



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1145 – Artificial intervertebral disc replacement in patients with cervical degenerative disc disease

Applicant: Spine Society of Australia

Date of MSAC consideration: 52nd MSAC meeting, 27 April 2011
54th MSAC meeting, 29 November 2011

1. Purpose of application

In January 2010 an application was received from the Spine Society of Australia requesting Medicare Benefits Schedule (MBS) listing of artificial intervertebral disc replacement (AIDR) in patients with cervical degenerative disc disease (AIDR-C). AIDR-C had been considered by MSAC in 2006 and not supported at that time, although AIDR for the lumbar spine (AIDR-L) was recommended for interim MBS listing. It was agreed that the application be considered as a pilot for a submission based application in line with Recommendation 9 of the HTA Review that by July 2010 MSAC strengthen and streamline its operations and improve the flexibility of its regulatory processes by: (a) providing advice to the Minister based on a critique of an applicant's clinical and economic evaluations, as an alternative to the current process and in the context of agreeing specific timeframes for assessment with the applicant.

MSAC initially considered the application at its 52nd meeting in March 2011 at which time, in recognition of the nature of the application as a 'pilot', it deferred a decision on its advice pending a request for further information from the applicant and from the department.

The applicant, department and the assessment group contracted by the department to critique the report met to facilitate the information request by MSAC. The additional information was submitted to MSAC and taken into consideration in arriving at its advice.

The applicant proposed that AIDR-C is indicated for the dynamic stabilisation of the spine following total discectomy for treatment of axial pain or neurological compression, in patients with degenerative disc disease (DDD) associated with radiculopathy (single level) and that AIDR-C is indicated for patients who have failed conservative therapy.

This application seeks a new MBS listing of approved indications for AIDR-C for patients with DDD in the cervical spine where cervical disc arthroplasty is indicated for dynamic stabilisation of spine following total discectomy for treatment of axial pain or neurological compression in patients who have failed to respond to conservative care.

2. Background

In 2004, a Consortium including Medtronic Australia Pty Ltd, Taylor Bryant and Johnson & Johnson Medical (DePuy Spine) applied to the Medical Services Advisory Committee (MSAC) to list AIDR, specifically using the Bryan®, Prestige®, ProDisc C®, SB Charité™ III and Prodisc, for the treatment of degenerative disc disease in the cervical and lumbar spine (MSAC application 1090). Based on the absence of adequate evidence of clinical effectiveness at the time of the evaluation, MSAC recommended that public funding for AIDR in the cervical spine should not be supported.

Since MSAC Assessment report 1090 was completed, new randomised head-to-head comparative evidence pertaining to AIDR in the cervical spine has been published. This evidence forms the basis of this submission. The application was supported through a health economics consultancy with extensive input from the Spine Society with funding support from Medtronic Australia, Johnson & Johnson Pacific Pty Ltd and Synthes Australia Pty Ltd.

3. Prerequisites to implementation of any funding advice

Four types of artificial discs that can be used for AIDR; Prestige® and Bryan® Cervical Disc (Medtronic Australasia Pty Ltd); ProDisc-C (Synthes Australia Pty Ltd) and Discover™ disc (DePuy Spine) were considered as part of this application. The Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) numbers and associated descriptions are as follows:

TGA approval of AIDR prostheses

Description	ARTG ID	Intended purpose
Medtronic: Bryan®; Prestige®	100706	To treat cervical disc disease while maintaining the motion of the treated level
Synthes: Prodisc-C	133399	A device that replaces or restores the platelike structure between two moving vertebrae
DePuy Spine (J&J): Discover™	147793	Used to replace spinal in spinal arthroplasty or skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

The report seen by the Committee contained information identified by the applicant as commercial-in-confidence* being the cost of each of the artificial discs, product specific cost-effectiveness results provided in the Appendices and utility weights used in the economic evaluation. This information was seen by MSAC and taken into consideration in determining its advice, but will be redacted from any published material.

4. Proposal for public funding

This application was developed prior to the introduction of the requirement for MSAC's Protocol Advisory Sub-committee (PASC) to consider and agree to a final Decision Analytical Protocol that specifies the questions for public funding and includes the opportunity for comment from professional bodies and consumers.

