Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1365 – Active middle ear implants for sensorineural hearing loss

Applicant: **MED-EL Implant Systems Australasia Pty Ltd**

Date of MSAC consideration: **MSAC 63rd Meeting, 1-2 April 2015**

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

A submission requesting MBS listing of partially implantable active middle ear implant (AMEI) for sensorineural hearing loss (SNHL) was received from MED-EL Implant Systems Australasia Pty Ltd by the Department of Health in September 2013.

2. MSAC's advice to the Minister

After considering the available evidence presented in relation to safety, clinical effectiveness and cost-effectiveness of partially implantable active middle ear implant (AMEI) for sensorineural hearing loss (SNHL), MSAC did not support public funding for the use of this device in patients with SNHL due to substantially uncertain cost-effectiveness.

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.

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

MSAC noted that in July 2010 MSAC had considered the request for public funding for AMEI in patients with SNHL, conductive hearing loss and mixed hearing loss (MSAC application 1137). MSAC rejected the application due to uncertainty regarding the service's cost-effectiveness, the definition of the appropriate patient population, the long term safety of the device and the effect of the availability of other devices. The current application is restricted to partially implantable AMEI and a narrower patient population.

MSAC noted that the AMEI is being proposed for use in patients with mild to severe SNHL who cannot wear conventional hearing aids for a number of reasons. MSAC considered that

the reasons listed for contraindication to hearing aids may not be restrictive enough and may result in leakage.

MSAC noted that there is a considerable unmet clinical need in the identified population as they are ineligible for other implants and are likely to benefit substantially. MSAC also noted that children and adolescents had not been included in the application due to lack of clinical evidence of benefit. MSAC noted that it is not uncommon when limited evidence is available for there to be no clinical evidence on children and adolescents. However, MSAC agreed that children and adolescents should still be included in the application, as it was unlikely that the effects of this intervention would be different in this population.

There were seven studies cited in the application that reported on safety. MSAC considered the evidence on safety and noted that adverse events were rare and 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.

MSAC considered the clinical efficacy and considered that the 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. There were substantial issues in terms of the potential for selection and reporting bias and substantial heterogeneity in study design. The study durations were short with an absence of follow up; as such long term efficacy is uncertain.

MSAC considered the economic analysis and expressed strong concerns regarding the considerable uncertainties around the cost effectiveness calculations. MSAC considered the inclusion of societal costs to be a major flaw in the economic evaluation due to considerable uncertainty around the costs, particularly as no societal costs were attributed to the treatment arm. In addition, costs that were not applicable to the non-treatment arm such as hearing aids and net cost of well-being, which constituted double counting, were included, making the treatment appear more cost-effective. MSAC noted other issues in the economic analysis including; that the QALY estimates were based on one study performed in a different population to that proposed in the application and that there was little applicability of the utility weights used in the evaluation to the effectiveness cited in the clinical studies, or the likely utility in the proposed population. MSAC was also concerned that the evaluation applied a 20-year time horizon that was in excess of the clinical evidence available. The economic analysis results were highly sensitive to this time horizon.

MSAC noted that due to the fundamentally flawed model used for the economic evaluation, no incremental cost effectiveness ratio (ICER) could be confidently stated for the treatment and the claims for cost-effectiveness could not be accepted. It was primarily for this reason that MSAC rejected the application.

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. MSAC also encouraged further consultation with experts in paediatrics, audiology and ear, nose and throat, to strengthen the application.

4. Background

MSAC previously considered a request for public funding for AMEI for use in patients with SNHL, conductive hearing loss (CHL) and mixed hearing loss (MHL) at its July 2010 meeting (MSAC Application 1137). MSAC rejected the application on the basis of its inability to identify particular subgroups of patients for whom listing could be justified in terms of comparative cost-effectiveness; uncertainty around long-term safety; and the availability of the bone-anchored hearing aid and cochlear implant as current alternatives for all middle ear implant (MEI) indications.

