



Medical Services Advisory Committee

Public Summary Document

Application No. 1090.1 – Review of Interim Funded Service: Artificial Intervertebral Disc Replacement - Lumbar

Applicant: Department of Health and Ageing
Sponsors: Medtronic Australasia Pty Ltd
Johnson & Johnson Medical Pty Ltd

Date of MSAC consideration: 52nd MSAC meeting, 27 April 2011

1. Purpose of application

In January 2010 the Department commenced the review of artificial intervertebral disc replacement (AIDR) lumbar and contacted the three applicants for the original Application 1090 as well as the Spine Society to request any additional data that had become available since the 2006 assessment conducted by the Medical Services Advisory Committee (MSAC). Johnson & Johnson and Medtronic Australasia agreed to participate in the review, whereas the third applicant from Application 1090 (Taylor Bryant Pty Ltd) noted the review but did not have anything to contribute as the company was no longer manufacturing lumbar disc replacements.

The purpose of this assessment is for MSAC to determine whether there is sufficient evidence, in relation to safety, effectiveness and cost-effectiveness, to continue public funding through the Medicare Benefits Schedule (MBS) for lumbar AIDR, in patients with single level intra lumbar disc disease in the absence of osteoporosis and prior fusion at the same level, who have failed consecutive therapy.

Sponsors also suggested MSAC consider publicly funding multi level AIDR.

Intervertebral discs reside between the vertebral bones and are composed of water, collagen and proteoglycans (Ann & Juarez 2004). The function of the intervertebral disc is to promote ventral movement through the combined effort of several discs and also to act as a shock absorber to prevent compression of the spine (Bridwell 2004). Artificial intervertebral discs have been developed to replace endogenous intervertebral discs and act as a functional prosthetic replacement similar to hip or knee prostheses (NICE 2003). Artificial intervertebral disc replacement (AIDR) or total disc arthroplasty is performed in either the cervical or lumbar spine.

Lumbar AIDR is designed to simulate the mobile load-bearing properties of the natural intervertebral discs. There are two types of artificial intervertebral discs: one type replaces only the nucleus pulposus, and the other replaces the entire intervertebral disc.

Prosthetic discs for total disc arthroplasty generally consist of: (a) two metallic endplates which articulate with each other (metal on metal), or (b) two metallic endplates which sandwich a polymer or plastic core (metal on polymer). The overall design and material composition, however, vary significantly between commercially available prosthetic discs, and new designs appear regularly in this rapidly growing field. Most current prosthetic discs use materials which have been used for many years in other well-established medical devices, eg hip and knee replacements.

All lumbar AIDR procedures are performed under general anaesthetic. Patient positioning and intraoperative real time fluoroscopy, depending on the device used, are critical to the exposure and successful insertion of the arthroplasty device. For lumbar disc arthroplasty a transperitoneal or retroperitoneal approach is required. Because most lumbar fusion procedures are performed posteriorly, many spinal surgeons require the assistance of an 'access surgeon' to minimise rare but serious approach-related complications when undertaking anterior AIDR. Important structures that need to be mobilised include the aorta, iliac vessels, sympathetic plexus, and intraperitoneal structures including the bowel and ureters. An access surgeon such as a general or vascular surgeon is often far more familiar with the approach. Whether an access surgeon is used is dependent on (a) spinal surgeon training and (b) the availability of access surgeons.

A complete discectomy is required prior to removing and shaping variable amounts of vertebral endplate. Small instruments and drills are used under magnification to remove disc material and osteophytes compressing nerve roots or the spinal cord. Finally, implanting the device requires precise sizing, placement and choice of prosthesis to achieve optimal performance. This requires a mixture of freehand surgical skill, fluoroscopy, milling guides and instruments. Implants, rather than being cemented or screwed in, rely on a precise press or friction fit bone implant interface.

The primary indications for AIDR considered in this assessment concern individuals suffering from significant axial back pain and/or radicular (nerve root) pain, secondary to disc degeneration or prolapse, who have failed nonoperative treatment (eg rest, modification of activities, muscle strengthening, weight control, aerobic training, the passage of time, and analgesic medications including anti-inflammatory medications and epidural steroid).

Pain from the lumbar spine can come from bulging or prolapsed discs pressing on pain-sensitive structures including nerves, ligaments or dura; from disease of the vertebral bone or the facet joints between vertebrae; or from the degenerating/injured disc annulus.

