

Submission by Cochlear Ltd to the Private Health Insurance Taskforce

PHI Consultation

Standard Clinical Definitions and Hospital Product Redesign

The following organisations were consulted during the preparation of this submission:
ASOHNS; Audiology Australia; Australian Hearing Hub; CICADA Australia; CRC Hearing;
Deafness Forum; Ear Science Institute Australia; Hearing Implants Australia; Hear for You;
Neurosensory; Royal Institute of Deaf and Blind Children – RIDBC; South Australian
Cochlear Implant Centre, SACIC; Royal Victorian Eye and Ear Hospital; The Shepherd
Centre.

Cochlear Limited

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Hear now. And always



1. Summary

Cochlear supports the principles of the private health insurance (PHI) reforms and is actively engaged in the reform process. We acknowledge that these reforms are complex and appreciate the opportunity to be involved in the consultation process.

Cochlear recommends the minimum coverage of “implanted devices for hearing loss surgery” (implanted hearing devices) be extended to Bronze, Silver and Gold product categories. We strongly oppose the proposed limitation of minimum coverage of implanted hearing devices to the Gold category for the following reasons:

- It will have a significant impact on a vulnerable patient population who currently rely on accessing implanted hearing device across the Basic/Low, Medium and Top categories of hospital treatment cover.
- The proposal appears to be based largely on prostheses cost with little consideration of volume, the overall impact to private health care costs and the resulting burden on the public healthcare and aged care systems.
- Constraining expenditure on implanted hearing devices will have little impact on reducing PHI expenditure on prostheses surgery”. Given this, it is unclear why minimum coverage is constrained to Gold whereas “heart and heart related conditions and services” (including stenting, pacemaker or defibrillator insertion) is covered in Silver and Gold. These services have a much higher impact on the benefits paid for prostheses and PHI premiums.
- It will have a significant impact on timely access to clinically efficacious and cost effective interventions for those suffering a significant disabling hearing loss. Delays in access have a negative impact on the health, quality of life of and productivity of individuals and their families.
- Hearing loss is the largest modifiable mid-life risk factor for dementia which calls for ambitious preventive measures including the management of hearing loss. Dementia prevalence would be halved if its onset were delayed by 5 years²⁴.

Given the significant clinical, social and economic returns to be achieved from treating hearing loss, any policy changes that lead to constraining access to timely intervention do not appear justifiable. It will not have a material impact on the cost of premiums and will adversely impact the health and productivity of Australians suffering a treatable, disabling hearing loss. In addition it will undermine Australia’s world renowned system of identifying and treating hearing loss and jeopardise its position as a global leader in hearing health.

2. Recommendations

1. Fully consider the stakeholder impact of the proposed changes to *Implanted devices for hearing loss surgery*, from a clinical, social and economic perspective as well.
2. Ensure that relevant ENT and Audiology MBS item numbers are included in the clinical definitions pertaining to *Implanted devices for hearing loss surgery*.
3. Revise the necessity of subcategorising the ENT therapeutic group into three standard clinical definitions in line with the evidence provided and the principles of the PHI reforms.
4. Maintain the single or three subcategories of the ENT therapeutic group across Bronze, Silver and Gold.
5. Monitor the utilisation rates of implantable hearing devices and consider reviewing minimum coverage levels if there is a sustained material increase.

3. About Cochlear

Cochlear is the global leader in the development and manufacture of implantable hearing solutions and related technology to address moderate, severe to profound hearing loss. Cochlear's range of innovative products including cochlear implants, implantable bone conduction implants and acoustic implants, address different types of hearing loss in all age groups.

Hearing implant systems consists of two parts: i) the surgically placed cochlear implant, designed to last a lifetime, ii) the externally worn sound processor, fitted by an Audiologist in an outpatient setting, worn every waking hour and requiring replacement every 4-6 years. Refer to Appendix for explanation of how hearing implant systems work.

Cochlear is an Australian headquartered global company with over 3,000 employees, around 1,500 of whom are based in Australia. Australian employees include over 800 engineers, scientists and researchers. The company invests more than AUS\$130 million each year in research and development and currently participates in over 100 collaborative research programs worldwide aimed at better understanding and treating hearing loss.

Over 475,000 people of all ages from more than 100 countries, now hear because of a Cochlear product. This includes around 15,000 people in Australia.