PASC noted during their consideration of this item in April 2014 that a separate application would be required for fully implantable AMEI devices, given the additional complexity of the surgery and length of time required to implant them. The use of partially implantable MEIs in patients with mild to severe conductive hearing loss (CHL) or mixed hearing loss (MHL) will be assessed in a separate application (MSAC Application 1364).

5. Prerequisites to implementation of any funding advice

The applicant's AMEI system has been registered for use in Australia since 2009 for patients (adults, adolescents and children) with mild to severe hearing impairment who do not achieve adequate benefit from traditional therapy. In addition to SNHL, TGA approval extends to CHL and MHL.

At this point in time, there are no other partially implantable AMEIs listed on the ARTG.

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. These may include (but are not limited to) conditions such as 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 CI (which is indicated for patients with severe to profound SNHL) or a BCI (which is indicated for patients with unilateral SNHL).

Table 1 below presents the MBS item descriptor for partially implantable AMEI, as proposed by the Applicant and agreed by PASC. The proposed item descriptor restricts use to patients with stable, bilateral and symmetrical, mild to severe SNHL with pure tone average at four frequencies (PTA4) below 80 dB HL, speech perception discrimination of at least 65% correct with appropriately amplified sound, a normal middle ear, and an inability to wear conventional hearing aids because of outer ear pathology.

Table 1: Proposed MBS item descriptor for insertion of AMEI

Category 3 – Therapeutic Procedures
MBS [item number] partially implantable MIDDLE EAR IMPLANT, insertion of, including mastoidectomy, for patients with: - sensorineural hearing loss that is stable, bilateral and symmetrical; and - air conduction thresholds in the mild to severe range with PTA4 below 80 dB HL; and - have speech perception discrimination of ≥65% correct with appropriately amplified sound; and - cannot wear conventional hearing aid because of outer ear pathology; and - no history of 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: $1,876.95 (based on mastoidectomy item)

Source: p22 of the Assessment Report
Abbreviations: dB HL, decibel hearing level; kHz; kilohertz; PTA, pure tone average.

Table 2: Proposed MBS item descriptor for revision or explantation surgery for AMEI

Category 3 – Therapeutic Procedures
MBS [item number] MIDDLE EAR IMPLANT, partially implantable, revision or explantation of. (Anaes) Fee: TBA

Source: Table 7, p13 of the Final Protocol

Changes proposed to the item during public consultation were agreed to by ESC, which considered them justified. MSAC agreed with ESC for the updated item descriptor to be adopted.

Category 3 – Therapeutic Procedures
MBS [item number] MIDDLE EAR IMPLANT, partially implantable, insertion of, including mastoidectomy, for patients with stable sensorineural hearing loss with outer ear pathology that prevents the use of a conventional hearing aid and with: - a PTA_4 ~~below~~ ≤80 dBHL, ~~with one of the following air conduction thresholds:~~ ~~○ mild hearing loss 25 dB ≤ $BEHL_{0.5\text{-}4kHz}$ < 40 dB; or~~ ~~○ moderate hearing loss 40 dB ≤ $BEHL_{0.5\text{-}4\ kHz}$ < 70 dB; or~~ ~~○ severe hearing loss 70 dB ≤ $BEHL_{0.5\text{-}4\ kHz}$ < 95 dB; and~~ ~~- speech perception discrimination of ≥65% correct with appropriately amplified sound; and~~ - bilateral, symmetrical hearing loss with PTA thresholds in both ears within 20 $dbHL_{0.5\text{-}4\ kHz}$ of each other; and - speech perception discrimination ~~of~~ ≥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 $dBHL_{0.5\text{-}4\ kHz}$ ~~at two or more frequencies~~ 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

No consumer impact statement was provided in the assessment.

8. Proposed intervention's place in clinical management

AMEI are partially- or fully implantable devices that increase sound transmission by vibrating and moving the small bones of the middle ear (the ossicular chain), transmitting sound vibrations to the inner ear (the cochlea). The devices are surgically implanted within the middle ear and generally leave the external ear canal unoccluded.

