MSAC Application 1803

Implantation of an active middle ear implant (vibroplasty) for treatment of mixed and conductive hearing loss

Applicant: MED-EL Implant Systems Australasia Pty Ltd

PICO Confirmation

Summary of PICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for implantation of an active middle ear implant in individuals with mixed or conductive hearing loss

Component	Description
Population	Individuals aged >5 years with mild to severe mixed hearing loss (MHL) or conductive hearing loss (CHL), who are not appropriate candidates for, or have not achieved adequate benefit from, surgical repair or reconstruction of the middle ear, and are unable to use a conventional (non-implantable) hearing device (non-implantable bone conduction hearing device or air conduction hearing device) due to medical or audiological reasons, and are not suitable candidates for a cochlear implant. **Subgroups (if evidence allows):** • Type of hearing loss – mixed or conductive; mild, moderate or severe, unilateral or bilateral • Age – children >5 years, adolescents, adults, older adults (e.g. aged >70 years)
Intervention	Implantation of an active middle ear implant (AMEI), unilateral or bilateral
Comparator/s	Implantation of an active bone conduction implant (BCI) in individuals who are suitable for a BCI. No further intervention (i.e. untreated hearing loss) in individuals who are contraindicated for, or unsuitable for, a BCI.

Outcomes	**Safety:**
	• intraoperative and postoperative complications
	• device-related adverse events (AEs) (e.g. extrusion, malfunction, processor issues, infection)
	• revisions or device explants, reimplantation
	• long-term implant durability (≥5 years)
	
	Effectiveness:
	• audiological outcomes
	  ○ effective gain
	  ○ functional gain
	  ○ speech recognition scores (e.g. Word Recognition Score [WRS], Speech in Noise [SIN] test)
	  ○ speech reception threshold in noise (e.g. SRT 50 test)
	  ○ sound localisation tests
	• patient-specific outcomes
	  ○ hearing-specific quality of life (e.g. Abbreviated Profile of Hearing Aid Benefit [APHAB]; Speech, Spatial and Qualities of Hearing Scale [SSQ])

Component	Description
	○ health-related quality of life (e.g. Health Utility Index Mark 3 [HUI3]; EuroQol 5-dimension [EQ-5D]) ○ patient satisfaction **Healthcare resources:** • device costs (internal and external components) • procedure duration and costs • maintenance/replacement costs (internal and external components) • costs associated with changes in clinical management (testing required before the procedure; follow up specialist or audiology visits) • costs associated with management of AEs, including reoperation **Cost-effectiveness:** • cost per quality-adjusted life year (QALY) gained • cost per unit/point improvement (based on audiological or patient-reported outcome thresholds) – only if utilities/QALYs are not well established in the proposed population **Total Australian government healthcare costs:** • total cost to the Medical Benefits Schedule (MBS) • total cost to other government health budgets (including the Australian Government Hearing Services Program) • total cost to the Prescribed List of Medical Devices and Human Tissue Products (PL)
Assessment question(s)	What is the safety, effectiveness and cost-effectiveness of implantation of an AMEI versus implantation of a BCI or no further intervention in individuals aged >5 years with mild to severe MHL or CHL who are not appropriate candidates for, or have not achieved adequate benefit from, surgical repair or reconstruction, and are unable to use a conventional (non-implantable) hearing device (non-implantable bone conduction hearing device or air conduction hearing device) due to medical or audiological reasons, and are not suitable candidates for a cochlear implant?

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of implantation of an active middle ear implant (AMEI) via vibroplasty for the treatment of mixed and conductive hearing loss (MHL and CHL) was received from MED-EL Implant Systems Australasia Pty Ltd by the Department of Health, Disability and Ageing. MED-EL is the manufacturer and sponsor of the Vibrant Soundbridge Active Middle Ear Implant System.

The clinical claim made in the application was that implantation of an AMEI in individuals with mild to moderate MHL or CHL results in superior health outcomes (in terms of audiological rehabilitation and sound localisation) and non-inferior safety compared to the main comparator, implantation of a bone conduction implant (BCI).[1]

The application provided no explanation for restricting use of AMEI to individuals with mild to moderate hearing loss. AMEIs can also be used in individuals with severe MHL and CHL if specific clinical criteria are met (e.g. the cochlea is functional; the middle ear allows for stable transducer placement; bone conduction thresholds and any sensorineural component is within the device fitting range).

Implantation of a middle ear implant (MEI) has been considered by the Medical Services Advisory Committee (MSAC) on 3 previous occasions (Table 2). The PICO elements of each of the previous applications are summarised in Appendix A.

Table 2 Prior MSAC applications for implantation of active middle ear implants

Application No.	Title of application	Meeting date	Outcome
1137	Middle ear implant for sensorineural, conductive and mixed hearing losses	**MSAC:** 29-30 July 2010	Not supported
1365	Active middle ear implants for sensorineural hearing loss	**PASC:** 16-17 April 2014 **ESC:** 12-13 February 2015 **MSAC:** 1-2 April 2015	Not supported
1364	Active middle ear implants for mixed and conductive hearing loss	**PASC:** 11-12 December 2014; 16 April 2015 (withdrawn prior)	N/A – withdrawn
1365.1	Active middle ear implants for sensorineural hearing loss (re-application)	**ESC:** 10-11 February 2016 **MSAC:** 30-31 March 2016	Supported

ESC = Evaluation Subcommittee; MSAC = Medical Services Advisory Committee; N/A = not applicable; PASC = PICO Advisory Subcommittee.
Source: MSAC website, Department of Health, Disability and Ageing.