The applicant has proposed that the use of cervical disc arthroplasty will be limited to patients with the following indications:

1. Cervical disc herniation with radiculopathy (arm pain, numbness, weakness) with failure to respond to conservative treatment.
2. Cervical spondylotic radiculopathy with failure to respond to conservative treatment.
3. Cervical spondylotic myelopathy

Contraindications associated with each disc differ. These are outlined in the Product Information for each product.

The applicant has proposed that non product-specific contraindications to cervical disc arthroplasty associated with the conditions outlined above include:

- osteoporosis (as indicated by a T-score < -2.5);
- spondylolisthesis at the symptomatic level;
- previous attempted anterior or posterior fusion at the symptomatic level;
- previous laminectomy or foraminectomy at the symptomatic level;
- recent/current infection at the symptomatic level;
- moderate-severe facet arthropathy or iatrogenic facet injury at the symptomatic level;
- fracture of either adjacent vertebra, recent or past;
- loss of disc height >50%;
- neck/arm pain of unknown aetiology;
- Paget's disease, osteomalacia or other (non-osteoporotic) metabolic bone disease;
- allergy to cobalt, chromium, molybdenum, titanium or (with the Prodisc-C) polyethylene; and
- sequestered disc fragment lying dorsal to a vertebra in the spinal canal.

The applicant has proposed that cervical disc arthroplasty will be performed by spinal surgeons (orthopaedic or neurosurgical) on a referral basis.