4. Hearing Health of Australians

Hearing is integral to good health, social interaction, education, employment and quality of life. Today, one in six Australian's are affected by hearing loss^{1a}, with a financial cost of \$15.9billion^{1b}. Hearing loss is a co-morbidity with six of Australia's current National Health Priority (NHP) areas (cancer, cardiovascular health, diabetes, arthritis & musculoskeletal conditions, obesity, and dementia) and is also a risk factor for two NHP areas (dementia and mental health). The impact of hearing loss can be prevented or managed with timely intervention. Coordinating continued investment into Australia's hearing health is required.

Following a wide ranging Inquiry, the Commonwealth House of Representatives Committee on Health, Ageing and Sport recommended hearing become Australia's 10th National Health Priority². In 2017 the World Health Organisation (WHO) updated the resolution on the Prevention of Deafness, urging member states to improve access to affordable, cost-effective, high-quality, assistive hearing technologies and products, including hearing aids, cochlear implants and other assistive devices, as part of universal health coverage³.

In Australia there is a good balance of funding for hearing technologies from Federal Government (Office of Hearing Services, National Disability Insurance, Veterans Affairs) State (Health budget allocations) and Private Health Insurance. This should be maintained as it supports timely access to clinically needed and cost effective^{26,27} intervention for all socioeconomic groups.

Given the significant clinical, social and economic returns to be achieved from treating hearing loss, constraining access to timely intervention does not appear justifiable. It will not have a material impact on the cost of premiums and will adversely impact the health and productivity of Australians suffering a treatable, disabling hearing loss. In addition it will undermine Australia's world renowned system of identifying and treating hearing loss and jeopardise its position as a global leader in hearing health.

5. Response to the proposed standard clinical definitions

As per Attachment B – Standard Clinical Definitions, issued by the Department of Health on April 16, 2018, the ENT therapeutic group has been subcategorised into three clinical definitions.

- Ear, Nose and throat conditions and services
- Implanted devices for hearing loss surgery
- Tonsils, adenoids and grommet surgery.

As discussed in Section 4 below, constraining access to implantable hearing devices will have little impact on the sustainability of private health insurance. It is therefore questionable, as to whether ENT, like the Cardiac/ Cardiothoracic therapeutic group (now combined into *Heart and heart- related conditions and services*), should be subcategorised at this time. It may be unnecessarily complicating, rather than simplifying, private health insurance products for the consumer, and at the same time further eroding the value of private health insurance for a vulnerable patient group.

Leaving aside the question of whether ENT should be subcategorised, Cochlear’s feedback on the accuracy of clinical definition “Implanted devices for hearing loss surgery” is presented below in Table 1.

Table 1. Feedback regarding Clinical Definition, Implanted devices for hearing loss surgery

Item	Details in Attachment B	Cochlear’s Feedback
Clinical Definition name	Implanted devices for hearing loss surgery	No further changes requested to the name of this clinical definition.
Description	Admission for the treatment to correct hearing loss, including implantation of a prosthetic hearing device and stapedectomy.	No further changes requested to the description of this clinical definition
MBS item numbers	11300 – 11339	<ul style="list-style-type: none"> • 11336 is duplicated in ENT conditions & services. • 11300 and 82300 should both be tabled. In all cases the programming of a cochlear sound processor is performed in an outpatient setting by an audiologist with specialised knowledge and training. • The 11300 is the number used when the audiologist performs this procedure under the instruction of the ENT and using the ENT’s Hospital Provider Number. • The 82300 is the number used by an Audiologist, who has their own Hospital Provider Number, when they are performing this procedure for a patient who has been referred to the audiologist by an ENT. • There are few devices on the Prostheses List that are not fitted in an inpatient episode of care, so this may be a new concept to some. Sound processors are <i>critical to the continuing function of the surgically implanted product</i>

Item	Details in Attachment B	Cochlear's Feedback
		and as such fulfil the Eligibility for Listing criteria defined in Section 72-1 (2) of the Act and therefore are included on Part A of the Prostheses List.
	41603 - 41618	<ul style="list-style-type: none"> This series of MBS item numbers adequately covers those utilised for this clinical definition. No changes are required.

6. Response to the proposed hospital product redesign

Cochlear strongly opposes minimum coverage of “Implanted devices for hearing loss surgery” being limited to the Gold product category.. Currently, the majority of products across the Bronze, Silver and Gold hospital treatment product categories cover implanted hearing devices (Refer Table 2). The proposed minimum coverage in Gold only will significantly affect consumer access and yet it is immaterial to the sustainability of private health insurance.

Table 2. Current coverage[†] of implantable hearing systems by hospital product category tier.