The internal component of the implant is crimped or attached to the long process of the incus to mechanically drive the ossicular chain. The amplified vibrations can be adjusted via an external auditory processor to suit different kinds and degrees of hearing loss.

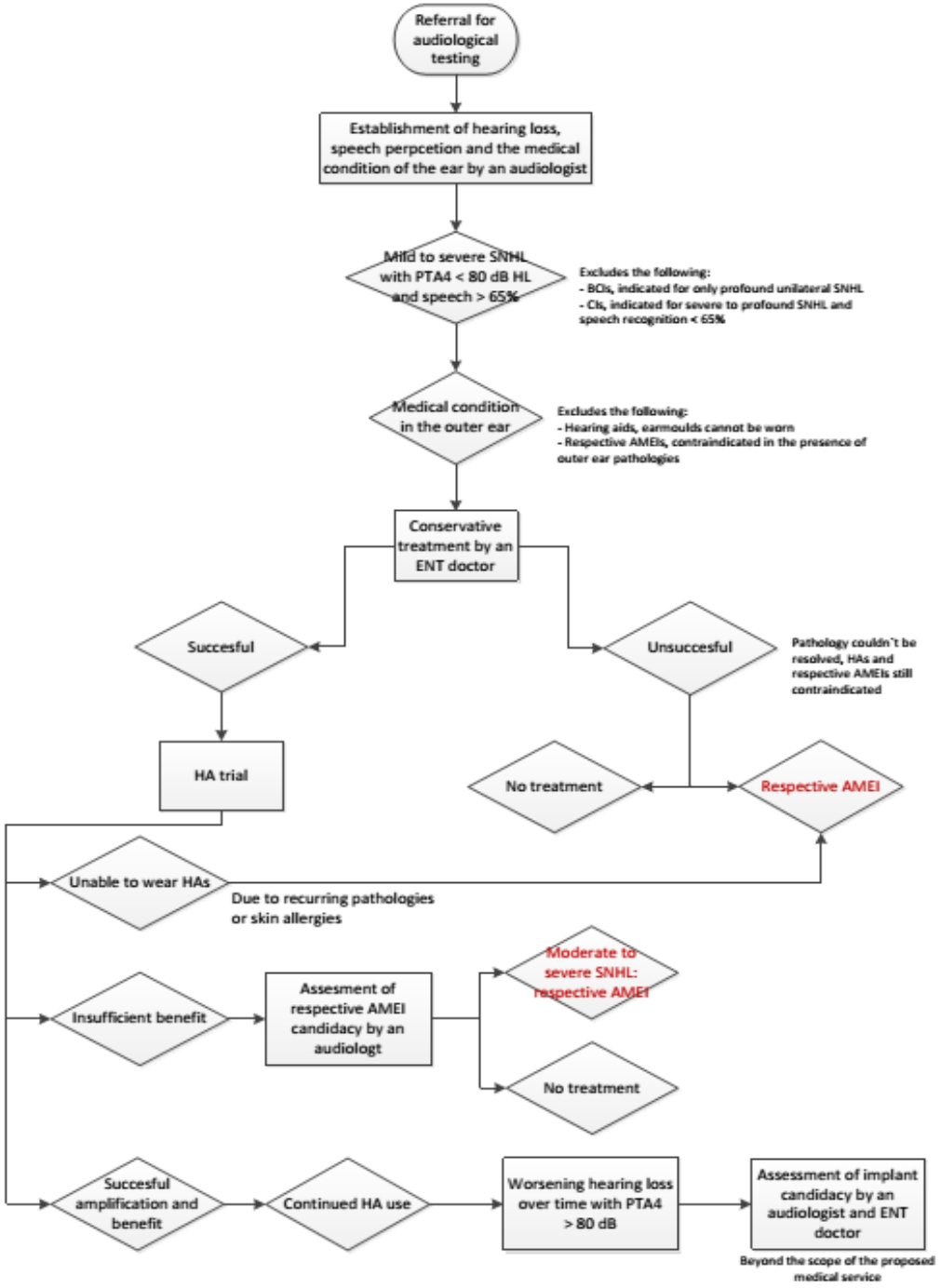
The surgical approach to the middle ear may be either via the facial recess route via a mastoidectomy and the posterior tympanotomy; and/or a transmeatal route via the ear canal. The choice of surgical approach is usually dependent on the medical status of the patient's ear and on the surgeon's preference.