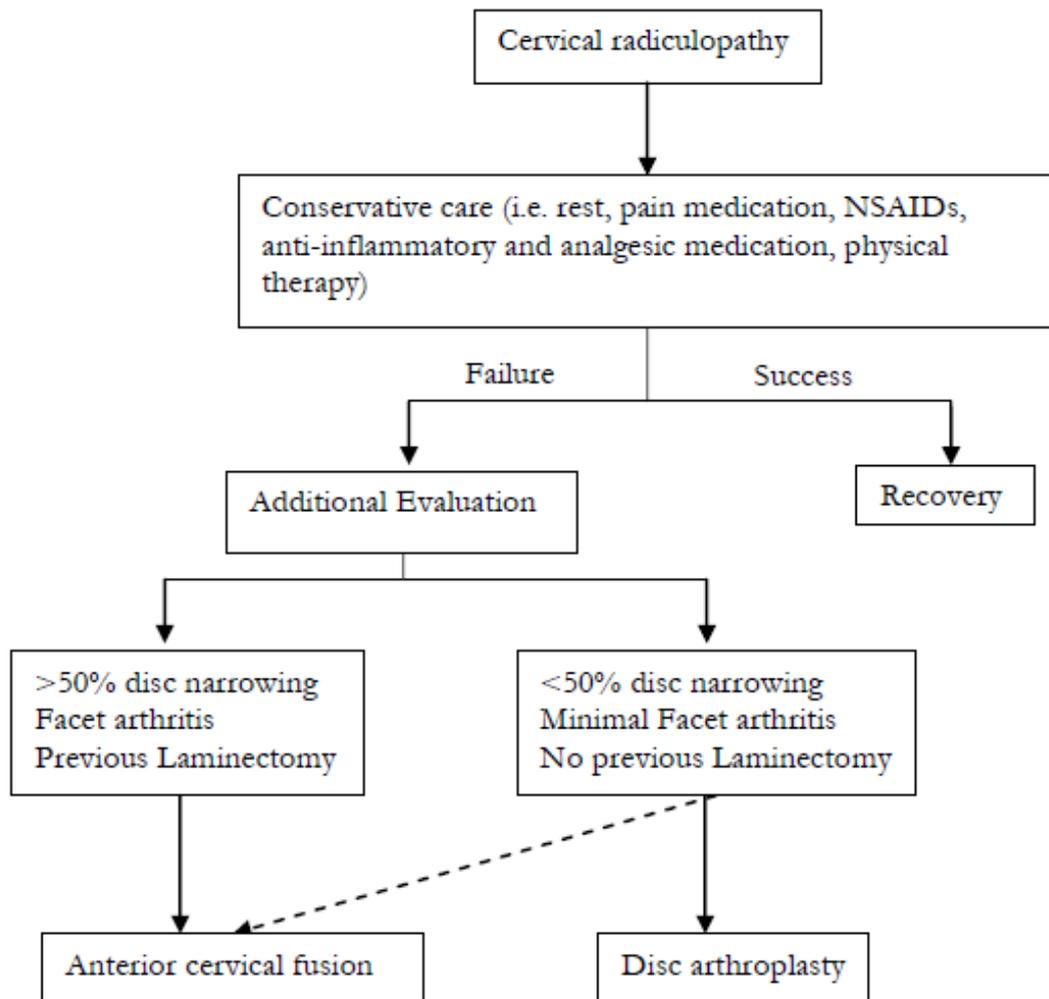
5. Consumer Impact Statement

No direct consumer input to this application was identified.

6. Proposed intervention's place in clinical management

AIDR-C is considered by the applicant to be an alternative procedure to anterior cervical discectomy and fusion (ACDF), which is currently the preferred treatment. AIDR-C is potentially indicated for patients with less than 50% disc narrowing, minimal facet arthritis and no previous laminectomy, as indicated by the solid line to disc arthroplasty in Figure 1 below (page 27 of the Critique of the SBA). However, not all patients with these indications will necessarily receive AIDR-C. Firstly, expert clinical input indicated that, with current clinical management, AIDR-C would only present an alternative treatment in a specific subset of patients with DDD as outlined in the relative indications and contraindications below and the dashed line in Figure 1.

Figure 1 Clinical flowchart for CDA in cervical DDD



Secondly, not all the indications and contraindications are listed for ACDF or AIDR-C. Further indications and contraindications include:

Relative Indications for AIDR-C

- radiculopathy or myelopathy* caused by spondylotic foraminal or canal stenosis and/or disc herniations;
- single or multiple levels from C3 to C7;
- at least 6 weeks of prior conservative treatment, including activity modification, physical therapy and medications;
- normal cervical spinal alignment and motion at the involved segment with no evidence of instability or hypermobility; and
- younger age group.

MSAC noted expert clinical advice (page 28 of the Critique of the SBA) concerning reservations about the use of AIDR-C in myelopathy, contrary to the indication provided in section 4.1 of the application. The clinical advice highlighted the limited literature published on clinical results of AIDR-C for myelopathy, concerns about the effect of ongoing motion on a chronically injured spinal cord where the preservation of range of motion may result in subsequent microtrauma to the spinal cord that may prevent recovery from myelopathic symptoms or promote recurrence.

Relative Contraindications

- instability:
 - >2 mm of spondylolisthesis;
 - >3 mm anterior subluxation on flexion-extension radiographs; and
 - >11 degrees of rotational difference relative to either adjacent segments.
- cervical kyphosis or reversal of lordosis;
- absence of demonstrated motion at the treatment level on preoperative flexion/extension films;
- myelopathy due to spinal canal compression behind the vertebral body, eg. due to posterior spurs requiring extensive resection of the vertebral body or ossification of the posterior longitudinal ligament;
- axial neck pain in the absence of radiculopathy or myelopathy;
- significant facet arthropathy;
- active infection;
- rheumatoid arthritis and ankylosing spondylitis; and
- osteoporosis.

7. Other options for MSAC consideration

At its April 2011 meeting MSAC noted that the Spine Society had requested MSAC to review the value of artificial intervertebral disc replacement in patients with degenerative disease of the cervical spine (single- and multi-level), and had agreed for this application to be piloted through the new Submission Based Assessment process whereby the applicant's submitted evidence was critiqued by an assessment group under contract to the Department.

MSAC noted that in 2006 (Application 1090) an application for public funding for cervical artificial intervertebral disc replacement (cervical AIDR or cervical disc arthroplasty – CDA) was not supported due to absence of adequate evidence of the effectiveness of the procedure. The evidence included in the recent submission consisted of six randomised comparative trials with follow-up duration of up to 24 months.