		Basic	Low	Mid	Top
Cochlear implant systems	Implant	43%	82%	95%	100%
	Initial Sound Processor	43%	82%	95%	100%
	Replacement Sound Processor	45%	81%	93%	98%
Bone conduction systems	Implant	45%	83%	95%	100%
	Initial Sound Processor	45%	83%	95%	100%
	Replacement Sound Processor	45%	83%	93%	98%

[†]Hospital treatment policy categorisation conducted by Cochlear Limited.

Constraining expenditure on clinically efficacious and cost effective Implantable hearing solutions will have little impact on reducing PHI expenditure on prostheses.

We understand subcategorising the ENT category into three clinical definitions is based on an actuarial approach aimed at classifying treatments into the four product tiers. However this approach does not adequately reflect the value of timely intervention to address hearing loss and the downstream savings resulting from the improved health and wellbeing of individuals whose hearing loss is well managed. It also doesn't consider the appropriate balance of procedures to be conducted in the public and private sectors of Australia's health care system.

The ENT category represents just 1% of the total benefits paid for prostheses by Private Health Insurance⁴. The prosthetic group for which the greatest amount of benefits paid was “cardiac”, comprising 17.1% (Refer Figure 1). The average cost of prostheses in private hospitals and day hospitals for the same period were \$608/ procedure for ENT and \$5,258/ procedure for Cardiac⁵. Constraining access to the ENT category of procedures, including the “Implanted devices for hearing loss surgery” will have little impact on improving the affordability and sustainability of PHI.

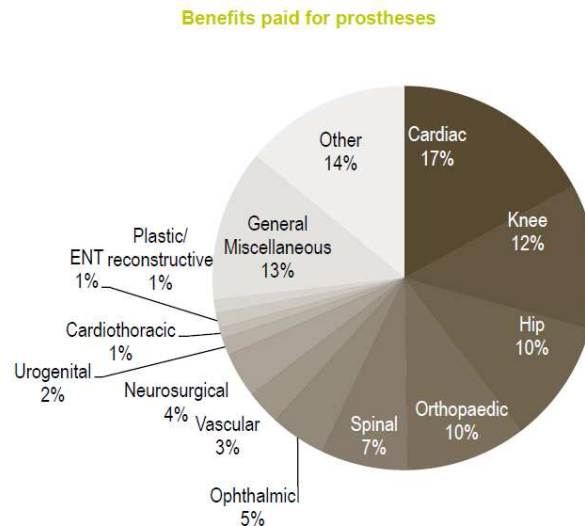


Figure 1. Benefits Paid by Private Health Insurance for Prostheses.

Cochlear maintains a portfolio of implantable hearing systems on the Department of Health's Prostheses List for use in the Private sector and offers these same products through the Public sector. The percentage of cochlear implant surgeries performed in the private sector is 55%^{6,7}, well below the two-thirds of non-emergency surgery in Australia⁸. This is a healthy balance between private and public sector funding and significantly less than other treatment categories that have a suggested minimum coverage of Gold Tier products. For example,

- 86% of retinal procedures, 82% of other shoulder procedures,
- 72% of knee reconstructions,
- 70% of lens procedures
- 66% of glaucoma and complex cataract procedures and
- 65% of knee replacements⁸.

Although the cost of implantable hearing system prostheses is one of the high cost per unit devices on the Prostheses List, the annual utilisation rates are relatively low, and the requirement for repeat surgery is also low^{9,28}. In contrast, it is not uncommon for patients in the *Heart and heart-related conditions and services* clinical definition to require replacement of their implant i.e. pacemaker or defibrillator and/or ongoing cardiac related surgery. This is not generally the case for patients receiving implantable hearing systems, however they will need to replace the external part of the device - the sound processor. Funding sources for these replacement sound processors, include Government (48%), Private Health Insurance (33%) and Self-funding (22%). This balance is not heavily weighted towards PHI.

Furthermore, given the hospital banding of the relevant procedures, it appears to further complicate private health insurance products by subcategorising the ENT product category, which is contrary to the principle of simplification.

On this basis:

- it appears inconsistent to limit coverage of procedures included in the Clinical Definition *Implanted devices for hearing loss surgery* beyond that of the *Heart and heart-related conditions and services* clinical definition
- it raises question to the appropriateness of subcategorising the ENT therapeutic group.