There is considerable uncertainty regarding the prevalence and incidence of axial back pain and/or radicular (nerve root) pain secondary to disc degeneration or prolapse. It is also unclear what proportion of these people suffer from discogenic back pain and would therefore be eligible for either artificial disc replacement or spinal fusion.

2. Background

This assessment updates a previous assessment (Application 1090) of AIDR Lumbar that was conducted on behalf on MSAC in 2006, and resulted in MSAC recommending interim funding for single level AIDR in patients with single level intra lumbar disc disease in the absence of osteoporosis and prior fusion at the same level, who have failed consecutive therapy. The interim listing was subject to further MSAC review in three years.

MSAC's finalised its first assessment of this technology on 28 February 2006. Subsequently to the Minister accepting MSAC's advice (6 June 2006), MBS items were created on a temporary basis, pending review in three years time. Interim funding was due to cease in November 2010.

3. Prerequisites to implementation of any funding advice

A range of prostheses used in spinal surgery (specifically AIDR lumbar) are TGA approved.

MSAC noted advice from the clinical experts on the Advisory Panel that the following lumbar artificial disc prostheses are the most commonly used in Australia:

- Maverick (Medtronic Australasia Pty Ltd)
- In Motion (previously marketed in Australia under the name 'Charité') (Johnson & Johnson Medical Pty Ltd T/A Depuy Australia)
- Flexicore (Stryker Australia Pty Ltd)
- ProDisc (Synthes Australia Pty Ltd)

4. Proposal for public funding

Lumbar AIDR is currently listed on the MBS as an interim funded item – Table 1 (from Assessment Report) refers:

Current MBS item numbers related to lumbar AIDR procedures

MBS item number	Description	Fee	Benefit
48691	LUMBAR ARTIFICIAL INTERVERTEBRAL TOTAL DISC REPLACEMENT including removal of disc, 1 level, in patients with single-level intralumbar disc disease in the absence of vertebral osteoporosis and prior spinal fusion at the same lumbar level who have failed conservative therapy, with fluoroscopy	\$1,695.20	75 per cent = \$1,271.40 85 per cent = \$1,626.10
48692	LUMBAR ARTIFICIAL INTERVERTEBRAL TOTAL DISC REPLACEMENT including removal of disc, 1 level, in patients with single-level intralumbar disc disease in the absence of vertebral osteoporosis and prior spinal fusion at the same lumbar level who have failed conservative therapy, with fluoroscopy (where an assisting surgeon performs the approach) - principal surgeon	\$1,142.60	75 per cent = \$856.95 85 per cent = \$1,073.50
48693	LUMBAR ARTIFICIAL INTERVERTEBRAL TOTAL DISC REPLACEMENT including removal of disc, 1 level, in patients with single-level intralumbar disc disease in the absence of vertebral osteoporosis and prior spinal fusion at the same lumbar level who have failed conservative therapy (where an assisting surgeon performs the approach) - assisting surgeon	\$552.60	75 per cent = \$414.45 85 per cent = \$483.50

The following are contraindications for AIDR in the lumbar region: spinal infection, spinal neoplasm, spinal trauma, instability eg spondylolisthesis, deformity eg scoliosis, severe osteoporosis, spinal canal stenosis, pars defects, facet joint arthropathy, posterior nerve root compression, unfavourable pelvic or vascular anatomy or pathology, previous abdominal surgery.

MSAC agreed that lumbar AIDR would provide significant benefit for selected individuals (without multi-level disease or osteoporosis and under 60 years of age), but is not a total substitution for spinal fusion.

The procedure is highly specialised and technically demanding and is largely performed by neurosurgeons and orthopaedic surgeons who have specialised exclusively in spinal surgery. Many spinal surgeons require the assistance of an ‘access surgeon’ to minimise rare but serious approach related complications. An access surgeon such as a general or vascular surgeon is often far more familiar with the approach. Whether an access surgeon is used is dependent on spinal surgeon training and availability.

5. Consumer Impact Statement

The procedure is only applicable to a narrow band of patients, and has only been performed in a relatively small number of patients in Australia since it was listed on the MBS.

Based on the studies included in this assessment, it is clear that patients can expect an improvement in pain as early as six weeks and up to five years after the procedure; however, the procedure may not necessarily eliminate pain. Therefore, it is important that patients discuss their expectations regarding pain relief with their treating surgeon prior to surgery, in order to determine if these expectations are realistic.