MSAC noted that the current proposal was for public funding of AIDR-C despite lack of long-term data, but given claims of AIDR-C having an acceptable safety profile, being at least as effective as anterior cervical discectomy and fusion (ACDF), and applicable to a younger age group (<60 years).

MSAC noted some deficiencies in the submission related to an incomplete literature search, non-inclusion of some relevant data (supportive of AIDR-C, such as reduced anaesthesia time, reduced length of stay and avoidance of bone graft), and absence of long-term (10-year) data which would assist to inform clinicians regarding the nature of device failure and the differential success rate of re-operations. This absence of long-term data is particularly important given findings from the National Institute for Health and Clinical Excellence (NICE), that a proportion of artificial cervical discs are expected to fuse approximately 10 years after implantation, but it is not known whether this would result in a re-operation on the patient.

MSAC found that the primary benefit of AIDR-C would be preservation of motion (hence the importance of longer term data), that the procedure would probably be most useful in younger patients, but that the evidence did not support its use for multiple levels of cervical vertebral discs or for re-operation, and it was not indicated for the treatment of axial pain (unlike AIDR-L).

MSAC agreed that AIDR-C is more effective than ACDF in terms of the composite measure of “overall success” at 24 months (which includes all of the following: greater than or equal to 15-point improvement over the pre-surgery score in the Neck Disability Index, neurologic status maintained or improved, no serious adverse event related to the artificial cervical disc or the procedure, and no subsequent surgery or intervention which would indicate that the original intervention was a failure). However, the clinical meaningfulness of this composite outcome was difficult to interpret and no data were available for the most expensive of the four registered cervical discs available. MSAC also had concerns with the long-term effectiveness of cervical discs, as data on this were only available for two years following a cervical disc replacement and there was uncertainty about whether there was a reduction in revision surgery in the long term. MSAC concluded that AIDR-C is probably as safe as, and may be marginally more effective than ACDF in the short term, but the magnitude and duration of that benefit was not clearly demonstrated.

MSAC found that, on average, AIDR-C was more costly than ACDF. Additional costs were driven predominantly by the prices of the artificial cervical discs, which vary widely across the four brands available. Using the average price of the discs, AIDR-C is estimated to be \$3,373 more expensive per patient overall than the comparator of ACDF, with an associated incremental cost per extra quality-adjusted life-year (QALY) gained of \$28,760 over a 5-year time horizon. To be consistent with its consideration of the healthcare perspective adopted with other applications, MSAC excluded the estimated productivity gains of treated individuals from its accepted base case of the economic analysis, as this is assumed to be included in the QALY and would hence constitute double counting if included.

MSAC considered the cost-effectiveness calculations in the applicant’s submission to be flawed. The critique of the analysis indicated that it did not account for patient out-of-pocket expenses, which MSAC considered would be similar to those of AIDR-L. If this assumption were correct, it would significantly increase the incremental cost-effectiveness ratio for AIDR-C over ACDF.

MSAC also questioned the applicant’s proposed MBS fee of \$1,695.20 for the AIDR-C procedure, given that it understood the AIDR-C would be less complex and time consuming than the AIDR-L procedure which has the same fee.

MSAC noted that the incremental total costs to the healthcare system, moving from ACDF to AIDR-C, were estimated as being \$1.8-\$2 million per annum. MSAC also noted that AIDR-C may be marginally cost-saving to the Medicare Benefits Schedule (MBS) (~\$135 per patient), but that the cost of the artificial cervical discs would be borne by either the patients or private health insurers.

MSAC identified many areas of uncertainty which precluded it from finalising its deliberations, such as interpretation of the measure of ‘overall success’ of the procedure, the quality-adjusted life-year estimates (both in terms of the conversion of the reported SF-36 results to SF-6D utility weights and the statistical significance of these quality of life data, particularly beyond two years), and pooling of clinical data for different artificial cervical discs.

MSAC had some concerns about how accurate the cost-effectiveness assumptions were in the submission and the evaluator’s critique. MSAC was not convinced that all four artificial cervical discs should be considered equal in terms of clinical effectiveness due to differences in their mechanisms and utilisation. Together with differences in the prices of the artificial cervical disc, this suggests that the incremental cost-effectiveness ratio would vary according to the disc being considered.

