$1,619.20 Benefit: 75% = \$1,214.40

- 41. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):**

Following decompression surgery with or without fusion surgery, patients undergo a period of recovery and rehabilitation. This usually involves conservative management and other additional guided therapies depending on the patient's recovery time. Some patients may undergo a revision, as is the case for current treatments for LSS, which will be explored in the ADAR. The clinical management pathway is summarised in Attachment A.

- 42. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

- In addition to (i.e. it is an add-on service)
 Instead of (i.e. it is a replacement or alternative)

- (b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:**

In MSAC Application 1099, it was estimated that approximately 30-35% of single level decompression procedures and 10-20% of multiple level decompressions would be candidates for non-fusion therapy.

- 43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):**

The change in how patients are currently managed will arise largely from a reduction in the length of hospital admission as well as fewer complications from surgery. Most patients will only require a day case hospitalisation following the delivery of the intervention, whereas this increases to several nights in patients undergoing decompression with or without fusion surgery. The reduction in complications is itself associated with decreased resource use, including hospitalisations.

Some patients undergoing treatment with IDs will require revision if treatment is unsuccessful or if there are complications. The rates of revisions and complications associated with IDs and their comparators will be explored in the ADAR.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

The main clinical claim in the submission will be that IDS is non-inferior to decompression with or without fusion surgery, in terms of clinical efficacy and safety.

45. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

46. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Clinical Effectiveness Outcomes:

Primary outcome

Patient assessed leg and/or back pain

Patient assessed QoL

Observer assessed functional status

Secondary outcome

Observer assessed patient pain and QoL

Patient assessed functional status

Analgesic usage

Hospital length-of-stay

Safety Outcomes:

Rate of reoperation

Device removal

Rate of complications

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

47. Estimate the prevalence and/or incidence of the proposed population

The AIHW reports that the prevalence of self-reported back problems was 15.7% in Australia in the year 2017-18 (AIHW, Back Problems, 2020). As shown in the table below, 8.6% (N=15,545) of back problem hospitalisations were associated with a diagnosis of spinal stenosis; however it is possible that a proportion of patients with NIC due to LSS would be captured under other diagnostic categories, such as “low back pain” or “other”. It is also not known what proportion of these patients would meet the proposed eligibility criteria, limiting use of IDs to patients with moderate LSS not responsive to conservative treatment (for at least 6 months).

Table 1: AIHW prevalence of self-reported back problems 2017-18

Diagnoses of back problems	Number	Per cent
Other specified intervertebral disc displacement	6,366	3.5
Neck pain (cervicalgia)	10,568	5.8
Spinal stenosis	15,545	8.6
Lumbar and other intervertebral disc disorders with radiculopathy	17,190	9.5
Low back pain	48,819	27.0
Other	82,330	45.5
Total	180,818	100.0

The table below presents the number of patients in private hospitals undergoing spinal decompression for one motion segment (MBS item 51011) or two segments (MBS item 51012) between January 2018 and December 2019. As noted above, the comparator consists of decompression alone, or decompression with spinal surgery. As such the utilisation of IDs is likely to be a fraction of the total services for decompression. Note that due to changes to the MBS items for spinal surgery in 2018, information on the utilisation of these services prior to 2018 is unavailable. Data for MBS items 40303 (laminectomy for recurrent disc lesion or spinal stenosis) and 40306 (laminectomy for spinal stenosis involving > 1 level) are available; however, it should be noted that the item descriptors are slightly different and do not reflect exactly the same range of procedures as the current MBS items.

Australian Refined Diagnosis Related Group (AR-DRG) round 21 cost estimates suggest that the split between private and public patients for minor, intermediate and major spinal procedures (B03A, B03B, B03C) is 65 per cent to 35 per cent. Therefore, decompression or fusion with/without decompression appears to be responsible for an estimated 4,837 public hospital separations. This indicates that a total of 21,820 decompression procedures for 1 level and 9,982 decompression procedures for two levels are predicted across private and public hospitals.