In Australia, the procedure is only performed in major private and public hospitals. In addition, it is important for patients who are considering the lumbar AIDR procedure to be aware that most public hospitals do not have a prosthetic budget that would enable them to offer this procedure. Therefore, patients who anticipate having their surgery in a public hospital will need to enquire about whether the hospital has a budget that would allow such a prosthesis to be used. Both of these factors raise the issue of equity of access for this procedure.

6. Proposed intervention's place in clinical management

MSAC noted that, for patients with degenerative lumbar disc disease unresponsive to conservative measures, a lumbar AIDR provides an alternative to a lumbar fusion procedure designed to relieve persistent discogenic pain and maintain motion.

Non-surgical treatments are generally first line treatment options, while lumbar spinal fusion and AIDR lumbar are only considered if non-surgical treatment fails (ie second line treatment).

MSAC noted the clinical decision-making pathway (Figure 1) in the Assessment Report, and that currently in Australia, only the anterior approach is used in AIDR lumbar operations. However, the clinical expert opinion of the Advisory Panel suggests that it is likely that a posterior approach will eventually be introduced into clinical practice.

A proportion of patients treated with AIDR may also be treated with lumbar fusion at the adjacent or multiple levels in the same procedure. This was not considered in this analysis due to a lack of clinical data. The cost-effectiveness results should not be considered to represent the cost-effectiveness of AIDR in combination with another fusion approach.

7. Comparator to the proposed intervention

The comparator procedure is lumbar spinal fusion, where a bone graft is used to stop the motion at a painful vertebral segment. There are two main approaches to spinal fusion, *posterolateral fusion* (PLF) and *interbody fusion*, which may be used in conjunction.

Posterolateral fusion involves placing the bone graft between the transverse processes in the back of the spine. The vertebrae are then fixed in place with screws and/or wire through the pedicles of each vertebra attaching to a metal rod on each side of the vertebrae.

Interbody fusion involves placing the bone graft between the vertebrae in the area usually occupied by the intervertebral disc. In preparation for spinal fusion, the disc nucleus and part of the annulus are removed, and endplates cleaned prior to placement of the graft. This allows the fusion to occur between the endplates of contiguous vertebrae. The graft can be placed in between the vertebral bodies in an interbody position using an anterior approach via an incision in the abdomen (anterior lumbar interbody fusion, ALIF), or a posterior approach (posterior lumbar interbody fusion, PLIF). When both an ALIF and a posterior lateral bone grafting and posterior instrumentation are performed it is commonly referred to as 360 degree or circumferential spinal fusion.

In Australia, most surgeons choose a posterior rather than anterior approach for lumbar spinal fusion.

The procedure is only performed in major private and public hospitals.

MSAC noted that the Assessment Report analysed MBS claims data that were provided by the Department of Health and Ageing on patients who claimed any of the following MBS items from July 2005 through to August 2010: 48648, 48651, 48654, 48657, 48660, 48663, 48669, 48672, 48675, 48684, 48690, 48691 and 48692. For these patients, any other MBS item claimed by the same patient on the same day was also provided. Due to complexity, a maximum of 20 items for each same patient/same day procedure were extracted and MBS items relating to anaesthesia time were not extracted. Only 10.4 per cent of patients claimed 20 items or more.

Analysis of MBS data indicates that there were:

- 852 claims for MBS items associated with lumbar AIDR procedures
- 26,114 claims for MBS items associated with spinal fusion procedures.

It is important to note that many procedures may involve claims for more than one relevant MBS item (ie some patients may claim for MBS items associated with both AIDR and spinal fusion procedures, while other patients may claim for MBS items associated with different types of spinal fusion procedures).

When procedures involving claims for MBS items associated with AIDR procedures are removed, there were 12,568 spinal fusion-only procedures (same patient, same day) involving 25,101 claims for spinal fusion MBS items. Some of these spinal fusion procedures can be identified as occurring in the lumbar or cervical region based on the MBS item claimed for initiation of anaesthesia; 4,331 spinal fusion-only procedures also involved claims for initiation of anaesthesia in the cervical region (approximately 866 per year) and spinal fusion 2,418 in the lumbar region (approximately 484 per year).