MSAC agreed that it would defer its decision pending further review of the economics by the applicant and information from the department.

8. Comparator to the proposed intervention

MSAC's consideration of information in the initial application, informed by the subsequent requested additional information and analyses is as follows.

The currently funded procedure of choice for decompression of the neural structures and stabilisation of the spine is ACDF. There are number of options for reconstruction and fusion of the spine following discectomy and these include no further intervention, allograft or autograft bone or prosthetic cages, with or without supplementary plate and screw fixation.

9. Comparative safety

The applicant provided six new studies for consideration by MSAC as part of their response to MSAC's concerns.

Four of the six studies provide longer follow up data than that provided in the original application. Three of these four studies include the same patients enrolled in the studies reported in the original application but have now been followed for 4-5 years. The fourth study provides eight-year follow-up data from another study. The other two studies provide new evidence on the most expensive of the four discs (considered in the original application (the Discover disc). Overall, the evidence shows a reduced rate of re-operation, in either the index disc or adjacent discs, with AIDR-C patients compared to the control group ACDF out to five years. MSAC agreed with ESC advice that AIDR-C appears to be at least as safe as ACDF. Case series follow-up data on AIDR-C out to eight years in 21 patients show no patients requiring any further spinal operation.

In responding to the query regarding spine fusion as highlighted in the recent (National Institute for Health and Clinical Excellence (NICE) report, the applicant refers to 'secondary surgical procedure' data (Delamater et al 2010) and 'adjacent level degeneration' data (Garrido et al 2010). Heterotopic ossification (HO) data, referring to bone tissue formation leading to the fusion of discs after implantation, is presented by four of the new studies (1.1.2). In the longest follow-up of 8 years, 33.1% of patients had this outcome (Quan et al 2011). Overall, 6 of the 10 patients with radiographic evidence of HO were reported as having grade 4 HO (fused), and 3 of the 9 had grade 3 HO. HO was more common in patients who had received bilevel disc replacements (48.1%).

Overall there was a reduced rate of reoperation for AIDR-C patients compared to control ACDF. Where reported, some of these differences were statistically significant (Burkus et al 2010, Delamater et al 2010).

Revision or reoperation surgery

Study ID	Disc (n/N)	Fusion (n/N)
Garrido et al 2010	1/18 (this patient had surgery for index and adjacent-level disease)	6/20 (2 index; 3 adjacent; 1 non-adjacent)
Burkus et al 2010	7 (removal), 4 (reoperation) / 144	5 (revision), 12 supplemental fixation), 13 (removal) 2 (reoperation) / 127 (these were significant)
Delamarter et al 2010	3/103 (index level conversion to fusion)	12/106 (6 were procedures at adjacent levels)
Quan et al 2011	0/21 (1 case of posterior migration but with no clinical effects)	-
Du et al 2011	0	-
Coric et al 2010	4/57 (1 at the adjacent level; 2 for 2-level arthroplasties)	3/41 (all at adjacent level)

10. Comparative effectiveness

MSAC noted the applicant's comments on the ESC Report, that meta-analyses were previously conducted and presented in the original application considered by MSAC in March 2011, which showed a statistically significant benefit of AIDR-C over ACDF in terms of overall success.

The composite outcome of 'overall success' used in the FDA trials at the 2 year time point was not reported in the longer-term data provided by the three studies in the response reporting longer term follow up for patients in the studies used in the original application (Garrido et al 2010, Burkus et al 2010, Delamarter et al 2010). However, select components of this overall outcome were reported in the randomised controlled trials (RCTs) and suggest that improvements were maintained at the longer follow-up. Common outcome measures were the Neck Disability Index (NDI), arm and neck pain (measured using a visual analogue scale (VAS) and SF-36 physical and mental component scores.

Where reported, most differences between arthroplasty and ACDF groups were not statistically significant, although in all cases where reported improvements were significantly improved compared to baseline pre-operative scores. Statistically significant improvements in favour of arthroplasty were seen in VAS patient satisfaction (Delamarter et al 2010), and NDI improvement (Burkus et al 2010).