The external audio processor (AP) is fitted by an audiologist six to eight weeks after surgery and is programmed to meet the particular hearing needs of the patient. Programming is done by an audiologist in either a hospital or private audiological clinic on an outpatient basis, and typically takes about 30-45 minutes.

There are several models of AMEI that are currently in use. The Applicant's device is the partially implantable Vibrant Soundbridge (VSB), which was first implanted in 1996. It consists of both internal implanted components and external components.

An AMEI is proposed to be used in individuals with mild to severe sensorineural hearing loss who cannot wear conventional hearing aids due to outer ear pathology. However, these individuals can still benefit from the amplification of sound. Individuals with sensorineural hearing loss will have air conduction hearing thresholds within the mild to severe range. All active middle ear implant candidates will have speech perception discrimination of at least 50% correct with appropriate amplified sound.

The Assessment Report presented the clinical management algorithm below for partially implantable AMEI in patients with SNHL and a medical condition that prevents the use of a conventional hearing aid.



Source: Figure 8, p34 of the Assessment Report
Abbreviations: AMEI, active middle ear implant; dB HL, decibel hearing level; ENT, ear nose throat; HA, hearing aid; PTA, pure tone average.

9. Comparator

MSAC agreed that comparator for the proposed subgroup of patients with SNHL is no treatment is appropriate. 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

Overall, there is wide variability in reporting of adverse outcomes by the included studies of AMEIs. This may be attributed to the surgical techniques used and the devices implanted.

The sensation of aural fullness and taste disturbance or damage to the chorda tympani nerve were the most commonly experienced adverse events. Most adverse events were relatively rare and of low severity. Serious adverse events such as facial nerve damage were rare.

Technical complications related to the device, including device malfunction, migration or insufficient gain, were relatively rare. The rate of revision surgery varied between studies, ranging from 1.4% to 15.6%, with an average of 2.82%.

Due to the absence of comparative evidence it is not possible to accurately compare the rates of adverse events between patients receiving the applicant's device and those receiving other the partially implanted devices.

Based on the available evidence, revision surgeries were more frequent with one of the fully implantable AMEI devices.

11. Comparative effectiveness

The Assessment Report identified 41 studies; 31 investigated partially implantable AMEI and 10 investigated fully implantable AMEI, encompassing a total of 2,233 patients.

Overall, the applicant's AMEI system appears to be effective in improving hearing when compared to unaided, pre-implantation levels in patients with mild, moderate, or severe SNHL. Almost all studies achieved a clinically relevant change in functional gain of 10 dB or greater.

12. Economic evaluation

The Assessment Report presented a series of economic evaluations. These included:

1. a cost-utility analysis achieved by assessing the incremental costs of the AMEI, using QALY data derived from the literature;
2. a cost-effectiveness analysis assessing incremental costs of AMEI and the increase in expected functional gain observed in clinical studies (in dBs); and
3. a cost-effectiveness analysis assessing the incremental costs of AMEI and the percentage change in expected word recognition score (WRS) observed in clinical studies.

MSAC noted that of the above economic evaluations, the cost-utility analysis was the most informative. MSAC was concerned that none of the analyses presented in the assessment report included a stepped economic evaluation, nor was a modelled economic evaluation undertaken. MSAC was also concerned that no comprehensive sensitivity analysis was included, which could have addressed some key areas of uncertainty.

Where possible, each analysis was undertaken for the applicant's AMEI versus No Treatment, as well as versus other AMEIs. In all cases, the analyses relied on non-randomised data. Health states, transition probabilities and events were not explicitly considered within these analyses. The evaluation calculates the ICERs in a simple manner without modelling transition through health states over the 20-year period (as would be the case in a Markov model, for example).