Similarly, when procedures involving claims for MBS items associated with spinal fusion are removed there were 346 AIDR-only procedures (same patient, same day), of which none involved claims for initiation of anaesthesia in the cervical region and 219 in the lumbar region.

8. Comparative safety

The medical literature was searched to identify relevant studies and reviews from 1 January 2005 until April 2010. From the search strategy, 1088 relevant articles were identified, of which 330 were retrieved for more detailed evaluation, including systematic reviews and primary studies. In total, 275 retrieved articles were excluded. A total of 60 studies, including four systematic reviews, five health technology assessments, four randomised controlled trials (RCTs) (comprising 12 studies), one nonrandomised comparative study, and 38 case series were eligible for appraisal and inclusion in this assessment.

Forty-three studies were identified for inclusion in the assessment of the safety of lumbar AIDR. This included five comparative studies and 38 case series. Comparative studies compared lumbar AIDR to anterior lumbar interbody fusion (ALIF), circumferential fusion, posterolateral lumbar fusion (PLF) or posterior lumbar interbody fusion (PLIF). Sample sizes ranged from 10 to 427 patients, with safety data reported for a total of 3,224 patients overall.

For the majority of adverse events reported, there were no obvious differences in incidence rates of overall complications between the lumbar AIDR and lumbar fusion groups, with two studies reporting no statistical differences. Wound infection was the most commonly reported adverse event, and demonstrated an incidence rate of 3.2 per cent in the lumbar AIDR population, and 5.1 per cent in the lumbar fusion population. Prosthesis-related adverse events were those relating to movement of the device, including collapse or subsidence (3 per cent), and displacement (0.78 per cent). Fusion-related adverse events included nonunion/pseudarthrosis (6.4 per cent) and bone graft donor-site pain (11.1 per cent). The rate of adjacent segment problems appeared higher following lumbar fusion (8.3 per cent) compared with lumbar AIDR (1.3 per cent).

Major adverse events such as major vessel injury, neurologic damage and nerve root injury were rare in both the lumbar AIDR and fusion groups. There was one reported death following lumbar AIDR which was narcotic-related, while no deaths were reported following lumbar fusion.

MSAC agreed that lumbar AIDR is as safe as and possibly safer than alternative lumbar fusion procedures despite the need for an anterior approach, because of reduced recovery time and avoidance of bone grafting. There were no clinically significant differences in rates of adverse events following lumbar AIDR or lumbar fusion procedures.

9. Comparative effectiveness

Thirteen comparative studies were identified and included to inform on the comparative effectiveness of lumbar AIDR, including a total of four RCTs (comprising 12 publications) that compared lumbar AIDR to ALIF, circumferential fusion, or PLF/PLIF, as well as one nonrandomised comparative study that compared lumbar AIDR to ALIF.

Clinical outcomes were the focus of the majority of comparative studies; however, a number of studies also reported radiographic outcomes following lumbar AIDR and lumbar fusion procedures.

All of the included comparative studies utilised the Oswestry Disability Index (ODI), one of the principal condition-specific measures used in the management of spinal disorders, and the gold standard for assessing the extent to which a patient's functional level is limited by low back pain. Three studies reported that patients in the lumbar AIDR group showed statistically greater improvements in ODI scores than lumbar fusion patients at various time points up to 1-year follow-up; however, none of the studies reported significant differences between the groups at 2- or 5-year follow-up. Similarly, two studies reported that at 2-year follow-up overall clinical success was significantly higher in the lumbar AIDR group compared with the lumbar fusion group, while the rate of reoperation was similar in both groups.

In two studies, patient satisfaction at 2-year follow-up was significantly higher in lumbar AIDR patients compared with lumbar fusion patients, with up to 81 per cent of AIDR patients saying they would have the procedure again, compared with 69 per cent of fusion patients. This may have reflected the fact that lumbar AIDR patients experienced significantly less pain and required less narcotic medication, reported better sexual function, and returned to work at higher rates, when compared with lumbar fusion patients up to two years after surgery.

Radiographic outcomes were reported in several studies; however, outcomes were reported differently across studies, and no statistical comparisons between the lumbar AIDR and lumbar fusion groups were reported, making it difficult to draw firm conclusions.

Five studies (four randomised controlled trials and one nonrandomised comparative study) were identified that compared perioperative outcomes for patients that underwent lumbar AIDR with patients that underwent ALIF (Blumenthal et al. 2005; Schroven and Dorofey 2006), circumferential fusion (Sasso et al. 2008; Zigler et al. 2007) or PLF/PLIF (Berg et al. 2009a) (Table 8).