Application 1137: MSAC (July 2010) considered the implantation of an MEI for the treatment of adults with mild to severe sensorineural hearing loss (SNHL), CHL and MHL and who had failed a trial of external hearing aids for at least 3 months. MSAC did not support the proposed listing on the basis of: (i) an inability to identify particular subgroups of patients for whom listing could be justified in terms of comparative cost-effectiveness, (ii) uncertainty around long-term safety, and (iii) the availability of bone-anchored hearing aids and cochlear implants as alternatives for all MEI indications.

Application 1364: PASC (December 2014, April 2015) considered the implantation of an AMEI for the treatment of mild to moderate MHL and CHL in individuals who were unable to wear conventional hearing

[1] The safety claim was confirmed at the pre-PASC meeting held on 24 June 2025.

aids due to anatomical or medical reasons, and unsuited to, or had not received benefit from, middle ear surgery or reconstruction (i.e. similar indication to the current application). The application was withdrawn prior to MSAC consideration.

MSAC 1365: MSAC (April 2015) considered the implantation of an AMEI for individuals with stable, bilateral, mild to severe SNHL. MSAC noted considerable unmet clinical need for the device in the proposed population but did not support public funding due to substantially uncertain cost-effectiveness.

Application 1365.1: MSAC (March 2016) reconsidered the application for implantation of an AMEI for individuals with stable, bilateral, mild to severe SNHL. MSAC was satisfied that the device was likely to be cost-effective in the proposed population and the financial implications of including AMEI on the MBS would be reasonable. MSAC supported public funding; the MBS item for MEI implantation in patients with SNHL (MBS item 41618, start date 1 May 2017) is shown in Appendix B, Box 3.

PICO criteria

Population

The applicant's original proposed population was individuals aged 5 years or older with persistent (chronic, non-resolving), mild to moderate MHL or CHL who are not appropriate candidates for, or have not achieved adequate benefit from, surgical repair or reconstruction of the middle ear, and are unable to use a conventional (non-implantable) hearing device due to medical or audiological reasons.

This population comprises children aged 5 years and older, adolescents and adults with persistent MHL (with both conductive and sensorineural components) or persistent CHL, for whom first line rehabilitative approaches (surgery and/or conventional non-implantable hearing devices)[2] are not feasible or effective due to anatomical, clinical or medical reasons. Current standard of care for these individuals are implantable solutions, namely bone-conducting implants (BCIs) or no further intervention for individuals who are contraindicated for, or unsuitable for, a BCI. Some can still benefit from sound amplification; however, their degree of hearing loss does not meet the severe/profound threshold requirement for cochlear implantation.

Note that the target population does not include individuals who have not achieved adequate benefit from a BCI. Use of the intervention in this group is not addressed in clinical practice guidelines, is not supported by the available clinical evidence, and is not established as standard clinical care (for example, Ontario Health Quality 2020; Souza et al. 2022; Vickers et al. 2023; Bruschini et al. 2024).

PASC considered whether the proposed population should be broadened from individuals with mild to moderate MHL/CHL (as proposed in the application) to include individuals with severe MHL/CHL. PASC noted that the Australian Register of Therapeutic Goods (ARTG) entry for the Vibrant Soundbridge System states that the system is indicated for use in patients with mild to severe hearing impairment who cannot achieve success or adequate benefit from traditional therapies. PASC noted that individuals with severe

[2] At the pre-PASC meeting held on 24 June 2025, the applicant clarified that the term 'bone conduction device' was intended to encompass devices that did not require surgical implantation (e.g. headband/softband or adhesive), not bone conduction implants.

MHL who are not suitable candidates for a cochlear implant represent a high-needs group with limited available treatment options.

PASC noted that the clinical evidence stratified by hearing loss severity may be limited, making it challenging to assess outcomes by hearing loss severity subgroups. However, PASC considered that there was no clinical reason to exclude the severe hearing loss subgroup and advised that the proposed eligible population should include individuals with mild to severe MHL or CHL. PASC noted that the applicant supported the inclusion of the population with severe MHL/CHL.

PASC noted the applicant proposed that the eligible population should be aged >5 years. PASC considered the potential need for an upper age limit restriction. PASC noted the apparent lack of published data on the performance of implants in older individuals yet considered that implantation procedures would entail inherent surgical risks in general, particularly in elderly patients with multiple comorbidities. PASC noted that this cohort might have a reduced capacity to both achieve the full functional benefit of, and effectively manage, an implantable hearing device. PASC noted that the applicant's clinical expert advised that, owing to their broader fitting range, AMEIs may provide greater adaptability, thereby sustaining clinical benefit in patients who subsequently develop age-related progressive sensorineural hearing loss (presbycusis). Accordingly, PASC advised that the assessment should critically evaluate the available evidence on the safety and clinical effectiveness of AMEIs in older patient cohorts, including longitudinal outcomes for the device and patients as age advances. PASC noted that the evidence might include non-randomised (comparative) studies if comparative randomised trials are not available.

In Australia, hearing loss is classified according to the average hearing threshold level, measured in decibels hearing level (dB HL), as determined by pure tone audiometry. This assessment involves the presentation of pure tones via air conduction (using headphones or insert earphones) and bone conduction (using a bone oscillator placed behind the ear) to each ear independently. Air conduction testing evaluates the entire auditory pathway, including the outer, middle, and inner ear, while bone conduction testing bypasses the outer and middle ear to assess the function of the inner ear and auditory nerve directly. Comparison of air and bone conduction thresholds enables differentiation between CHL, SNHL, and MHL.

Pure tone audiometry provides a quantitative assessment of hearing loss type and severity, which is essential for diagnosis, clinical decision making, and determining eligibility for hearing devices or surgical interventions.

Classification of hearing loss severity applies consistently across all types of hearing loss, including CHL and MHL, and across all age groups.