Table 3. Benefit and utilisation rates of high cost prostheses in ENT, Cardiac and Cardiothoracic product categories

Product Category	Prostheses	Listed Benefit ^a	MBS Item	Volume ^b	Band ^c
02 – Ear Nose and Throat	Cochlear implants	\$13,027	41617	846	8 – Advanced Surgical
02 – Ear Nose and Throat	Speech processors - initial	\$11,040 - \$12,432	11300 82300	846 (assume 1:1 with 41617)	1A - Medical
02 – Ear Nose and Throat	Osseointegrated Fixtures & Abutments		41603 41604	278 210	4 – Surgical 2 - Medical
02 – Ear Nose and Throat	Speech Processors – bone conduction	\$6,552	11300 82300	278 Assume 1:1 with 41603	1A - Medical
08 - Cardiac	Cardiac Resynchronisation Therapy Cardioverter Defibrillator	\$39,879	38365, 38368 38654	533, 1335 50	6 Surgical 6 Advanced Surgical 7 Advanced Surgical
09 - Cardiothoracic	Ventricular Assist System	\$96,000	38615	13	10- Advanced Surgical
	Aortic Valve	\$5,760	38488	2669	12-Advanced Surgical

- February 2018 issue of the department of Health's Prostheses List
- Medicare Australia Statistics, Medicare item reports, July 2016 – June 2017
- National Procedure Banding Committee schedule available from DVA September 2017

The proposed minimum coverage of hearing loss surgery in the Gold Tier PHI products, will have a significant impact on timely access to clinically efficacious and cost effective interventions for those suffering a significant disabling hearing loss.

As illustrated in Table 3 above, under the current arrangements approximately 1,100 patients per year receive an implantable hearing system covered by private health insurance. Figure 3 below, presents the profile of patients receiving cochlear implants in the private sector, under MBS item number 41617. 60% of these people are aged 55-84 years at the time of surgery¹⁰.

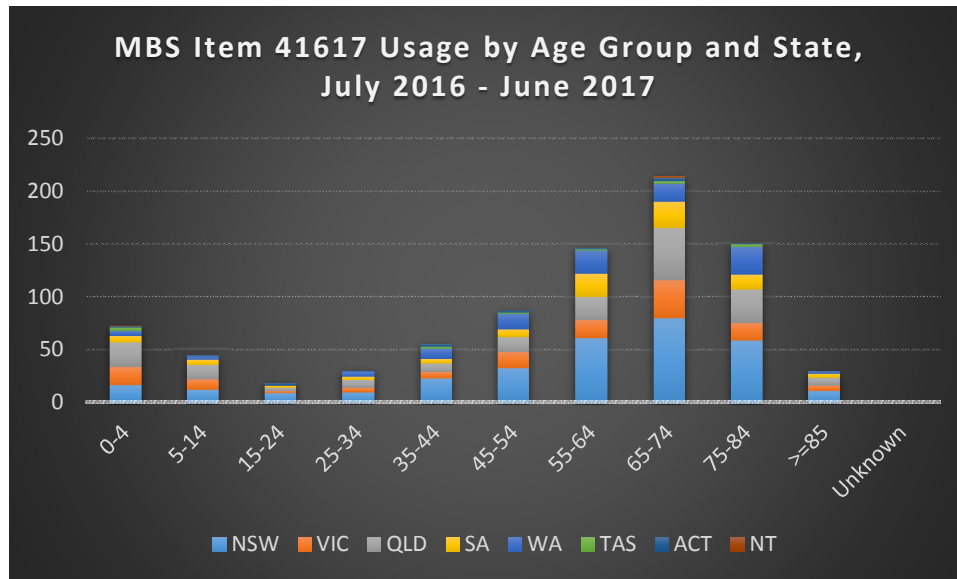


Figure 3. Profile of patients receiving cochlear implants in the private sector in FY 17.

Feedback from implant programs indicate that a significant number of their patients may not have top tier cover and may not be able to afford top tier products. A survey of a sample population of adults using cochlear implant systems indicates that approximately 60% of survey respondents do not hold a top tier hospital treatment product, 42% of respondents have held their current private health insurance policy for more than 20 years, and only 17.5% would be in a position to upgrade their policy to top tier³⁰.

This is consistent with:

- i) the literature that reports higher rates of hearing loss are reported among the more disadvantaged socioeconomic groups¹¹; hearing loss in adults is linked to higher rates of unemployment^{12,13}, and high socio economic disadvantage^{1b} having the lowest levels of PHI¹⁴.
- ii) the National Health Survey Data 2014-2015 reports that there were lower rates of private health insurance ownership for people who were unemployed (32.2%) people born in Oceania (other than Australia) (42%), or in North Africa and the Middle-East (41.9%), and for those with a profound or severe core activity limitation (40.4%). People living in areas with relatively high levels of socio-economic disadvantage had the lowest levels of private health insurance in Australia (33.6%), while people living in areas of low disadvantage had the highest levels (79.4%)¹⁴.