Case series data (Quan et al 2011, Du et al 2011) also show 'favourable clinical and radiological results' at up to 8 years follow-up.

MSAC noted ESC advice that although 'overall success' as defined in the original studies was not calculated in longer-term follow-up studies, various components of overall success suggest AIDR confers incremental benefit out to 4-5 years. For example:

- Neck disability index improvement 86% AIDR-C with Bryan disk compared to 67% ACDF;
- Neck pain score improvement 82% AIDR-C with Bryan disk compared to 67% ACDF; and
- Arm pain score improvement +52.5 points compared to +47.7 points (Prestige® disc)

MSAC also agreed with ESC advice that for the disc-specific results, assumed effectiveness of each disc is the same. There is no statistical evidence to support a difference across the discs.

11. Economic evaluation

MSAC noted that the same Markov model was used from the original application. A cost-utility analysis with a five year time horizon in base case was also undertaken, with the comparator being ACDF.

A total of 13 revisions were made to the model to accommodate MSAC concerns and issues raised. The main revisions included were:

- omission of gains arising from the avoidance of productivity losses from the base case;
- removal of the differences in utility weights between AIDR-C and ACDF; QALY gains reflect only the changes on proportions of patients achieving success and do not reflect a higher utility score for patients achieving success with AIDR-C; and
- reduction of the price of the disc used in the model.

When all 13 revisions are included, the incremental cost per QALY gained from AIDR-C is lower than the comparable result in the original application (\$23,102 cf \$28,760). That is, the cost-effectiveness of AIDR-C has improved.

The original proposed Schedule fee of \$1,695.20 was on parity with AIDR Lumbar. The re-analysed model adopted the reduced fee put forward by the Spine Society (\$1,023.25, equal to that associated with ACDF) in the base case. MSAC agreed with ESC that setting the MBS Schedule fee for AIDR-C on parity with ACDF should improve the cost-effectiveness of AIDR-C compared with ACDF.

The out of pocket costs were not included in the original analyses, however, they were later included in the sensitivity analyses. MSAC agreed with ESC advice that the identified out of pocket costs favours AIDR-C 'since there is also a differential in the expected rate of re-operation, favouring AIDR-C, the increase in total expected cost of ACDF is greater than that of AIDR-C.'

There are no implications for the Extended Medicare Safety Net as the surgical procedures are performed on an inpatient basis.

12. Financial/budgetary impacts

The likely volume of use for the proposed intervention per year is 355 in 2011; 385 in 2012; and 415 in 2013.

The frequency of use per patient per year over a lifetime for one primary procedure on index disc plus reoperation is 30% over 3 years.

Patient numbers should be less than the volume of use due to re-operation rates.

MSAC agreed that the net total annual saving to the health care system would be \$209,143 in 2013 (compared with a previously calculated annual cost to the health care system of \$1.98 million in 2013).

The total cost of the charges for services to the public was not ascertained as out of pocket costs totals were not reported.

MSAC also agreed that the net financial cost/year to the MBS (with and without Safety Net impacts) was \$7,215/year (2013).

13. MSAC key issues

MSAC agreed that AIDR-C appears to be at least as safe as ACDF.

MSAC agreed with ESC that the additional evidence available since the original application suggests incremental effectiveness of AIDR-C extends to 5+ years. However, there are concerns regarding the longer term viability of effectiveness which currently favours AIDR-C. While the follow-up studies are too small, the trend (2 years+) is that AIDR has a 2-5% improvement in the quality of life. MSAC also noted the absence of longer term effectiveness data for the Discover disc which is the most expensive disc. Analysis suggests that in the absence of any evidence of superior effectiveness, the Discover disc does not appear to be cost-effective. The analysis suggests that the cost of AIDR-C is highly sensitive to the cost of the disc, and cost-effectiveness of the intervention appears better at the average price of the discs than at the most expensive Discover disc.

MSAC noted (from the Applicant comments to the ESC Report) that reoperations, and the observed differences between study arms across the studies considered, were included in the base case economic evaluation. The re-submission also provided a sensitivity analysis considering results once the difference in reoperations was removed.