- **Mild hearing loss** is defined as a pure tone average (PTA) between 21 and 40 dB HL. Individuals may have difficulty hearing soft speech or following conversation in noisy environments.
- **Moderate hearing loss** is defined as a PTA between 41 and 70 dB HL. Individuals typically have difficulty understanding conversational speech without amplification, even in quiet settings.
- **Severe hearing loss** is defined as a PTA between 71 and 90 dB HL. Individuals generally have significant difficulty hearing and understanding speech, even with amplification, and may rely on visual cues such as lip reading to support communication.

- **Profound hearing loss** is defined as a PTA greater than 90 dB HL. Individuals are unlikely to perceive speech, even with amplification, and typically require alternative communication strategies such as lip reading, sign language, or cochlear implantation.[3]

In Australia, hearing loss is commonly assessed using the three-frequency average hearing loss (3FAHL) calculated as the average hearing threshold at 0.5, 1, and 2 kilohertz (kHz), measured in dB HL. This method reflects the frequencies most important for understanding speech. At each test frequency, the sound is initially presented at a low intensity (decibel level) and gradually increased until the individual indicates they can hear it. The lowest intensity at which the tone is consistently detected is recorded as the hearing threshold for that frequency.

For the purposes of determining eligibility for the Australian Government Hearing Services Program (HSP), an individual is considered to have a hearing loss if the 3FAHL in the better hearing ear is equal to or greater than 23.3 dB HL.[4]

The HSP provides subsidised hearing services and devices to eligible individuals through 2 key components:

- Voucher Scheme – Enables access of eligible individuals [5] to contracted HSP providers for one hearing assessment and one device fitting every five years, with additional support for rehabilitation and ongoing maintenance were applicable.
- Community Service Obligations (CSO) – Delivered by Hearing Australia, this component provides services to individuals under 26 years of age, eligible Aboriginal and Torres Strait Islander peoples, and voucher-eligible individuals who live in remote areas or require specialist hearing services.[6]

The HSP funds hearing assessments, rehabilitation services and approved hearing devices, including hearing aids and assistive listening devices, which may be either fully subsidised or partially subsidised, depending on the device. The program reimburses contracted providers for the hearing services and devices they deliver, in accordance with the current Schedule of Service Items and Fees. The CSO component also supports specialist hearing services, including those for individuals using implantable hearing devices, primarily through the provision of external processor upgrades, maintenance, batteries, and repairs.

Causes of mixed and conductive hearing loss

CHL arises from impaired transmission of sound through the outer or middle ear. It is typically identified on audiometry by the presence of an air-bone gap, indicating better bone conduction hearing thresholds relative to air conduction thresholds. MHL refers to the coexistence of both conductive and sensorineural components in the same ear. It is characterised by an air-bone gap (reflecting the conductive component) in combination with elevated bone conduction thresholds (indicating sensorineural impairment).

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[3] Hearing loss thresholds from Aussie Deaf Kids and Next Sense.

[4] Eligibility for the HSP, in terms of hearing loss, is based on the average across the 3 specified frequencies. Individuals are not required to demonstrate hearing loss at all 3 individual frequencies.

[5] Eligibility criteria include being an Australian citizen or permanent resident aged 21 years or over, and meeting at least one of the following: (i) holder or spouse of a pensioner concession card; (ii) Department of Veterans' Affairs Gold or White Card (hearing-specific) holder or spouse; (iii) Australian Defence Force member; or (iv) referred by a Commonwealth-funded Disability Employment Service.

[6] Specialist hearing services includes individuals with a 3FAHL of ≥80 dB in both ears, or hearing loss and severe communication impairment (including those with an implanted hearing device who are unable to wear an air conduction hearing aid).

MHL or CHL can result from a range of medical conditions that impair the transmission of sound through the external or middle ear (Table 3). These conditions may be congenital, acquired, or progressive and can affect individuals across the lifespan.

Table 3 Causes of persistent mixed or conductive hearing loss

Cause	Description	Site affected	Additional information
Chronic otitis media	Long-standing inflammation or infection of the middle ear, often with persistent fluid or discharge	Middle ear	May result from repeated acute infections or Eustachian tube dysfunction; can cause perforation of the eardrum and ossicle damage, leading to persistent CHL. MHL may occur if inner ear is damaged.
Otosclerosis	Abnormal bone growth around the stapes bone, causing its fixation and impaired sound transmission	Middle ear	Progressive, often hereditary; usually presents in young adults; may cause MHL if cochlea is affected.
Cholesteatoma	Abnormal skin growth in the middle ear that can erode bones and disrupt hearing mechanisms	Middle ear	Can develop as a complication of chronic ear infections; may cause persistent discharge, HL, and risk of infection spread.
Ossicular chain discontinuity	Disruption or fixation of the tiny bones (ossicles) in the middle ear	Middle ear	May result from chronic infection, trauma, or surgery; leads to persistent CHL.
Tympanosclerosis	Scarring or thickening of the eardrum or middle ear tissues	Middle ear	Often a sequela of chronic infections or repeated ear surgeries; reduces eardrum mobility and sound conduction, resulting in CHL.
Congenital ear malformations	Structural abnormalities present from birth (e.g. atresia, microtia)	Outer/middle ear	May involve absence or narrowing of ear canal, malformed ossicles, or abnormal middle ear spaces; often requires surgical intervention. May result in CHL or MHL (depending on the extent of inner ear involvement).
Tumours (benign or malignant)	Growths in the outer or middle ear that persistently block or damage hearing structures	Outer/middle ear	Includes glomus tumours, exostoses, and other neoplasms; may require surgical removal. Typically cause CHL, but MHL may occur if there is inner ear involvement or associated damage.
Previous ear surgeries	Surgeries that alter ear anatomy or function, sometimes resulting in lasting HL	Outer/middle ear	Procedures like tympanoplasty, mastoidectomy, or ossicular reconstruction may result in persistent CHL if unsuccessful.
Mixed: Age-related HL + conductive cause	SNHL from aging combined with a persistent conductive issue	Inner + outer/ middle	Common in older adults; persistent conductive pathology (e.g. chronic otitis media) adds to underlying sensorineural deficit.