Should minimum coverage of implantable hearing systems be limited to Gold Tier products only, such change is likely to further erode the value proposition of PHI for these socioeconomically constrained patients and force them into the public sector. This will place additional burden on limited State Government Implantable Hearing System/ Cochlear Implant budget allocations and increase waiting lists. Delays in access to intervention will negatively impact the health and productivity of Australians suffering a treatable, disabling hearing loss.

Delays in access to timely intervention for permanent disabling hearing loss has an avoidable, negative impact on the health, quality of life of and productivity of the individual, their family, friends and society.

For children who are born with or acquire a permanent hearing loss in the first few years of life speech, language and cognitive development are substantially impaired without early auditory stimulus. This impacts directly on the child's literacy, learning, social and emotional development, educational attainment and future employment¹⁵.

The Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study being conducted in Australia clearly shows that the age at which a child with a bilateral permanent childhood hearing loss receives their cochlear implant (down to 6 months of age) results in significantly better language outcomes at 5 years of age¹⁶ (Refer Figure 4).

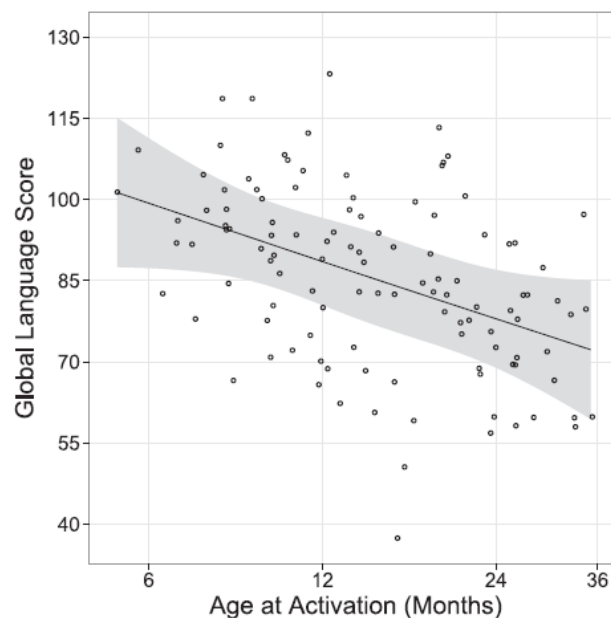


Figure 4. Adjusted global language scores by age at CI activation (log transformed). The regression line shows predicted mean score, and the shaded band depicts the 95% CI.

The results of an Australian-first study into the education, employment and social outcomes of hearing impaired children who receive early intervention therapy, including the use of hearing aids, cochlear implants other devices shows that:

- 95% of deaf children who received early intervention attended mainstream high schools
- 86% completed Year 12 (secondary education in Australia)
- 82% of these children were accepted into higher education and training courses after school
- 62% had completed university degrees (compared with 43.3% of the general population)
- 77% had been in regular employment for at least six months between the ages of 18-28 years¹⁷.

In light of these outcomes and Australia's reputation as the global leader in addressing hearing loss in children, it is unacceptable that children requiring hearing implants do not receive them at the clinically appropriate time whether that be in the public or the private sector. Unnecessary constraints

placed on access to timely intervention must be avoided, whether that be by waiting periods for claiming under higher level hospital product policies or waiting lists in the public sector.

Adults who suffer from a progressive or a sudden onset hearing loss also need timely access to intervention. Extended periods of hearing loss and the resulting impaired communication affects the health condition of adults. The emotional distress and social restrictions caused by hearing loss in adults give rise to depression, social introversion, suspiciousness, social anxiety and loneliness. Hearing loss is associated with diabetes, heart disease, stroke, psychiatric illness¹⁸, cognitive decline^{19,20} and falls in the elderly²¹. There are also significant productivity losses for the individual, their informal carer network, employer, and society at large¹.

Similar to children, the earlier the age at which an adult receives their cochlear implant, the better their rate of improvement in speech understanding²² (Refer Figure 5), maximising their quality of life benefit²³ (Refer Figure 6) and the higher the probability of modifying a significant risk factor for dementia²⁴ (Refer Figure 7). This is particularly relevant for Australia given our ageing population and the increasing prevalence of dementia and the costs associated.