For each of the interventions, the implantation costs represent the greatest cost drivers of the result over the duration of the 20- year model. With regards to the No Treatment option, all costs comprise indirect/societal costs. The incremental cost-effectiveness of treatment versus

no treatment improved as the time horizon increased. This is due to the compounding of the societal cost of no treatment applied to the evaluation, which increases at a more rapid rate than the ongoing costs of treatment. MSAC considered the appropriateness of the twenty year time horizon in light of the clinical evidence presented in the assessment report. MSAC agreed that a twenty year time horizon appeared reasonable but was concerned that the time horizon was extrapolating beyond the evidence available and as such was a source of considerable uncertainty. MSAC also noted that failure to systematically outline the basis for the extrapolation assumption introduces considerable uncertainty to the economic evaluation.

MSAC noted that the no treatment arm costs are high due to the inclusion of societal costs. These societal costs included; annual productivity losses, cost of informal carers, annual direct health care costs, education, support and aid, deadweight loss and net cost of the loss of wellbeing. A number of the societal costs were inappropriate including fixed costs such as the cost of research and the costs of hearing aids and cochlear implants, which the patient population would not be eligible for. MSAC also noted that no societal costs were included in the treatment arm and considered this inappropriate as after treatment some societal costs would still apply. For these reasons the calculation of the societal costs in the no treatment arm was considered by MSAC to be highly uncertain. The cost effectiveness results are highly sensitive to these societal costs.

The three analyses used in the economic evaluation rely on health related quality of life (HRQoL) for the cost-utility analyses and both mean functional gain (in dB) and percentage change in WRS for the cost-effectiveness analyses. In the case of the cost-effectiveness analyses, the values used for the surrogate outcomes could not be reconciled with those presented elsewhere in the assessment report.

MSAC was highly concerned by the utility weights used in the analysis for a number of reasons. MSAC noted that no attempt was made to link the clinical studies and the literature-sourced utility data applied to the economic evaluation. This lead to substantial uncertainty regarding whether the utility data applied is representative of the clinical studies. MSAC was very concerned by the method by which the data was applied. MSAC noted that the method was flawed and applied an inflated utility weight of 2.79 to the treatment arm only and ignored the HRQoL of hearing impairment in patients who do not receive the implant.

Table and Table below summarise the results of the economic evaluation of the proposed intervention during the year of the intervention and over the 20-year timeframe, showing the cost-utility analysis of AMEI versus No Treatment. MSAC noted that these were corrected results, made in the Critique.

Table 3: Incremental cost-utility of AMEI versus No Treatment in the year of the intervention

	VSB	No Treatment	Increment
Costs	*$18,982.90*	*$5,426.42*	*$13,556.49*
QALY	*0.66*	*0.57*	*0.09*
Incremental cost- effectiveness ratio			*$150,627.63*

Source: *Re-calculated during the Critique to correct for errors included in the Assessment Report*
Abbreviations: QALY, quality-adjusted life years

In the year of the intervention, AMEI is associated with both a positive net cost and QALY benefit relative to No Treatment. MSAC noted the high incremental cost relative to the net benefit and that treatment could not be said to be cost-effective relative to no-treatment in this instance.

Table 4: Incremental cost-utility of AMEI versus No Treatment, 20-year time horizon, discounted at 5% p.a.

	VSB	No Treatment	Increment
Costs	*$32,994.81*	*$73,061.55*	*-$40,056.74*
QALY	*8.28*	*7.67*	*0.61*
Incremental cost- effectiveness ratio			*-$66,181.40*

Re-calculated during the Critique to correct for errors included in the Assessment Report
Abbreviations: QALY, quality-adjusted life years

Over the duration of the 20-year model, AMEI is estimated to offer a net utility gain of 0.61 while also being associated with a substantial reduction in costs relative to No Treatment. MSAC noted that this is driven by the inclusion of societal costs in the no treatment arm and that the finding that treatment is cost-saving over the long term is dependent upon accepting these costs.