CHL = conductive hearing loss; HL = hearing loss; MHL = mixed hearing loss; SNHL = sensorineural hearing loss.

Treatment options for mixed and conductive hearing loss

The initial assessment of patients presenting with hearing loss comprises a comprehensive clinical history, otoscopic examination, and formal audiological testing, including pure tone audiometry and tympanometry, to confirm the diagnosis and characterise the severity and nature of hearing loss.

Where a reversible or treatable cause is identified – such as impacted cerumen, otitis media, tympanic membrane perforation, or ossicular chain disruption – patients are managed with appropriate medical or surgical interventions. These may include microsuction, pharmacological therapy, or surgical procedures such as tympanoplasty or ossiculoplasty, with the aim of restoring normal middle ear function and resolving the conductive component of the hearing loss.

For patients whose hearing loss persists following optimal medical and/or surgical management, the standard of care is the provision of conventional air conduction hearing aids (e.g. behind-the-ear or in-the-ear devices). These devices are widely accessible and are considered first line management for mild to moderate MHL and CHL, provided the patient has suitable ear canal and middle ear anatomy and can tolerate and benefit from amplification.

In patients for whom conventional air conduction hearing aids are contraindicated, not tolerated, or provide insufficient benefit – such as those with ear canal eczema, chronic otitis externa or media, congenital aural atresia, or persistent conductive pathology – non-implantable bone conduction devices (i.e. headband/softband options such as the Cochlear Baha Softband and Oticon Ponto Softband, or adhesive options such as the MED-EL ADHEAR) may be trialled as an interim (or in some cases long-term) solution (Koro et al. 2025). Where these are unsuitable or inadequate, implantable hearing solutions may be considered, including BCIs or AMEIs, or cochlear implants if sensorineural hearing loss is severe or profound.

Table 4 summarises treatment options for individuals with persistent MHL or CHL.

Table 4 Treatment options for persistent mixed or conductive hearing loss in adults and children

Treatment modality	Description	Typical use in adults	Typical use in children	Limitations/ contraindications
Middle ear reconstructive surgery	Includes tympanoplasty, ossiculoplasty, or stapedectomy to repair or reconstruct ossicular chain	Often appropriate for acquired ossicular disease, tympanic membrane perforation, or otosclerosis	Performed for congenital or acquired anomalies, often deferred until older age depending on anatomy	Not always successful; risk of recurrence; some cases require multiple surgeries or are not surgically correctable
Passive middle ear implants	Ossicular prostheses (e.g. PORP/TORP) inserted during surgery to replace damaged ossicles	Used when ossicular continuity cannot be restored directly	Used selectively in cases of congenital ossicular abnormalities or sequelae of chronic otitis	Requires middle ear surgery; at risk of extrusion or failure, especially in ongoing middle ear disease
Conventional air conduction hearing aids	External hearing devices worn in or behind the ear to amplify sound and deliver it via the ear canal	Widely used for CHL/MHL with normal ear canal and stable middle ear condition	Common first line treatment; may be challenging in cases with otorrhoea or small ear canals	Ineffective with chronic otorrhoea, canal atresia, stenosis, or intolerance; can be dislodged or rejected in younger children; cosmetic concerns
Bone conduction hearing devices (implantable and non-implantable)	Transmit vibrations through skull bone directly to cochlea; percutaneous or transcutaneous types	Used for anatomical ear canal abnormalities or intolerance to air conduction aids	Often used in microtia, canal atresia, or chronic otorrhoea; commonly trialled with headband/ softband first	Cosmetic concerns (non-implantable devices and those with an abutment); may cause soft tissue issues; lower tolerability in some children
Active middle ear implants (AMEI)	Delivers mechanical stimulation to middle or inner ear	Appropriate when conventional aids or surgery are not effective or tolerated	Used in select older children (>5 years) with stable anatomy and HL not manageable by other means	Not appropriate for very young children or unstable middle ear pathology

Treatment modality	Description	Typical use in adults	Typical use in children	Limitations/ contraindications
Cochlear implants	Electrodes placed in cochlea to directly stimulate auditory nerve for severe SNHL	Rarely used for mild to moderate MHL/CHL unless progressive or associated with poor speech understanding	Reserved for severe/ profound SNHL or progressive mixed losses	Not indicated unless HL progresses to cochlear level; requires lifelong follow-up and mapping

CHL = conductive hearing loss; HL = hearing loss; MHL = mixed hearing loss; PORP = partial ossicular replacement prosthesis; SNHL = sensorineural hearing loss; TORP = total ossicular replacement prosthesis.

Refer to the 'Clinical management algorithms' section for a description of the clinical management of individuals with MHL/CHL and determination of suitability for an implantable hearing device.

Intervention

The proposed intervention is the implantation of an AMEI, either unilateral or bilateral. AMEIs provide direct mechanical stimulation to middle or inner ear structures, bypassing the external auditory canal and tympanic membrane to restore auditory perception.

Device design and function

Partially implantable AMEI systems, such as the Vibrant Soundbridge, comprise both external and internal components that work together to capture, process, and transmit sound.

The external component is an audio processor worn behind the ear. It houses microphones that detect environmental sounds, a digital signal processor that shapes and amplifies sound, and a transmitter coil that sends the processed signal across the skin via radiofrequency (RF) transmission. The external unit also powers the internal device and may include connectivity features such as Bluetooth and telecoil compatibility for integration with compatible audio or assistive listening systems. The audio processor is secured over the implant using magnetic attraction, with the magnet strength adjustable to ensure a comfortable and stable fit.