MSAC agreed that the issue of mobility success for AIDR-C is conservative in this analysis as the cost-effectiveness model in the Applicant's response to request for further information does not use higher utility weights for the AIDR-C group.

MSAC agreed the re-analysed model adopted the reduced fee in the base case (\$1,023.25, equal to that associated with ACDF). The Applicant did not incorporate the proposed fee reduction into the financial/budget impact calculations in the re-submission (at odds with the cost-effectiveness analysis) on the basis that the difference is negligible. This will result in a conservative approach with regards to the financial impact. MSAC noted and agreed with the Applicant's comments to the ESC Report that previous uncertainties around the economics have now been resolved since the re-submission and that the uncertainty due to differences in disc prices is expected to be resolved once the PLAC advises on the group benefit.

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

In its consideration of this application at its 52nd meeting in March 2011, MSAC deferred formulation of its advice to the Minister pending provision by the applicant and the Department of additional information requested in relation to evidence around longer term effectiveness, overall success rates and functional outcomes for artificial intervertebral cervical disc replacement (AIDR-C) compared to anterior cervical discectomy with fusion (ACDF) in patients with cervical degenerative disc disease, the approach likely to be taken by the Prostheses List Advisory Committee (PLAC) regarding the management of cost variation in the discs, the proposed MBS fee and any impact on out-of-pocket expenses for patients.

MSAC considered the additional information received from the applicant and Department at its 54th meeting.

MSAC considered the requested additional information on longer term effectiveness noting that this assessment referred to evidence from FDA regulated trials which was available for three of the four AIDR-C discs (ie. Bryan®, Prestige®, ProDisc-C but not the more recent Discover™disc).

MSAC was satisfied that the additional evidence (four studies) available since the original application suggests incremental benefit of AIDR-C extends to 5 years, noting that one case series had data out to 8 years. Accordingly MSAC also noted that although 'overall success' as defined in the original studies was not reported in longer-term follow-up studies, various components of overall success suggest AIDR-C confers incremental benefit out to 4-5 years. For example:

- Neck disability index improvement 86% with Bryan disk AIDR-C compared to 67% with ACDF;
- Neck pain score improvement 82% with Bryan disk AIDR-C compared to 67% with ACDF; and
- Arm pain score improvement +52.5 points with AIDR-C compared to +47.7 points with ACDF (Prestige® disc).

MSAC agreed that while the follow-up studies are small, the trend measured over 2 years indicates that AIDR-C confers a 2-5% improvement in the quality of life. It was also noted that the estimates for functional outcomes were conservative in this analysis. MSAC noted that due to insufficient data there is some remaining uncertainty regarding longer term re-operation rates (and reasons for reoperation) – however the trends based on available data reported to date are favourable for AIDR-C.

MSAC also noted that specific clinical skills were required to perform the procedure, and noted advice from the Department that there was no current mechanism to restrict Medicare benefits.

MSAC concluded that AIDR-C appears to be at least as safe as ACDF, and is possibly associated with fewer re-operations in the long term.

MSAC had requested the Department, the applicant and the contracted assessment group to clarify assumptions in the economic model used and undertake re-analysis to take account of a range of issues raised by MSAC. The same Markov model from the original application was used in the re-analysis. MSAC noted the comments by the contracted assessment group that provided a critique of the model used in the original application.

A cost-utility analysis with 5-year time horizon in base case was undertaken. MSAC agreed that the comparator (ACDF) was appropriate. It was noted that a total of 13 revisions was made to the model to accommodate MSAC's concerns about double counting of gains arising from the avoidance of productivity losses and that this should be omitted from the base case analysis. MSAC also noted that the differences in utility weights between AIDR-C and ACDF had been removed, and that price for the ProDisc-C had been reduced to that of the two least expensive discs in line with advice from the PLAC Secretariat.

This resulted in an improvement in incremental cost per quality adjusted life year (QALY) from \$28,760 in the original application to \$23,102. It was noted that the main cost offset was from the reduced re-operation rate.

This result was also based on an unweighted average cost of all four discs. The analysis was highly sensitive to the price of the disc, with one disc shown not to be cost-effective at its current price. Therefore, a weighted analysis reflecting a lower usage rate of the higher priced disc would be expected to show a further improvement in the cost utility of AIDR-C.