MSAC was not able to determine an appropriate ICER from the economic evaluations performed in the assessment. Consequently MSAC recommended that the application be re-submitted with a new economic evaluation that accounts for the issues outlined above.

13. Financial/budgetary impacts

An epidemiological approach was used as the basis of the financial estimates. The number of patients with SNHL who would be eligible for AMEI under the proposed MBS item is estimated to be 855 in the first year of an MBS listing, rising to 914 in the fifth year.

To calculate the number of services each year, the applicant has assumed that the entire prevalent pool of eligible patients would receive an implant within a 10- to 15-year period. Furthermore, during the first five years of an MBS listing there would be a 5% increase each year in the number of patients that receive an implant. Taken together, this equates to roughly 71 to 92 services in each of the first five years.

MSAC noted that there was no justification for the choice of studies used to inform the epidemiological estimates. MSAC also noted that it is unlikely for everyone eligible for the implant to undergo the procedure in the first fifteen years. As such MSAC considered the estimation of the expected usage of the procedure to be highly uncertain.

The estimated financial impact of the proposed intervention is shown below, applying the costs used in the economic evaluation.

Table 5: Estimated total cost to the MBS of the proposed intervention (VSB)

Description	2016	2017	2018	2019	2020
Cost to MBS of the proposed item	$133,263	$142,648	$152,033	$161,418	$172,679
Cost to MBS of associated items[a]	$144,895	$155,099	$165,303	$175,508	$187,752
Total cost to MBS	$278,158	$297,747	$317,336	$336,926	$360,431
Total non-MBS costs[b]	$1,074,988	$1,150,691	$1,226,394	$1,302,098	$1,392,942
Total cost of the proposed intervention	$1,353,145	$1,448,438	$1,543,730	$1,639,023	$1,753,373

Source: Calculated during the Critique based largely on the approach used in the Assessment Report, including corrections
Abbreviations: MBS, Medicare Benefits Schedule; VSB, Vibrant Soundbridge.
[a] Includes co-administered services, pre-operational services, post-operational services, and MBS costs associated with re-implantation (assuming that 2.72% of implants will require re-implantation).
[b] Includes cost of the VSB implant, processor, batteries, counselling, hospital stay, and non-MBS costs associated with re-implantation, which are met by hospital budgets, private health funds and patient self-pay.

14. Key issues from ESC for MSAC

ESC agreed that the intended population group would be patients who are unable to use an external device and do not qualify for a cochlear implant. ESC agreed that this was a niche patient population. However, whether the proposed population should include children is uncertain. ESC agreed that this is an alternative treatment for patients that currently have no other option.

ESC agreed that the comparator is no treatment for the proposed subgroup of patients with SNHL.

ESC discussed that clinical trial data studies were small, level four and statistically underpowered. ESC was concerned that there were no head to head trials presented and agreed that small trials were not unexpected due to the small intended patient population. ESC noted that the lack of high level evidence may be related to ethical issues regarding randomising patients to receive different types of surgical implantation or sham surgery.

Overall, ESC noted that there was wide variability in reporting of adverse outcomes of AMEIs. ESC agreed, however, that most adverse events were relatively rare and of low severity. ESC agreed that serious adverse events were not common. ESC also agreed that technical complications were rare.

ESC noted that the revision of surgery varied across studies. ESC discussed whether there is a need to include a separate revision MBS item, as was requested by PASC. ESC agreed that a separate item for revision surgery is not necessary but may be beneficial for monitoring purposes.

ESC was concerned that there was considerable variability regarding patient enrolment, study design and length of follow-up in the included studies. ESC also discussed that some of the studies were also over ten years old and may have used first generation systems that have now been improved.

Despite the limited trial evidence, ESC agreed that superior outcomes, when compared to the comparator (no treatment), were associated with the proposal. ESC noted that only one trial did not find at least a 10 dB improvement. The outcomes were based on functional gain, speech recognition and speech reception threshold (in noise and quiet).