The internal component is surgically implanted in the temporal bone and consists of a receiver-stimulator and a vibrating transducer. The receiver-stimulator is placed in a subperiosteal pocket within the mastoid bone and is connected to the transducer by an internal lead. It receives the RF signal from the external processor and converts it into electrical energy, which is used to drive the transducer.

The vibrating transducer, commonly referred to as the floating mass transducer (FMT) in the Vibrant Soundbridge System, transforms electrical signals into mechanical vibrations. This transducer is coupled to a targeted anatomical structure within the middle ear– such as the long process of the incus, the stapes, or the round window membrane – based on individual anatomy and pathology. These vibrations are transmitted to the cochlear fluids, effectively bypassing impaired portions of the auditory system. To ensure device stability and optimal energy transfer, the transducer is secured using soft tissue grafts (e.g. cartilage or fascia) or dedicated couplers.

AMEI are intended to be implanted once per affected ear and to remain in situ for the lifetime of the patient. These devices are designed for long-term use and are hermetically sealed to ensure biocompatibility and durability within the middle ear environment. The external processor may be upgraded over time as new technologies become available.

Careful patient selection, appropriate coupling techniques, and ongoing long-term monitoring are important for optimising outcomes and reducing the likelihood of revision, especially in paediatric patients.

Comparison with other implantable hearing technologies

AMEIs differ from other hearing technologies in both mechanism and patient applicability:

- **Passive MEIs** are entirely mechanical devices used to reconstruct or replace damaged ossicular chain components. They rely on the tympanic membrane and natural sound conduction without electronic processing, and do not amplify sound actively.
- **BCIs** bypass both the outer and middle ear, transmitting vibrations through the skull directly to the cochlea. These systems are appropriate for individuals with chronic ear disease, canal atresia, or other conditions that prevent the use of conventional hearing aids.
- **Fully implantable AMEIs**, such as the Esteem system (not currently approved for use in Australia), contain all components – including the microphone, processor, and battery – entirely within the body. These systems detect ossicular movement via implanted sensors and offer cosmetic advantages by eliminating external hardware. However, they are more surgically invasive, require battery replacement via revision surgery, and are associated with greater device and surgical complexity.
- **Cochlear implants** are electronic devices that bypass damaged cochlear hair cells by directly stimulating the auditory nerve, enabling perception of sound. They are indicated for individuals with severe to profound SNHL, or MHL with a severe to profound sensorineural component, who obtain limited or no functional benefit from conventional amplification.

Each technology addresses different anatomical and clinical needs. Partially implantable AMEI offers a solution for individuals who are unsuitable for traditional amplification and require active mechanical stimulation of the auditory system to achieve functional hearing outcomes.

Patient selection

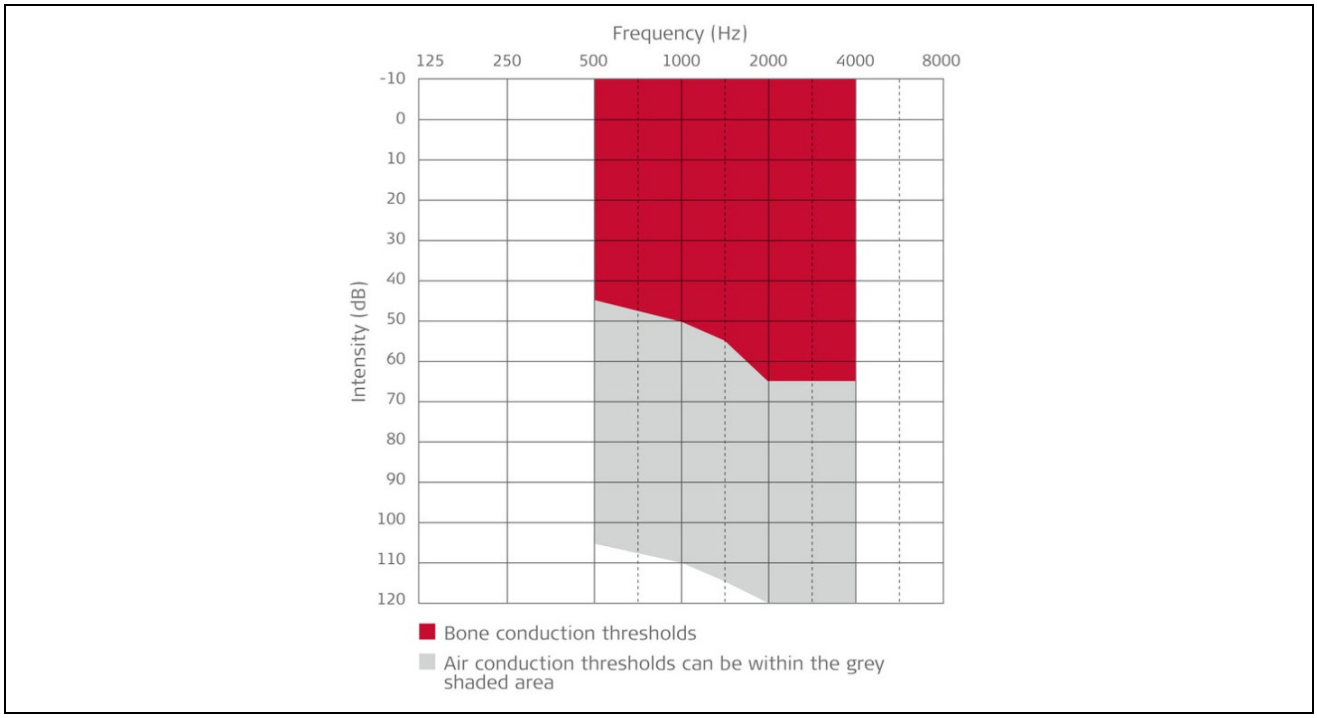
Determining candidacy and the optimal timing for implantation requires input from a multidisciplinary team, who consider the patient's medical history, the planned management of middle ear disease, the severity and type of hearing loss, and the patient's or family's expectations regarding hearing outcomes. In all cases, the underlying pathology causing hearing loss must be managed before an AMEI can be placed.