In their revised analysis, the applicants removed the previously claimed gain in utility that accrued to AIDR-C patients; previously they had suggested there was slightly higher utility weight for AIDR-C patients because of their greater flexibility compared with patients who had undergone fusion. In the re-analysis, utility weights were set as the same across both arms so the incremental \$23,000 per QALY for AIDR-C appears to be a conservative estimate.

It was also noted that the Spine Society as the applicant now proposed a lower fee of \$1,023.25 (compared with the original proposed fee of \$1,695.20). This new figure had been taken into account in the re-submitted cost-effectiveness analysis, but had not been incorporated into the figures presented on the overall financial implications.

MSAC noted that the calculations on the financial and budgetary impacts/health costs were based on an 85% MBS rebate level. However, as AIDR-C relates to a professional service provided in the hospital inpatient setting the appropriate MBS rebate level should be 75%. After correcting for this as well as incorporating the lower fee (\$1023.25) into the analysis, MSAC agreed with the following estimates:

- likely volume of use per year of 385 in 2012 and 415 in 2013 (355 in 2011)
- net financial cost/year to the MBS in 2013 of \$7,215
- net total annual saving to the health care system of \$209,143 in 2013 (compared with a previously calculated annual cost to the health care system of \$1.98 million in 2013).

MSAC noted that no likely Medicare Safety Net implications were identified in the analysis.

In conclusion, MSAC was satisfied with the clinical place of AIDR-C and its benefits over ACDF. Regarding the strength of the evidence, MSAC had previously noted benefits out to 24 months and that the additional evidence was now re-assuring that benefits are likely to be maintained at 4-5 years. While there appears to be a trend towards significantly fewer re-operations for patients undergoing AIDR-C compared with ACDF, MSAC noted that uncertainty remained as to whether these benefits will be realised beyond 5 years.

MSAC acknowledged that the submission has taken a conservative approach in almost all of its analyses resulting in an incremental cost-effectiveness ratio of \$23,000 per QALY which incorporates the unweighted average cost including the most expensive disc.

MSAC noted advice from the Department that PLAC would require a minimum of two years' clinical data before listing any device, and that the three less expensive discs are likely to be listed at the same benchmark benefit for that class of device, as required by HTA Review recommendations. MSAC also noted advice that applicants may apply to PLAC for individual consideration, based on evidence of superior benefit which warrants a higher price. MSAC agreed that PLAC should be advised of MSAC's view that there is a lack of evidence in relation to the most expensive disc and that it cannot be assumed to be equivalent to the other three discs MSAC also noted that there is no evidence to support a statistically significant difference in benefit amongst the three other discs.

On this basis, MSAC recommended that PLAC be advised of MSAC's view that discs used in AIDR-C should be listed for no more than the price of the cheapest disc in this analysis, noting that the cost-effectiveness of AIDR-C is highly sensitive to the price of the discs, and that currently available evidence of benefit of the most expensive disc is limited. MSAC also accepted the revised lower MBS fee put forward by the Spine Society of \$1,023.25, which is on parity with ACDF (MBS Item number 48660), rather than \$1,695.20 originally sought.

15. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, effectiveness and cost-effectiveness of artificial intervertebral disc replacement for dynamic stabilisation of the cervical spine (AIDR-C), MSAC supports public funding of AIDR-C for symptomatic single level cervical degenerative disc disease in skeletally mature patients with a mechanically stable cervical spine who have not responded to conservative therapy and who have not had prior cervical spine surgery.

Draft Item Descriptor:

MBS item number	Description	Fee	Benefit
	CERVICAL ARTIFICIAL INTERVERTEBRAL TOTAL DISC REPLACEMENT including removal of disc, 1 level only, in skeletally mature patients with single-level cervical degenerative disc disease with radiculopathy in the absence of vertebral osteoporosis or prior spinal fusion at the same cervical level who have failed conservative therapy, with fluoroscopy	\$1,023.25	75% = \$767.44

16. Context for decision

This advice was made in accordance with 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.

17. Linkages to other documents

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

The Assessment Report is available at
<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/app1145-1>