



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1365.1 –Active middle ear implants for sensorineural hearing loss

Applicant: MED-EL Implants Systems Australasia

Date of MSAC consideration: MSAC 66th Meeting, 30-31 March 2016

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

The resubmission from MED-EL comprised a new economic analysis and proposed Medicare Benefit Schedule (MBS) item descriptor in response to the Public Summary Document (PSD) from the April 2015 Medical Services Advisory Committee meeting. No changes were made to the other sections of the previous assessment report.

2. MSAC's advice to the Minister

After considering the available evidence presented in relation to safety, clinical effectiveness and cost-effectiveness, MSAC supported public funding of active middle ear implants (AMEIs) for sensorineural hearing loss (SNHL). MSAC was satisfied that the device is likely to be cost-effective in the proposed population and the financial and budgetary implications of including AMEI on the MBS would be reasonable.

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

MSAC noted that the proposed public funding of partially implantable AMEIs for SNHL had been considered by MSAC in April 2015. While MSAC acknowledged that there was an unmet clinical need in the proposed population, the application was rejected due to substantial uncertainty regarding the economic analysis conducted.

MSAC reaffirmed that there is considerable unmet clinical need for the device in the proposed population as they are ineligible for other implants and are likely to benefit substantially as a consequence. In April 2015, MSAC recommended that children and adolescents also be included in the application, noting that despite the scarcity of data related to this population, but that it was unlikely that the intervention would affect them differently, and that the clinical need was similar in this age group.

MSAC noted that the resubmission did not provide any new evidence concerning the comparative safety and effectiveness of the device. MSAC reiterated that adverse events associated with AMEIs are rare and of low severity. However, uncertainty regarding the magnitude of harm associated with the need for surgery and general anaesthetic as part of the procedure, remains. Evidence of clinical effectiveness, as presented in the initial submission, supported the view that the technology led to superior outcomes compared to no treatment, despite MSAC noting that the evidence was of low quality, with small sample sizes and high potential for selection and outcome reporting bias.

MSAC considered the revised economic analysis presented in the resubmission and acknowledged key improvements made to address the concerns raised regarding the previous application. MSAC noted that the use of a 10-year time horizon was more appropriate than the 20-year time horizon applied previously, which was in excess of available clinical evidence. MSAC also noted that the revised analysis was based on direct health care costs only and excluded societal costs from the treatment and non-treatment arms, which was a major flaw in the previous economic evaluation. Despite these improvements, MSAC highlighted a number of inherent uncertainties in the model including the method used to estimate the QALYs and the translation of improvements in hearing gain over a 10-year time frame. MSAC noted that apart from minor structural and calibration issues, the Evaluation Subcommittee (ESC) had no concerns with the new economic model.

MSAC noted that the primary cost-utility analysis which compared the Vibrant Sound Bridge (VSB) implant to no treatment, as calculated by ESC, revealed an ICER of \$37,964 per QALY gained. MSAC also noted that the sensitivity analyses indicated that the economic model was relatively robust, with the largest variation in incremental cost per QALY observed when the time horizon was altered by five years in either direction to a 5-year (\$46,164 per QALY) and 15-year duration (\$29,687 per QALY). MSAC also noted that changing the cost of the VSB implant by 25% in either direction led to a 20% change in the ICER, although the upper limit ICER in this case was approximately \$40,000 per QALY. MSAC indicated that these values remained within acceptable cost-effectiveness limits.

MSAC considered the financial impact of the implant, noting that the device is estimated to have relatively modest total cost to MBS of \$278,159 and total intervention cost of \$1,340,594 in 2016, projected to increase to \$301,665 and \$1,453,883, respectively, in 2021. MSAC noted that the reasonably substantial cost for the implantation of one VSB device at approximately \$19,000, is largely driven by the cost of the implant (\$7,470) and the associated processor (\$6,500). MSAC stressed that the cost-effectiveness of the intervention relied upon these cost estimates. The Department noted that the technology is to be considered under a separate listing by the Prostheses List Advisory Committee (PLAC). MSAC noted that comment would be provided to PLAC to emphasise that the estimated costs for the implant and processor are the upper limit of what would be supported by MSAC as costs exceeding these estimates are likely to render the technology cost ineffective.

MSAC recommended the following changes to the MBS item descriptor:

- Modification of wording from '*insertion of, including mastoidectomy*' to '*insertion via mastoidectomy*' given that a partial or complete mastoidectomy is required for the procedure.
- Removal of the listed middle and inner ear conditions as they are not exhaustive and could be misinterpreted.
- Modification of wording from '*no history of other inner ear disorders*' to '*no other inner ear disorders*', thereby focussing on the current health state.