In individuals with CHL or MHL, the Vibrant Soundbridge System is specifically indicated for those aged 5 years or older with:[7]

- stable bone conduction thresholds that fall within the red shaded area in Figure 1
- absence of active middle ear infections
- ear anatomy that allows the FMT to be positioned on a suitable vibratory structure
- ability to benefit from amplification
- absence of retrocochlear and central auditory disorders (e.g. acoustic neuroma, auditory neuropathy), and
- have adequate motivation and expectations.

[7] MED-EL indications for the Vibrant Soundbridge Active Middle Ear Implant System, accessed 16 June 2025.

Figure 1 Indicated bone conduction (red) and air conduction (grey) thresholds for the Vibrant Soundbridge System in patients with mixed or conductive hearing loss



dB = decibels; Hz = Hertz.
Source: MED-EL indications for the Vibrant Soundbridge Active Middle Ear Implant System, accessed 16 June 2025.

AMEIs are mostly implanted unilaterally in patients with CHL or MHL. Bilateral implantation is relatively uncommon, occurring in less than 10% of cases, but may be suitable for selected patients with bilateral hearing loss who meet the candidacy criteria for both ears (Agterberg et al. 2024; Knölke et al. 2025). Bilateral procedures may be performed either simultaneously or in a staged, sequential manner.

Expected uptake of the technology

The application estimated that over the first 5 years of the proposed MBS listing, 24 to 44 patients would be implanted annually with an AMEI. This estimate was derived from MBS services for BCI implantation and ossicular chain reconstruction, with uptake based on advice from clinical experts and verified against utilisation data from Germany.

Implantation procedure

According to the application, the ear, nose and throat (ENT) surgeon performing the implantation procedure needs to be a qualified medical practitioner and otology specialist. No additional accreditation is required. MED-EL offers specialised training to professionals (audiologists and surgeons), but this is not mandatory.

Implantation of an AMEI is typically undertaken as an inpatient procedure in either public or private hospital settings under general anaesthesia. General anaesthesia is required to ensure complete patient immobility, effective pain management, and optimal surgical access, given the need for precise positioning and secure coupling of the implant to middle ear structures.

In adults, the procedure generally takes approximately 2 hours when performed in patients with MHL or CHL by an experienced surgical team. Operative time is typically longer in paediatric patients (2 to 3 hours),

cases involving congenital anomalies or revision surgery (which could take 2 to 3 hours or more), and during simultaneous bilateral implantation (3 or more hours), due to anatomical factors and increased intraoperative complexity.

The most common surgical approach for AMEI implantation is a mastoidectomy with posterior tympanotomy (facial recess route). This involves a retroauricular incision, followed by a cortical mastoidectomy to expose the facial recess and middle ear space. A subperiosteal pocket is created in the mastoid bone to secure the implant body (receiver-stimulator). The FMT is then positioned and mechanically coupled to an appropriate vibratory structure in the middle ear (e.g. incus, stapes or round window). Stabilisation materials such as cartilage or fascia may be used in some cases to optimise coupling and reduce the risk of transducer migration. Once all internal components are positioned and tested (intraoperatively, if appropriate), the surgical site is closed in layers.

In cases where access via the facial recess is limited or contraindicated, alternative or combined approaches such as an epitympanotomy (also known as atticotomy) may be used to improve visualisation and placement. Selection of the surgical technique is based on patient-specific anatomical and clinical considerations.

PASC noted that optimal sound transmission would depend on accurate positioning and secure fixation (coupling) of the FMT to middle ear structures and queried how surgeon competency would be assured, given that specific training offered by the applicant would not be mandatory.

PASC noted that the applicant's clinical expert advised that case volumes would be low, and that the proposed implantation procedure would be limited to subspecialist otologic surgeons experienced in implantable hearing devices rather than general ENT surgeons. The applicant's clinical expert also advised that the assistance of a multidisciplinary team was important in selecting appropriate patients for surgery and advising on the best coupling method following review of the patient's imaging.

PASC noted that the applicant's expected uptake of 24–44 patients per year was estimated using MBS service data for BCI implantation and ossicular chain reconstruction rather than an epidemiological approach. PASC advised that the assessment report should quantify the degree of overlap between individuals eligible for BCI and AMEI implantation and include consideration of uptake from individuals with severe MHL/CHL.

Postoperative care

Patients are generally discharged on the day of surgery or after an overnight stay, depending on clinical factors and local protocols. Initial postoperative care includes routine wound monitoring and pain control with oral analgesics. Where middle ear pathology or surgical complexity is present, prophylactic antibiotics may be considered.

Activation of the audio processor occurs approximately 4 to 6 weeks post-surgery by an audiologist, once healing is confirmed (refer to the 'Clinical management algorithms' section for a description of follow up after implantation, and to Appendix B for relevant MBS items).