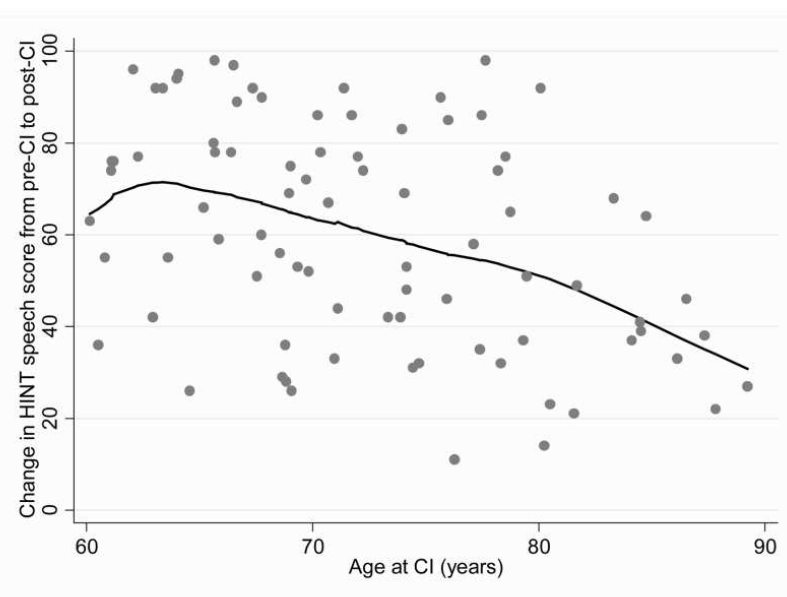
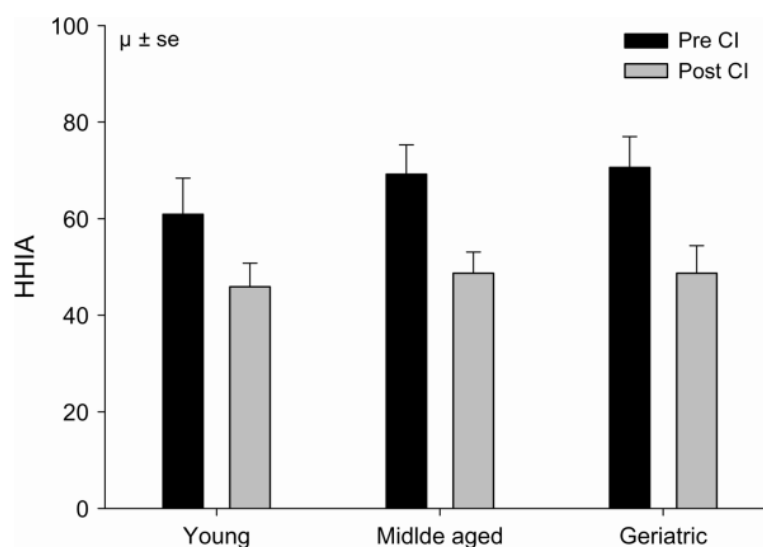


Figure 5. Change in HINT speech scores from Pre-CI to 1 year post CI by age at cochlear implantation²².



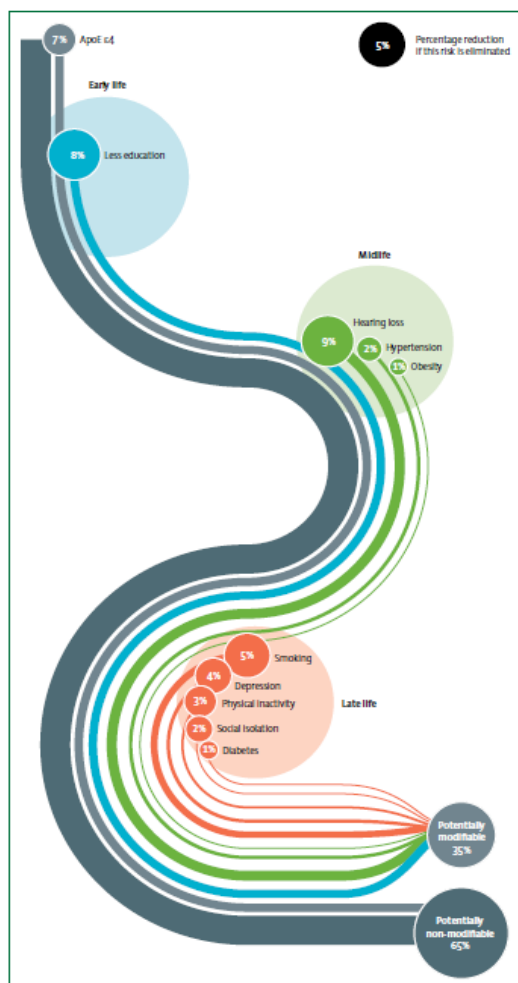


Figure 6. Quality-of-life benefit from cochlear implantation in young adults (≤ 55 years); Middle aged (56-69 years) and Geriatric (≥ 70 years)²³.