4. Background

At its April 2015 meeting, MSAC considered a request from MED-EL for public funding of partially implantable AMEI for use in patients with mild to severe SNHL whom cannot wear conventional hearing aids due to a number of reasons (MSAC Application 1365). MSAC acknowledged the focussed eligible patient population was better targeted to an unmet clinical need for this device and accepted the clinical effectiveness claim, albeit supported by low quality data. However, MSAC did not support public funding for due to substantially uncertain cost-effectiveness.

MSAC encouraged a resubmission of the application with a more robust economic analysis. MSAC advised that any future analysis should include a simple economic modelling, utility estimates that are more applicable to the intended population, a more careful consideration of societal costs in both the treatment and no treatment arms, a full sensitivity analysis and a more realistic time horizon may be more appropriate to determine the cost effectiveness.

The Public Summary Document is available at:

<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1365-public>

5. Prerequisites to implementation of any funding advice

The implant (Vibrant Sound Bridge (VSB)) has been registered for use in Australia since 2009 for adults, adolescents and children with mild to severe hearing impairment, who do not achieve adequate benefit from traditional therapy. In addition to SNHL, Therapeutic Goods Administration approval extends to conductive hearing loss (CHL) and otolaryngologists deliver the implantation procedure in a hospital setting. Expert colleagues, supported by the device manufacturer, would provide training.

6. Proposal for public funding

Public funding is sought for partially implantable AMEI for use in patients with mild to severe SNHL (defined with reference to air conduction thresholds and speech perception discrimination scores) and cannot wear conventional hearing aids for a variety of medical reasons including (but not limited to) chronic otitis externa, psoriasis, exostosis of the ear canal, persistent excessive cerumen blocking the ear canal, absent or deformed pinnae following skin cancer, unusual morphology affecting the ear canal, or pinna that prevent the use of conventional hearing aids. These patients are ineligible for a Cochlear implant (which is indicated for patients with severe to profound SNHL) or a bone conduction implant (which is indicated for patients with unilateral SNHL).

Proposed Item Descriptor in submission 1365.1

Category 3 – Therapeutic Procedures
MBS [item number] partially implantable MIDDLE EAR IMPLANT, insertion of, including mastoidectomy, for patients with: <ul style="list-style-type: none">- sensorineural hearing loss that is stable, bilateral and symmetrical; and- air conduction thresholds in the mild to severe rang with PTA below 80 dB HL, and- have speech perception discrimination of $\geq 65\%$ correct with appropriately amplified sound; and- cannot wear conventional hearing aid because of outer ear pathology; and- no history of other inner ear disorders such as Meniere’s syndrome; and- a normal middle ear (no history of middle ear surgery or of post-adolescent chronic middle ear infections, and normal tympanometry, and on audiometry the air-bone gap is < 10 dB HL at two or more of the following frequencies 0.5, 1, 2 and 4 kHz) (Anaes) Fee: \$1,876.59 (based on mastoidectomy item).

Proposed MSAC item descriptor as recommended at its April 2015

Category 3 – Therapeutic Procedures
MBS [item number] MIDDLE EAR IMPLANT, partially implantable, insertion of, including mastodectomy, for patients with stable sensorineural hearing loss with outer ear pathology that prevents the use of a conventional hearing aid and with: <ul style="list-style-type: none">- a PTA₄ < 80 dBHL- bilateral, symmetrical hearing loss with PTA thresholds in both ears within 20 dBHL_{0.5-4kHz} of each other; and- speech perception discrimination $\geq 65\%$ correct for word lists with appropriately amplified sound; and- a normal middle ear (no history of middle ear surgery or of post-adolescent, chronic middle ear infections); and- normal tympanometry- on audiometry, the air-bone gap is < 10 dBHL_{0.5-4 kHz} across all frequencies; and- no history of other inner ear disorders such as Meniere’s disease (Anaes) Fee: \$1,876.59 (based on mastoidectomy item).