Three studies reported that operative time was significantly shorter for lumbar AIDR patients compared with patients undergoing lumbar fusion, while one study reported no difference between the groups. Similarly, two studies reported that estimated blood loss was significantly lower during lumbar AIDR compared with circumferential fusion. In four studies, length of stay in hospital was shown to be significantly shorter following lumbar AIDR compared with lumbar fusion.

Overall, MSAC found that a lumbar AIDR is at least as effective as a lumbar fusion procedure (in the short to medium term), but that results vary by fusion approach and by the clinical outcome of interest, including the ODI, pain scores, rate of re-operation, work status, and patient satisfaction. The evidence reviewed also indicates a lumbar AIDR is initially more effective than a lumbar fusion procedure for some outcomes (ODI scores up to one year, and clinical 'overall success' and patient satisfaction up to two years). Most studies utilised validated assessment instruments, although patients and investigators were not blinded to the treatment received. One randomised trial conducted sub-group analyses, which showed that this comparative effectiveness conclusion was not changed according to whether the patient had undergone prior surgery or not. MSAC noted the short- to medium-term (2-5 years) follow-up of patients, and acknowledged differences in Australian clinical practice with regards to the use of narcotics.

10. Economic evaluation

The economic evaluation adopted a cost-effectiveness analysis and a cost-utility analysis framework.

For AIDR compared with fusion the incremental costs, incremental costs per patient discontinuing narcotic medication at two years, incremental costs per additional overall clinical success at two years and incremental costs per additional ODI success at two years were presented. For AIDR compared with PLF/PLIF the incremental cost per quality-adjusted life year (QALY) gained was presented. This mixed approach was undertaken due to uncertainty about the outcome of most clinical relevance and whether the results were statistically significant.

A Markov model was developed to synthesise data from a variety of sources. Following the decision to treat the patient surgically, patients receive either lumbar AIDR or one of five lumbar fusion approaches. If the initial surgery is considered a success, patients enter the 'successful surgery' health state. If surgery is considered a failure, patients enter the 'failed surgery' health state in which patients may require a re-operation. If re-operation is required patients enter the 'successful surgery post re-operation' health state. Other adverse events and death from complications or other causes are not considered. It is assumed that only one re-operation is conducted, and that AIDR devices and all types of bone grafts are similar in effectiveness.

Estimates of effectiveness, anaesthesia time and time in hospital were obtained from published randomised controlled trials. MBS item numbers were determined by the Advisory Panel and resource use was obtained by analysis of MBS claims data provided by the Department of Health and Ageing. Unit costs were obtained from standard sources. MBS average co-payment data were provided by the Department of Health and Ageing.

The incremental costs associated with each procedure demonstrate that compared with PLIF, combination and circumferential fusion, AIDR is cost saving. Compared with ALIF, AIDR is marginally more expensive. Overall, compared with the average fusion cost, AIDR represents a cost saving of \$1,600 per patient.

AIDR was both less costly and more effective than lumbar fusion overall for patients discontinuing narcotic medication and in terms of overall success. In terms of ODI success, AIDR was both less costly but less effective than lumbar fusion overall. The incremental cost per additional patient achieving ODI success was estimated to be \$126,191 with lumbar fusion compared with AIDR.

The results varied considerably by fusion approach. AIDR was more costly but achieved a higher rate of patients discontinuing narcotic medication, overall success and ODI success than ALIF. The incremental cost per additional patient discontinuing narcotic medication, achieving overall success, and achieving ODI success with AIDR compared with ALIF was estimated to be \$46,439, \$20,433 and \$34,883, respectively. AIDR was less effective in terms of ODI success compared with PLIF and PLF. PLF was also less costly and thus PLF was considered to dominate AIDR. PLIF was more costly and the incremental cost per additional patient achieving ODI success with PLIF was estimated to be \$35,373. AIDR was both less costly and more effective than circumferential fusion for all measures of efficacy. Therefore AIDR is considered to dominate circumferential fusion.

PLIF and PLF were estimated to be more effective in terms of QALYs gained compared with AIDR. PLF was also less costly and thus PLF was considered to dominate AIDR. The cost per QALY gained was estimated to be \$598,794 with PLIF.