There is now a very clear association of severe hearing loss and cognitive decline with dementia. Dementia prevalence would be halved if its onset were delayed by 5 years²⁴.

Hearing loss is the largest modifiable mid-life risk factor for dementia which calls for ambitious preventive measures to be taken. As illustrated in Figure 7, hearing loss represents 9% of all modifiable risk factors for dementia and 70% of mid-life risk factors. A modifiable risk factor means that people have the ability to change their risk of developing dementia with things they do every day. This includes early identification and treatment of hearing difficulties²⁵.

Maintaining timely access to necessary *Implanted devices for hearing loss surgery* for adults aged 50-70 years (mid-life), should be emphasised. As Figure 2 illustrates, this age group represents a significant percentage of Australians current receiving cochlear implantation. The proposed constraints that would result from a minimum coverage of *Implanted devices for hearing loss surgery* under Gold Tier products is contrary to this evidence and these policy

recommendations²⁴.

Figure 7. Life-course model of contribution of modifiable risk factors to dementia
Figure shows potentially modifiable or non-modifiable risk factors²⁴.

Patients requiring multiple procedures who do not hold Gold tier hospital treatment products may now be subject to multiple surgical episodes separated in time, or be at risk of not having their hearing loss treated.

There are a number of reasons why it may be clinically appropriate for a patient to have multiple procedures, spanning procedures now classified under different clinical definitions, in the one surgical episode. Examples of such cases are presented below and include:

- Tympanoplasty, from *Ear, nose and throat conditions and services*, and the placement of a cochlear implant, *Implanted devices for hearing loss surgery*.
- Removal of acoustic neuroma, *Ear, nose and throat conditions and services*, and the placement of cochlear implant, or fixture for the bone conduction hearing system, *Implanted devices for hearing loss surgery*

- Cholesteatoma, from *Ear, nose and throat conditions and services*, and the placement of a middle ear hearing system, *Implanted devices for hearing loss surgery*.

Should the portfolio of ENT category of procedures be subcategorised, across different clinical definitions, that have different minimum coverage criteria, clinically appropriate and cost effective episodes of care will be disrupted. Those privately insured patients, without a Gold Tier policy will not be able to have their hearing loss treated. There options may be to:

- upgrade their hospital treatment cover and wait 12 months
- be referred to the public health sector and join the waiting list for their hearing implant surgery
- forgo the opportunity to have their hearing loss addressed.