ESC was concerned whether participants in the studies are a true representation of the intended population, as described in the proposed item descriptor. ESC noted that there was no comparison of the populations of the studies used with that expected in Australian clinical practice.

ESC was concerned that the included studies enrolled adult subjects only and discussed that there is no evidence to support the use of AMEIs in children and adolescents with SNHL. Due to this, ESC discussed whether the proposed listing should be restricted to adults.

ESC noted that several types of economic evaluation were presented in the assessment report, but agreed that the cost-utility analysis was the most informative. However, there were multiple issues identified within the analysis that make its conclusions flawed and markedly uncertain. ESC was primarily concerned with the uncertainty around utility weights and the calculation of indirect societal costs. ESC discussed that this concern would partly be due to

unavailability of information and partly due to flawed methods in applying available information. ESC agreed that the economic evaluation was very sensitive to these parameters.

ESC discussed translation issues. In terms of applicability, ESC was concerned that the QALY data were based on a different population (mixed types of hearing loss in European adult population) and was not necessarily applicable to the Australian context. In terms of extrapolation, ESC was concerned that the economic evaluation applied a time horizon of 20 years. ESC was concerned that this was in excess of the clinical study evidence. ESC agreed that this was a key assumption, potential source of uncertainty, and noted that conclusions were sensitive to time span. Regarding transformation issues, ESC was concerned that there was no justification for the quality-adjusted life year estimates in the economic evaluation, and ESC were highly concerned that there was no link between the clinical studies for clinical effectiveness and the utility data applied to the economic evaluation. QALY data were based on *one* study, which, as noted above, was a different population to that proposed in the protocol.

ESC agreed with the critique that the economic model was flawed. One major issue was an implausible incremental utility weight was applied to the treatment arm, substantially over-estimating the benefit of the treatment.

ESC also considered the calculation and application of societal costs to be a major issue, with substantial uncertainty around these costs. ESC discussed that the economic model assumed no societal costs in the treatment arm. ESC questioned whether this was a reasonable assumption. ESC agreed that adding societal costs to the treatment arm would reduce cost-effectiveness and that technically, as the model stands, reducing utility gain to very low levels still results in cost-saving due to societal costs only being applied in non-treatment arms. Further, the societal costs included costs that were not applicable to the no-treatment arm (e.g. hearing aid costs) and net cost of well-being (which constitutes double-counting), making the intervention appear more cost-effective than it would be if these costs were not included. ESC was concerned that societal cost is applied to all years of the model, which ESC noted has a profound impact on the ICERs calculated.

ESC noted that an epidemiological approach was used as the basis of the financial estimates. ESC agreed that there is no justification for the choice of studies used to inform the epidemiological estimates. ESC noted that this approach does not take into consideration patient preference for AMEI. That is, some patients may choose not to receive an AMEI due to the invasiveness of the VSB implantation procedure or the high cost (although the VSB implant and processor may be added to the Prostheses List if there was an MBS item for the procedure). The estimates do not consider that some procedures may be undertaken in public patients at public hospitals. The financial impact to the MBS of the proposed service may therefore be an overestimate.

ESC noted that if the proposal gets funded, then it will also need to be listed on the Prosthesis list.

15. Other significant factors

Nil.

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

Although disappointed with the unfortunate outcome, the applicants are satisfied with MSAC's conclusion that there is *"considerable unmet clinical need in the identified population as they are ineligible for other implants and are likely to benefit substantially". Furthermore, "MSAC considered the clinical efficacy and safety and considered that the evidence did show a superior outcome for treatment compared to the comparator".*
Nonetheless, MSAC expressed concerns regarding the uncertainties around the cost effectiveness calculations performed by the applicant. On this account, the applicants will re-submit a more robust economic analysis for this application of Sensorineural hearing loss as well as for the second application for Mixed and Conductive hearing loss in due time, to overcome the one concern MSAC concluded to not support public funding for the treatment of Sensorineural hearing loss with a partially implantable middle ear implant.

17. Further information on MSAC

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