Table 2: Medicare utilisation of items for spinal decompression

Year	MBS item 40303	MBS item 40306 (>1 level)	Total
2010	3,904	6,589	10,493
2011	4,430	6,823	11,253
2012	5,036	7,199	12,235
2013	5,527	7,686	13,213
2014	5,989	8,235	14,224
2015	6,054	8,319	14,373
2016	6,121	7,882	14,003
2017	6,418	8,373	14,791
2018	5,709	7,300	13,009
	MBS item 51011 (1 level)	MBS item 51012 (2 levels)	
2018	1,560	660	2,220
2019	14,183	6,488	20,671

48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Patients are likely to require one medical service per lifetime; however, in instances where patients experience complications additional services for revision or removal of the device may be required.

49. How many years would the proposed medical service(s) be required for the patient?

As above, IDSs are a lifetime procedure in the majority of patients.

50. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

The data on utilisation of MBS items 40303 (laminectomy for recurrent disc lesion or spinal stenosis) and 40306 (laminectomy for spinal stenosis involving > 1 level) indicate that from 2010 to 2017 these items were growing at a rate of 7% per year and 3% per year respectively.

Utilisation data of MBS items 51011 (one level) and 51012 (two levels) shows that there were a total of 14,183 decompression procedures for one level and 9,982 decompression procedures for two levels in 2019. If the growth rates for MBS items 40303 and 40306 are applied to the MBS items 51011 and 51012 the projected utilisation of these items in 2023 are 17,551 and 7,190, respectively.

In MSAC Application 1099, it was estimated that approximately 30-35% of single level decompression procedures and 10-20% of multiple level decompressions would be candidates for non-fusion therapy. Applying this to the projected number of patients receiving one and two-level laminectomies gives an estimated total of 6,397-8,083 candidates. Assuming an uptake of 5% in the first year of listing gives an estimated utilisation of 320-404 patients.

Table 3: Estimated utilisation of proposed IDS items

Year	MBS item 51011 (one level) 7% growth rate	MBS item 51012 (two levels) 3% growth rate	Total
2019	14,183	6,488	20,671
2020 (projected)	14183	6488	20671
2021 (projected)	15227	6714	21710
2022 (projected)	16347	6948	22801
2023 (projected)	17551	7190	23948
<i>Candidates for non-fusion therapy</i>	30-35%	10-20%	-
<i>Estimated number of candidates</i>	5653-6595	744-1488	6397-8083
<i>Uptake</i>	5%	5%	-
<i>Estimated utilisation of proposed IDS items</i>	283-329	37-74	320-404

51. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

It is assumed that the growth rates of 7% for MBS item 51011 and 3% for MBS item 51012 will continue into the second and third year of listing. The proportion of eligible candidates is expected to remain constant. The uptake of IDSs, however, is expected to increase from 5% in the first year of listing to 15% in the final year due to increased familiarity with the service among neurosurgeons. It is unlikely that the devices will be used in populations not requested in the proposed listing, as there is no evidence for efficacy nor a clinical need in other groups.

Table 4: Estimated uptake of proposed IDS items in the first three years of listing

	2023	2024	2025
Estimated number of candidates	6397-8083	6867-8678	7373-9316
Uptake rate	5%	10%	15%
Estimated utilisation	320-404	343-434	369-466