Overall the results were most sensitive to using the direct approach to apply utility weights, changes in the relative risk of overall or ODI success and the time in hospital with AIDR. The results were somewhat sensitive to the proportion of fusion patients requiring BMP. When hospitalisation costs with AIDR were assumed to be equal to that with fusion, fusion became less costly compared with AIDR. If a direct approach was used to apply utility weights, the average QALYs gained with lumbar AIDR and PLIF/PLF was 1.25 QALYs and 1.16 QALYs, respectively. Thus QALYs experienced increased by 0.10 QALYs with lumbar AIDR compared with PLIF/PLF. Using this approach AIDR was estimated to be less costly and more effective compared with PLIF. While compared with PLF, AIDR was estimated to be more costly and more effective, and had an additional cost per QALY of \$8,443.

The major cost drivers of fusion compared with AIDR were consumable costs, mainly due to the use of BMP, and hospital costs. Total MBS fees were higher for AIDR compared with ALIF, PLIF and PLF. Patient out-of-pocket costs were higher for AIDR compared with all fusion approaches; however, it was unclear what proportion of these out-of-pocket costs are covered by private health insurance.

The impact on the Extended Medicare Safety Net (EMSN) is unknown. The majority of MBS items are for procedures undertaken in the inpatient setting; therefore these do not contribute to the EMSN. Some MBS items, such as the initial and follow-up consultations, will occur in the outpatient setting and may therefore contribute toward the patient's out-of-pocket expenses. However, it is unknown whether these accumulative co-payment charges will be higher than the current EMSN threshold.

11. Financial/budgetary impacts

In 2009 and 2010 the number of AIDR procedures was 263 and 258, respectively.

MSAC estimated the modest likely volume of use per year could be expected to grow in line with population ageing.

There is considerable uncertainty regarding the prevalence and incidence of:

- axial lumbar back pain with changes secondary to degeneration of the disc or disc prolapse
- radicular pain from compression or irritation of nerve roots
- referred pain from other lumbar spinal structures including facet joints.

Therefore, there is uncertainty about the number of individuals who may be eligible for AIDR.

Using the analysis of costs in the economic evaluation, the total cost of AIDR would be \$6.23 million in 2013. If these patients instead received lumbar fusion the total cost would be \$6.66 million. Hence the cost savings of performing lumbar AIDR as a direct replacement for lumbar fusion would be \$0.43 million. The bulk of the cost savings would be due to the cost of consumables and other hospital costs.

MSAC noted that there would be an increase in costs borne by patients with total national out of pocket costs estimated to be \$392,967 per annum, although this figure does not take into account any rebates paid by private health insurance providers.

MSAC noted a small increase in costs likely to be borne by the MBS with the additional cost to the MBS in 2013 estimated to be \$25,165 per annum.

12. MSAC key issues

Overall, the safety of lumbar AIDR is comparable to that of lumbar fusion. It appears that the lumbar AIDR procedure is relatively safe, and is not associated with serious adverse events.

The eligibility criteria used to recruit patients was similar across studies, and most studies included patients who had undergone previous spinal surgery, which may impact on patient outcomes following lumbar AIDR or lumbar fusion procedures. Subgroup analyses conducted in one RCT showed that the rate of adverse events (as well as a variety of clinical outcomes including ODI scores, pain scores, rate of reoperation, work status and patient satisfaction with the procedure) was not significantly different in lumbar AIDR and lumbar fusion patients who had undergone previous lumbar decompressive surgery (including microdiscectomy, laminectomy or minimal medial facetectomy), compared with those who had not undergone previous surgery.

Most studies utilised well-known, validated instruments for the assessment of patient outcomes; however, patients and investigators were not blinded to the treatment, which may have led to bias in the reporting of results. A further limitation of the studies included in this assessment was the length of follow-up reported. Certain adverse events and problems associated with the durability of the prosthesis may only become apparent after many years of follow-up. However, the majority of studies in this assessment reported short- to medium-term (2-5 year) follow-up of patients. In addition, a variety of different prostheses and lumbar fusion techniques were used across studies. Importantly, two of the four included RCTs compared lumbar AIDR to circumferential fusion; however, this approach represents only 1 per cent of all spinal fusion procedures performed in Australia.

While the number of patients who remained on narcotics was comparable following lumbar AIDR and lumbar fusion procedures, the clinical expert opinion of the Advisory Panel suggests that this proportion is significantly higher than that observed in clinical practice in Australia.