Regulatory status

Currently, the only active middle ear implant system included in the ARTG for use in Australia is the Vibrant Soundbridge Active Middle Ear Implant System (MED-EL Implant Systems Australasia Pty Ltd), which has been registered since 2009.[8]

Table 5 provides a summary of the 3 main components of the Vibrant Soundbridge System.[9]

The indication approved by the Therapeutic Goods Administration (TGA) is broader than the applicant's original proposed MBS population in terms of severity (mild to moderate) and type of hearing loss (any, not specified). The TGA indication restricts use of the Vibrant Soundbridge System to individuals who cannot achieve success or adequate benefit from traditional therapy, though this is not defined.

Table 5 ARTG summary for the 3 components of the Vibrant Soundbridge partially implantable middle ear implant system

Product name	Vibrating Ossicular Prosthesis VORP 503 Implant Kit	Vibroplasty Coupler	Samba 2 Audio Processor
Sponsor	MED-EL Implant Systems Australasia Pty Ltd	MED-EL Implant Systems Australasia Pty Ltd	MED-EL Implant Systems Australasia Pty Ltd
Manufacturer	Med-EL Elektromedizinische Geraete Gesellschaft m.b.H.	Med-EL Elektromedizinische Geraete Gesellschaft m.b.H.	Med-EL Elektromedizinische Geraete Gesellschaft m.b.H.
ARTG ID	389014	185533	353970
ARTG start and effective dates	24 May 2022 24 May 2022	17 June 2011 30 September 2021	1 February 2021 1 February 2021
Product category	Medical Device Class III	Medical Device Class III	Medical Device Class III
GMDN	30084 Partially-implantable middle ear implant system	30084 Partially-implantable middle ear implant system	47369 Partially-implantable middle ear implant system sound processor
Functional description	The VORP 503 is the implanted part of the VSB System, surgically implanted into the temporal bone under the skin. It is designed to be used with a Vibroplasty Coupler, as decided by the surgeon, when attaching the FMT to a vibratory structure of the ear, or alone, when placing the FMT directly at the round window. When activated, the FMT vibrates in a controlled manner causing the structure of the middle ear to vibrate. These vibrations are interpreted by the patient as sound.	The couplers are made of varying grades of titanium and provide placement options for the FMT to functional middle ear vibratory structures - incus; stapes; round window. The different types of couplers account for the anatomic condition variability in compromised ears and provide more options for fixation and adaptation to middle ear characteristics when anatomy does not allow for perpendicular placement.	An external component of the VSB system, the AP is worn behind the ear via opposing magnets in the AP and VORP implant. Powered by a single standard battery, the AP includes 2 microphones to pick up sound from the environment, sound processing circuitry to modify the output signal to customer's specific requirements, and a digital compression processor. Fitting the AP activates the VSB System. Exchangeable components allow the AP to be customized.

[8] A Cochlear Ltd fully implantable middle ear implant system is included in the ARTG (ID 288466) but the entry is Medical Device Class I export only.

[9] The predecessor audio processor (Samba Audio Processor, ARTG ID 271112, ARTG start date 23 February 2016) also remains on the ARTG (accessed 11 June 2025).

Product name	Vibrating Ossicular Prosthesis VORP 503 Implant Kit	Vibroplasty Coupler	Samba 2 Audio Processor
Intended purpose	The VSB VORP 503 Implant Kit contains one implant VORP 503 and other items. The VORP 503 is the implanted part of the VSB System. It is an active implant, which is implanted into the temporal bone under the skin during a surgical procedure. The VORP 503 is designed to be used with one of the Vibroplasty Couplers, as decided by the surgeon, when attaching the FMT to a vibratory structure of the ear, or alone, when placing the FMT directly at the round window. This treatment of hearing loss via vibratory stimulation in the middle ear is called Vibroplasty. The VSB is indicated for use in patients who have mild to severe hearing impairment and cannot achieve success or adequate benefit from traditional therapy.	The Vibroplasty Couplers are intended to be used in combination with the VSB to facilitate the coupling between the FMT and a Vibratory Structure of the middle ear. The prosthesis type is chosen on the basis of the ossicular remnants once all primary disease has been removed from the middle ear.	The SAMBA 2 AP is an external part of the VSB system. The VSB system is indicated for use in patients who have mild to severe hearing impairment and cannot achieve success or adequate benefit from traditional therapy.

AP = audio processor; ARTG = Australian Register of Therapeutic Goods; FMT = floating mass transducer; GMDN = Global Medical Device Nomenclature; ID = identification number; VSB = Vibrant Soundbridge.
Source: ARTG Public Summaries, accessed 11 June 2025.

Current funding of the procedure and device

According to the application, AMEI implantation in individuals with CHL or MHL is occasionally funded via public hospitals or self-funded by patients.

MBS funding of AMEI implantation is currently limited to individuals with SNHL (MBS item 41618). The MBS item descriptor and fee for the implantation procedure, via mastoidectomy, is shown in Appendix B, Box 3. Utilisation of MBS item 41618 is shown in Appendix B, Figure 4.

The Vibrant Soundbridge System is the only partially implantable AMEI listed on the Prescribed List of Medical Devices and Human Tissue Products (PL) and is currently intended for individuals with SNHL who meet the criteria listed in MBS item 41618. Private health insurers may make ex gratia payments to privately insured patients with MHL or CHL seeking assistance with the cost of the device.

The PL billing codes and benefits for the 3 components of the Vibrant Soundbridge System are shown in Table 6.[10] The total PL benefit for the 3 components is $14,986 and for the audio processor alone is $7,166 (effective 01 July 2025). MED-EL typically designs new processors to be backward compatible with older implants, but this is not guaranteed. New audio processor models are generally released every 5–7 years.

There are no explicit conditions in the PL listing that restrict use of the Vibrant Soundbridge system in terms of hearing loss severity or type.

[10] Audio processor (AP) upgrades for the Vibrant Soundbridge System have included the transition from Amadé to Samba to Samba 2. The Samba AP was also listed on the PL at 11 June 2025 (Billing code US020, Benefit $6,825).