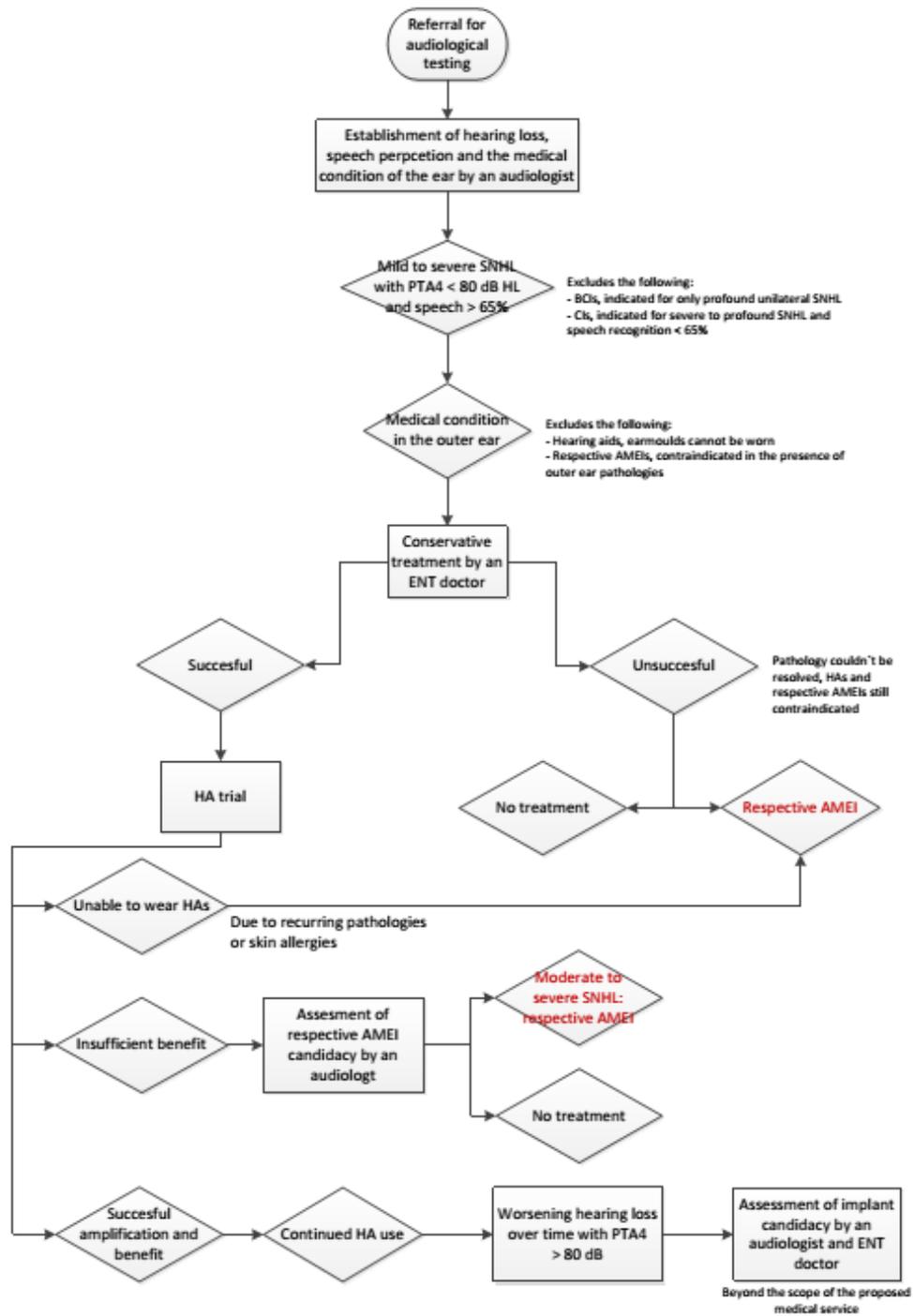
7. Summary of Public Consultation Feedback/Consumer Issues

Consumers support access to this device and procedure if the safety & quality assessment is correct and it provides an option for people who currently have none. Consumers support the inclusion of children and adolescents if clinically relevant, and supports the use of international data if it is the best available. However, there is concern that lack of resolution of cost issues is delaying access to the service.

8. Proposed intervention’s place in clinical management

This treatment is proposed as an additional option to the current practice for a sub-population of patients that are currently left untreated. The clinical management algorithm is shown below. The critique of the resubmission considered that, though the probability of undergoing more than two attempts for a successful AMEI implantation is small, the model provides no mechanism to limit use beyond second-line treatment. This is unlikely to alter the conclusions to be drawn from the evaluation.