Overall, MSAC found that a lumbar AIDR is at least as effective as a lumbar fusion procedure (in the short to medium term), but that results vary by fusion approach and by the clinical outcome of interest, including the Oswestry Disability Index (ODI), pain scores, rate of re-operation, work status, and patient satisfaction. The evidence reviewed also indicates a lumbar AIDR is initially more effective than a lumbar fusion procedure for some outcomes (ODI scores up to one year, and clinical 'overall success' and patient satisfaction up to two years).

There were a number of limitations with the approach to the analysis including: a proportion of AIDR procedures may be combined with other fusion approaches (this was not considered due to a lack of clinical data); there is a lack of a standard definition of overall success; and the proportion of patients who discontinue narcotics does not account for lower doses of narcotics following surgery.

Key uncertainties that drive the estimation of costs were the proportion of patients receiving bone morphogenetic proteins (BMP), which was based on a previous MSAC report (1090), the length of hospitalisation, which was based on the published randomised controlled trials, and the AIDR device cost. Only the costs incurred in the first two years were included in the analysis (there is a potential increased risk of re-operations at adjacent levels following fusion surgery which has not been considered).

MSAC noted that there was a lack of data on utility weights following treatment success or failure, which limits the ability to estimate the incremental cost per extra quality-adjusted life year (QALY) gained for the comparison, and that further research on utility impacts following surgery would assist in reducing uncertainty around the additional benefit of lumbar AIDR.

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

MSAC noted that artificial intervertebral disc replacement for single-level intralumbar disc disease (lumbar AIDR or lumbar disc arthroplasty) was listed on the Medicare Benefits Schedule (MBS) in 2006 on an interim basis for patients who had neither vertebral osteoporosis nor prior spinal fusion at the same lumbar level, and who had failed conservative therapy. The interim MBS listing was to have been reviewed in three years to ascertain whether longer term safety, effectiveness and cost-effectiveness has been demonstrated. MSAC noted that interim funding was previously provided only for single-level lumbar disc disease on the basis of uncertainty regarding longer term health outcomes in determining equivalence or superiority of single-level AIDR compared with the posterior fusion technique when used at more than one level of the lumbar spine.

MSAC noted that, for patients with degenerative lumbar disc disease unresponsive to conservative measures, a lumbar AIDR provides an alternative to a lumbar fusion procedure designed to relieve persistent discogenic pain and maintain motion. MSAC noted that the approach in the assessment report to inform a comparison of these alternatives by assuming equivalence in patient outcomes across various lumbar AIDR products, and similarly generally assuming equivalence in patient outcomes across various types of lumbar fusion procedures, had not been contested. Lumbar AIDRs are performed by credentialed spinal surgeons (mostly orthopaedic and neurosurgeons) and require an anterior approach facilitated by an 'access' surgeon.

MSAC noted that interim MBS listing has been followed by a modest number of procedures (approximately 60 per year) with no adverse economic impact; and no major safety issues have been identified. MSAC noted that lumbar AIDR is not a total substitution for lumbar laminectomy and/or fusion, and is not used for re-operations. The peak age group for the procedure is 40-50 years.

Overall, MSAC found that a lumbar AIDR is at least as effective as a lumbar fusion procedure (in the short to medium term), but that results vary by fusion approach and by the clinical outcome of interest, including the Oswestry Disability Index (ODI), pain scores, rate of re-operation, work status, and patient satisfaction. The evidence reviewed also indicates a lumbar AIDR is initially more effective than a lumbar fusion procedure for some outcomes (ODI scores up to one year, and clinical 'overall success' and patient satisfaction up to two years). Most studies utilised validated assessment instruments, although patients and investigators were not blinded to the treatment received. One randomised trial conducted subgroup analyses, which showed that this comparative effectiveness conclusion was not changed according to whether the patient had undergone prior surgery or not. MSAC noted the short- to medium-term (2-5 years) follow-up of patients, and acknowledged differences in Australian clinical practice with regards to the use of narcotics.

MSAC noted that there was a lack of data on utility weights following treatment success or failure, which limits the ability to estimate the incremental cost per extra quality-adjusted life year (QALY) gained for the comparison, and that further research on utility impacts following surgery would assist in reducing uncertainty around the additional benefit of lumbar AIDR.