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8. Appendix

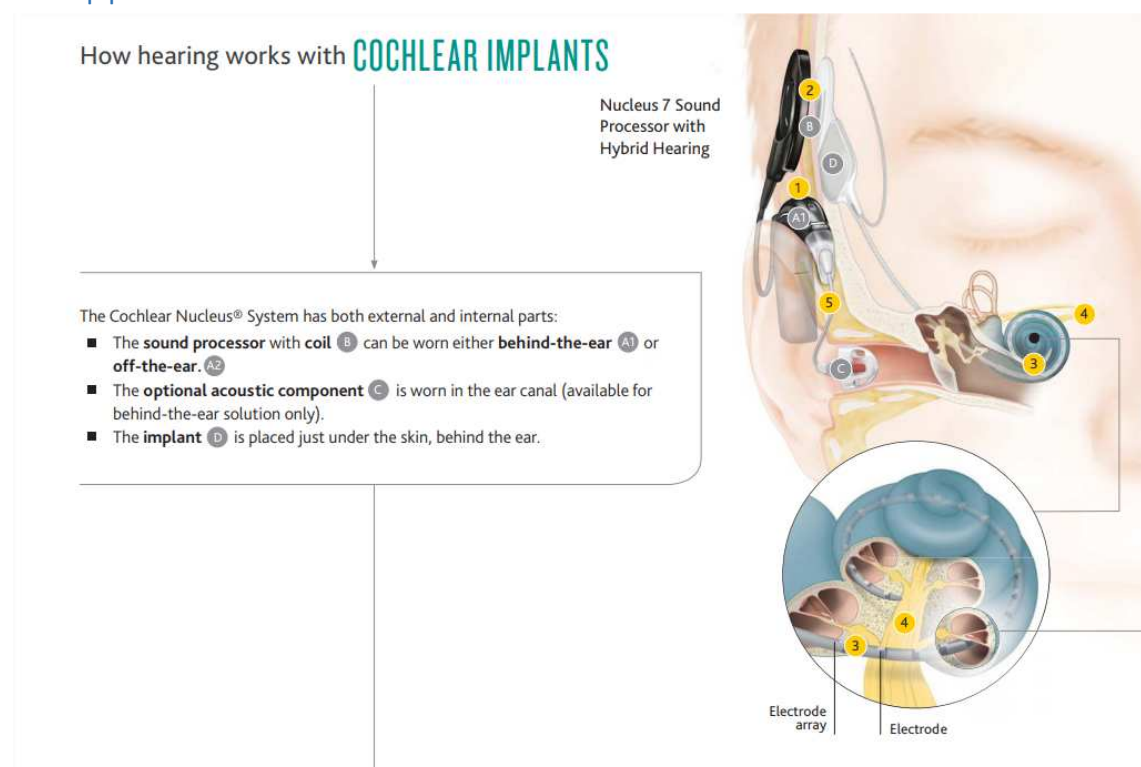


Figure 8. How a Nucleus® Cochlear Implant System works.

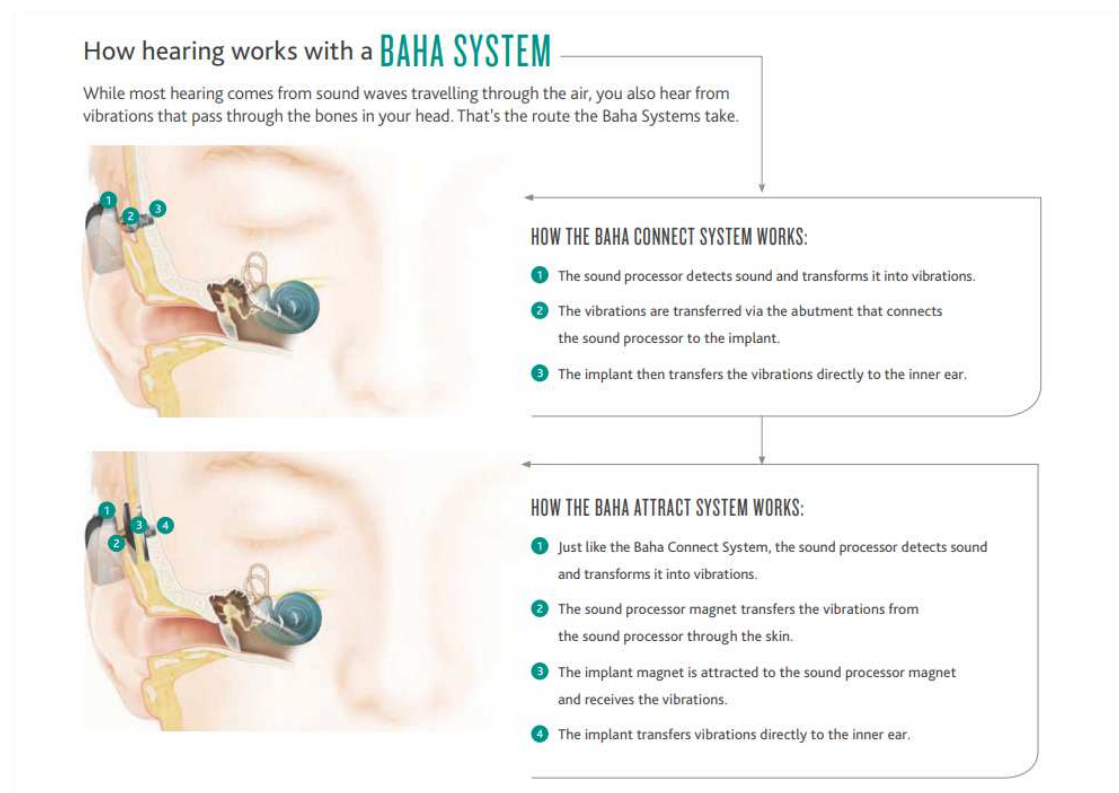


Figure 9. How a Baha® implantable bone conduction hearing system works.