Proposed clinical management algorithm



9. Comparator

In the April 2015 PSD, MSAC agreed that the appropriate comparator for the proposed subgroup of patients with SNHL is no treatment. MSAC also agreed with the decision to extend the evaluation to other the partially implanted devices, as well as fully implantable middle ear devices.

10. Comparative safety

The critique noted that, in the April 2015 PSD, MSAC indicated that there were seven studies cited in the assessment report regarding safety. MSAC considered the evidence and noted that adverse events were rare and of low severity. Technical complications were also noted to be relatively rare. MSAC noted that the requirement of surgery and general anaesthetic means that AMEI implantation was associated with greater harm than no treatment, with some uncertainty around the magnitude of that harm.

11. Comparative effectiveness

In the April 2015 PSD, MSAC considered that the clinical evidence did show a superior outcome for treatment compared to no treatment. Almost all studies considered by MSAC achieved a clinically relevant change of 10 decibels (dB) or greater. MSAC noted that the data supporting clinical effectiveness were predominantly low quality, with small numbers of study subjects and some overlap between studies

12. Economic evaluation

The resubmission presented two model-based (Markov) economic evaluations:

- Primary analysis: a cost-utility analysis comparing VSB versus no treatment:
 - Analysis was conducted over a 10-year timeframe
 - Rely on non-randomised data
 - Total cost to the MBS \$278,159 (2016) [new item \$133,263+associated items \$144,895]
 - Overall total cost of intervention \$1,340,594 (2016)

- Secondary analysis: a cost-effectiveness analysis comparing VSB versus Maxum/Soundtec :)
 - The ICER is presented as an incremental cost per point improvement in the APHAB Global Score (repressing patient perceived benefit)
 - Analysis was conducted over a 10-year timeframe
 - Rely on non-randomised data
 - Total Cost to MBS \$248,811 (2016) [new item \$133,263+associated items \$115,548}
 - Overall total cost of the intervention \$743,642

The model was a state-transition model representing the pathways by which a person might or might not receive an AMEI and the clinical events that may follow. For VSB versus no treatment, the ICER was presented as an incremental cost per QALY. For VSB versus Maxum/Soundtec, an incremental cost per point improvement in APHAB Global Score was calculated. In each case, the model used a 10-year time horizon.

The critique noted that the cost utility analysis of VSB versus no treatment is the most informative as the findings of secondary analysis are more difficult to interpret, although it is

acknowledged that no utility data were sourced in studies evaluating different partially implantable AMEIs.

Table 1 summarises the results of the cost-utility analysis of VSB versus no treatment over the 10-year timeframe.

Table 1: Base case results produced by the state-transition model comparing VSB versus No intervention

Strategy	Total cost	Incremental cost	QALY	Incremental QALY	ICER (\$/QALY)
No intervention	\$839.48		4.49		
VSB implantation	\$24,848.98	\$24,009.50	5.20	0.71	\$33,717.99

Source: Calculated during the Critique

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life year; VSB, Vibrant Soundbridge

Table 2 summarises the results of the cost-effectiveness analysis of VSB versus Maxum/Soundtec over the 10-year timeframe.

Table 2: Base case results produced by the state-transition model comparing VSB versus Maxum/Soundtec

Strategy	Total cost	Incremental cost	APHAB Global Score	Incremental APHAB Global Score	ICER (\$/APHAB)
Maxum/Soundtec implantation	\$13,816.30		400.8		
VSB implantation	\$24,848.98	\$11,032.26	300.0	-100.8	\$109.46

Source: Calculated during the Critique

Abbreviations: APHAB, Abbreviated Profile of Hearing Aid Benefit; ICER, incremental cost-effectiveness ratio; VSB, Vibrant Soundbridge

Notes: The APHAB Global Score is scored such that lower scores represent better outcomes. For this reason, a negative incremental score represents a relative benefit.

Sensitivity analyses showed the base case model to be reasonably robust, with all univariate analyses resulting in a ratio of less than \$50,000 per QALY.

MSAC noted that ESC recalculated the primary cost-utility analysis which compared the VSB implant to no treatment as shown in Table 3.

Table 3: Base case results comparing VSB versus No intervention

Intervention	Total cost	Incremental cost	QALYs	Incremental QALYs	ICER (\$/QALY)
No treatment	\$1,441	22,175	3.68	0.58	37,963.98
VSB implantation	\$23,616		4.26		

Source: Calculated by ESC

13. Financial/budgetary impacts

The estimated service numbers associated with the insertion of partially implantable middle ear implants in 2017–2021 are shown in Table 4.