MSAC agreed that lumbar AIDR is as safe as and possibly safer than alternative lumbar fusion procedures despite the need for an anterior approach, because of reduced recovery time and avoidance of bone grafting. There were no clinically significant differences in rates of adverse events following lumbar AIDR or lumbar fusion procedures.

MSAC agreed that lumbar AIDR would provide significant benefit for selected individuals (without multi-level disease or osteoporosis and under 60 years of age).

MSAC noted that a cost-effectiveness and cost-utility analysis framework was used to evaluate the procedure, which allowed for different overall costs to be estimated for different lumbar fusion procedures. MSAC found that lumbar AIDR represents cost savings of \$2650 per patient versus the average across all lumbar fusion procedure types; that lumbar AIDR is cost saving compared with posterior lumbar interbody fusion (PLIF), posterior lumbar fusion (PLF) and circumferential fusion; and that lumbar AIDR costs more than anterior lumbar interbody fusion (ALIF).

MSAC estimated the modest likely volume of use per year could be expected to grow in line with population ageing. Based on likely volume of use, the cost savings of performing lumbar AIDR as a direct replacement for lumbar fusion is estimated to be \$431,000 in 2013, with the bulk of the cost savings due to the reduced cost of consumables and other hospital costs. MSAC noted a small increase in costs likely to be borne by the MBS with the additional cost to the MBS in 2013 estimated to be \$25,165 per annum. MSAC also noted that there would be an increase in costs borne by patients with total national out of pocket costs estimated to be \$392,967 per annum, although this figure does not take into account any rebates paid by private health insurance providers.

MSAC also noted that the economic analysis in the assessment report only included costs incurred in the first two years after the procedure due to the uncertainty in costs incurred after two years. In particular, MSAC acknowledged the potential increased risk of subsequent operations at adjacent lumbar levels following fusion surgery.

MSAC noted that, in Australia, the lumbar AIDR procedure is only performed in major private and public hospitals, and many public hospitals may not have a prosthetic budget that would enable them to offer this procedure more widely. Therefore, MSAC noted that there are issues of equity of access for this procedure with it being funded through the MBS and the artificial intervertebral disc consumables being funded through private health insurance, but not provided for public hospital patients.

MSAC supported continued public funding as per the current item descriptors and consequently the removal of the current interim funding arrangements. MSAC considered that there was no evidence to support the option of expanding lumbar AIDR beyond a single-level procedure.

MSAC noted the low level of voluntary reporting (25 per cent of disc replacement spinal surgery) to the National Joint Replacement Register (NJRR). The under reporting of this type of surgery to the Register means there are insufficient data to analyse the success/failure rate of the five discs used in spinal lumbar surgery that are currently listed on the Prosthesis List. MSAC advised that spinal surgeons should be encouraged to report their use of these devices to the NJRR.

MSAC also advised that the Department should monitor utilisation and report back on trends (both failure rates requiring re-operations and subsequent operations at adjacent lumbar levels) after five more years of listing.

14. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of lumbar artificial intervertebral disc replacement (lumbar AIDR), MSAC supports ongoing rather than interim public funding in line with the current Item Descriptors (Items 48691, 48692 and 48693): *Lumbar artificial intervertebral total disc replacement: including removal of disc, one level, in patients with single-level intralumbar disc disease in the absence of vertebral osteoporosis and prior spinal fusion at the same lumbar level who have failed conservative therapy, with fluoroscopy.*

15. Context for decision

This advice was made under the MSAC Terms of Reference.

MSAC is to:

- Advise the Minister for Health and Ageing on medical services that involve new or emerging technologies and procedures and, where relevant, amendment to existing MBS items, in relation to:
 - the strength of evidence in relation to the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
 - whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
 - the proposed Medicare Benefits Schedule (MBS) item descriptor and fee for the service where funding through the MBS is supported;
 - the circumstances, where there is uncertainty in relation to the clinical or cost-effectiveness of a service, under which interim public funding of a service should be supported for a specified period, during which defined data collections under agreed clinical protocols would be collected to inform a re-assessment of the service by MSAC at the conclusion of that period;
 - other matters related to the public funding of health services referred by the Minister.
- Advise the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.
- MSAC may also establish sub-committees to assist MSAC to effectively undertake its role. MSAC may delegate some of its functions to its Executive sub-committee.

16. Linkages to other documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.

The MSAC Assessment Report/Critique is available at [*link inserted when published*].