PART 8 – COST INFORMATION

52. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

In MSAC Application 1099, the best estimate of the unit cost of inserting a non-fusion interspinous device was the MBS item 48678 (SPINE, simple internal fixation of, involving 1 or more facet screw, wire loop or similar, being a service associated with a service to which items 48642 to 48675 apply (Anaes.) (Assist.)). Based on the Medicare Benefits Schedule (MBS) Review Taskforce’s recommendations in response to the Spinal Surgery Clinical Committee Report, MBS item 48678 has been removed; however it can be assumed that MBS item 51020 (simple fixation of part of one vertebra (not motion segment) including pars interarticularis, spinous process or pedicle, or simple interspinous wiring between 2 adjacent vertebral levels) is analogous to MBS item 48678. For patients requiring IDSs at two levels, it is assumed that this fee will be multiplied by 1.5 (using the MBS multiple item rule). **Thus, the expected fees for implantation are \$789.35 and \$1,184.03 for one level and two levels respectively.** Note that this is an estimate and a full fee justification will be presented in the final ADAR. The total amount requested is less the proposed fee for Coflex in MSAC Application 1422; however, the lower amount is justified by the reduced complexity of the procedure (Coflex requires adjunctive decompression).

As per the calculations provided in MSAC Application 1099, it is assumed that the number of levels treated would be the same for the comparator treatment of fusion surgery (i.e. 69% at one level, 31% at two levels).

Based on these assumptions, **Error! Reference source not found.** table below shows the estimated cost-components associated with inserting IDSs. Note that additional cost associated with IDS insertion include the cost of the prosthesis itself, and the cost of a day hospital stay. In contrast to decompression and fusion surgery, which require an in-hospital stay of up to several nights, IDS placement in Australia would typically be performed as a same-day inpatient admission.

Table 5: Estimated procedure cost for proposed MBS items for IDS

Procedure component	1 level		2 levels	
	MBS item	Cost	MBS item	Cost
Anaesthesia				
Anaesthesia initiation	20670	\$163	20670	\$163
Time units 46 minutes-1 hour	23045	\$82	23045	\$82
Age modifier (over 70 years) (27%)	25014	\$6 (\$17.15 x 27%)	25014	\$6 (\$17.15 x 27%)
Total	\$250		\$357	
Surgery a				
Proposed item	one level	\$789	two levels	\$1,184
Assistant 20% of surgery	51303	\$158	51303	\$237
Imaging (fluoroscopy)	60506	\$65	60509	\$65
Total	\$1,262		\$1,843	
Weighting b	69%		31%	
Weighted average	\$1,411			

a When two or more operations are performed on the patient on one occasion, the schedule fee is as follows: 100% of most expensive item, 50% of next most expensive item, 25% of remaining items (Health Insurance Commission 2003); b weighting based on number of vertebral levels treated

53. Specify how long the proposed medical service typically takes to perform:

As noted above, the procedure is expected to take between 46 minutes and one hour.

54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

The proposed item descriptors for IDS insertion (one and two levels) are presented below. The populations proposed are consistent with the TGA-registered indication for Superior. As noted above, the proposed service does not include interspinous devices that require an adjunctive decompression procedure (e.g. Coflex or other IDSs registered on the ARTG). Therefore, it has been specified that the proposed service cannot be associated with any of the procedure codes for spinal decompression.

Category 3 – Therapeutic Procedures
MBS: TBD MINIMALLY INVASIVE INTERSPINOUS DECOMPRESSION SPACER, insertion, removal or replacement of, to alleviate pain in patients with: <ul style="list-style-type: none">• Moderate lumbar spinal stenosis - one lumbar motion segment.• After failure of conservative management for at least 6 months.• Moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion• With or without low-grade spondylolisthesis Not being a service associated with a service to which item 51011, 51012, 51013, 51014 or 51015 applies Multiple Services Rule (Anaes.) (Assist.) Fee: TBD

Category 3 – Therapeutic Procedures
MBS: TBD MINIMALLY INVASIVE INTERSPINOUS DECOMPRESSION SPACER, insertion, removal or replacement of, to alleviate pain in patients with: <ul style="list-style-type: none">• Moderate lumbar spinal stenosis - two lumbar motion segments.• After failure of conservative management for at least 6 months.• Moderately severe functional impairment with symptoms exacerbated in extension and relieved in flexion• With or without low-grade spondylolisthesis Not being a service associated with a service to which item 51011, 51012, 51013, 51014 or 51015 applies Multiple Services Rule (Anaes.) (Assist.) Fee: TBD

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