Table 4: Estimated eligible population of patients

Description	current (2016)	2017	2018	2019	2020	2021
Estimated number of Australian adults eligible for implantation	855	870	884	899	914	929
Estimated number of services per year	71	72	74	75	76	77

The estimated overall net financial impact to the MBS of the proposed listing, including associated items, is shown in Table 5.

Table 5: Estimated total costs for the VSB device

Description	current (2016)	2017	2018	2019	2020	2021
Total costs to the MBS	\$278,159	\$28,077	\$289,912	\$293,830	\$297,748	\$301,665
Overall total costs	\$1,340,594	\$1,359,475	\$1,397,239	\$1,416,120	\$1,435,002	\$1,453,883

Table 6 presents the total cost of successful implantation, which was supplied in the resubmission and amended during the critique process. These costs comprise consumables, pre-operational, operational and post-operational costs.

Table 6: Total costs per patient for successful VSB implantation in the first 6 month

VSB	Source of unit cost	Units	Unit cost (\$)	Total (\$)
<i>Consumables</i>				
Implant	Manufacturer	1	7470.00	7470.00
Processor	Manufacturer	1	6500.00	6500.00
<i>Pre operational</i>				
ENT specialist	MBS item 104	2	85.55	171.10
Anaesthesia prep	MBS item 17610	1	43.00	43.00
Audiogram (ENT)	MBS item 11315	1	49.20	49.20
Impedance audiogram (ENT)	MBS item 11327	1	19.75	19.75
Impedance additional to audiogram (Audiologist)	MBS item 82327	1	15.80	15.80
Surgery consultation	MSB item 17615	1	85.55	85.55
Counselling & mental assessment	DVA fee schedule item US03	1	126.75	126.75
Subtotal			425.60	511.15
<i>Operational</i>				
CT Scan	MBS item 56016	1	290.00	290.00
Facial nerve monitoring	MBS item 11015	1	149.90	149.90
Implant procedure (ENT) - proposed service	MBS item 41554	1	1876.95	1876.95
Assistance	MBS item 51303	1	375.39	375.39
Anaesthesia, initiation	MBS item 20225	1	237.60	237.60
Anaesthesia, time-based attendance	MBS item 23111	1	217.80	217.80
Hospital stay	AR-DRG (Version 6.0 round 17)	1	995.96	995.96
Subtotal			4143.60	4143.60
<i>Post operational</i>				
Brain stem evoked audiometry	MBS item 82300	1	153.95	153.95
(ENT/Audiologist) follow up consultation	MBS item 10952	2	62.25	124.50
Battery cost	Modeller assumption	26	1.00	26.00
ENT specialist	MBS item 104	1	85.55	85.55
Subtotal			302.75	390.00
Total consumables				13,970.00
Total direct costs				5044.75
Total cost of VSB implantation				19,014.75

Source: Table 37, p113 of the Assessment Report and *corrections made during the Critique*

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Group; CT, computed tomography; DVA, Department of Veteran Affairs; ENT, ear, nose and throat specialist; MBS, Medical Benefits Schedule; VSB, Vibrant Soundbridge

14. Key issues from ESC for MSAC

ESC had no concerns with the economic model beyond some structural and calibration issues:

- There was uncertainty about the methods for capturing quality of life impacts.
- ESC noted MSAC concerns regarding utility weights, to which the applicant, in its pre-ESC response stated that "...there are no studies that have published clinical outcomes as well as generic health-related quality of life measures." and "...we cannot estimate varying utility values with different health states.
- ESC noted that the time horizon had been shortened to 10 years in the resubmission, which was formerly a 20-year horizon in MSAC application 1365. ESC considered this time horizon to be more appropriate. However, ESC questioned the assumption of a continuous effect over such a long extrapolation period.
- ESC noted MSAC concerns regarding the inclusion of societal costs in MSAC application 1365. In the resubmission only direct health care costs were included.
- During the economic model re-analysis comparing MEI with no treatment, the following figures were calculated. ESC noted that they differed from the figures in the independent critique, revising health care costs, applying a discounting rate appropriately and revising utility weights given the cycle length.

15. Other significant factors

Nil.

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

We are delighted with MSAC's decision to support the public funding of partially implantable active middle ear implants for sensorineural hearing loss. With access to a cost-effective solution, affected individuals will now be able to participate more in society and enjoy a higher quality of life. The recommended changes to the MBS item descriptor are minor and reasonable.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.