Table 6 PL listings for the 3 components of the Vibrant Soundbridge System

Product name	Vibrant Soundbridge System – Vibrating Ossicular Prosthesis VORP503	Vibrant Soundbridge System – Vibroplasty Couplers	SAMBA 2 Audio Processor
Sponsor	MED-EL Implant Systems Australasia Pty Ltd	MED-EL Implant Systems Australasia Pty Ltd	MED-EL Implant Systems Australasia Pty Ltd
Product grouping	02 – Ear, Nose & Throat 02.01 – Ear 02.01.05 – Ossicle/Middle Ear Prosthesis 02.01.05.05 – Active Middle Ear Implants	02 – Ear, Nose & Throat 02.01 – Ear 02.01.05 – Ossicle/Middle Ear Prosthesis 02.01.05.05 – Active Middle Ear Implants	02 – Ear, Nose & Throat 02.01 – Ear 02.01.05 – Ossicle/Middle Ear Prosthesis 02.01.05.05 – Active Middle Ear Implants
Suffix	-	Coupler	Programmable, Wireless-enabled, Autoscan
Billing code	US021	US019	US029
Benefit	$7,470	$350	$7,166
Description	Part of the VSB System, VORP503 is an active implant, which is implanted into the temporal bone under the skin. The VORP 503 consists of the FMT, a conductor link, the electronics (demodulator), fixation wings and a magnet surrounded by a receiver coil.	Middle ear prostheses used with the VSB System VORP implant. Facilitate coupling between the FMT and a vibratory structure of the middle ear.	Single Unit AP for the VSB System, worn off the ear it is held in place by magnetic attraction over the implant. Designed to function similarly as the SAMBA AP but with improved battery life, noise reduction, ingress protection and Intelligent Sound Adapter 2.0.
ARTG ID	389014	185533	353970

AP = audio processor; ARTG = Australian Register of Therapeutic Goods; FMT = floating mass transducer; VSB = Vibrant Soundbridge.
Source: Prescribed List of Medical Devices and Human Tissue Products, Part A, effective from 1 July 2025.

According to the application, batteries for the audio processor cost approximately $56/year (based on an estimated 8 cards of batteries at $7/card) and are an out-of-pocket expense for patients.

Individuals under 26 years of age, as well as other eligible HSP participants (refer to 'Population' section), may receive financial support for audio processor maintenance – including battery replacement, repairs and upgrades – through the program's CSO component.[11] The cost of surgery and implanted components is not covered under the program.

Comparator(s)

The application nominated implantation of an active transcutaneous BCI as the comparator for the proposed intervention. AMEI is expected to replace some use of BCIs and will also provide an option for individuals in whom implantation of a BCI is not feasible due to anatomical reasons or skin quality.

BCIs represent the current standard of care for individuals with mixed or conductive hearing loss who are not appropriate candidates for surgical repair or reconstruction of the middle ear, are not appropriate candidates for a cochlear implant, and are unable to use conventional air conduction hearing aids due to

[11] The specialist hearing services documentation for the HSP refers to 'implantable bone conduction devices', which covers bone anchored devices and middle ear implants.

medical reasons. In this population, BCIs function by transmitting sound vibrations directly to the cochlea via bone conduction, thereby bypassing the external and middle ear.

Individuals who are candidates for cochlear implants are excluded from the population. Cochlear implants are intended for individuals with severe to profound SNHL (typically with bone conduction thresholds >70 dB HL) and are not indicated for use in those with normal or near-normal cochlear function. Implantation involves the surgical insertion of an electrode array into the cochlea, a procedure that typically results in the loss of any residual natural hearing. This is inconsistent with the clinical objective of preserving natural cochlear function in patients for whom maintenance of residual hearing is a priority.

PASC advised that active BCIs should be the main comparator for the population of individuals with mild to severe MHL or CHL who are not candidates for repair or reconstruction, and who cannot use conventional air conduction hearing aids, noting the applicant's clinical expert advice that passive devices are being phased out and active BCIs are the current standard of care (provided their bone-conduction thresholds fall within device fitting ranges and anatomy permits).

PASC advised that the assessment should also include 'no further intervention' (untreated hearing loss) as a comparator for individuals who are contraindicated for, or unsuitable for, active BCI implantation. In such individuals, AMEI may represent an alternative treatment option where no other therapeutic options are available.

Bone conduction hearing devices available in Australia

The application stated that, following the introduction of active transcutaneous BCIs in Australia, there has been a general shift away from use of passive BCIs, including both percutaneous and transcutaneous types.

Passive percutaneous BCIs provide direct mechanical coupling between the external sound processor and the skull, resulting in efficient transmission of the sound directly to the inner ear, avoiding skin and subcutaneous attenuation of the vibration. However, they are associated with adverse skin reactions, risk of infection, and the need for ongoing site hygiene and maintenance (Bruschini et al. 2024; Koro et al. 2025), which may impact long-term adherence and patient satisfaction.

Passive transcutaneous systems offer an alternative approach that avoids skin penetration by using magnetic coupling between the implanted internal magnet and the external processor. These systems improve cosmetic outcomes and reduce the incidence of skin complications, but the force of the magnets can cause pain and the presence of skin and soft tissue between the external processor and the bone leads to a degree of vibratory attenuation compared with passive BCIs (Koro et al. 2025).

Non-surgical passive bone conduction hearing devices (BCHDs), such as those worn on a headband (softband) or adhesive adapter, are typically used in younger children or in individuals for whom surgery is contraindicated. Although these options offer a non-invasive means of amplification, they are often associated with discomfort, cosmetic concerns, and limited output, making them less suitable for long-term use in older children and adults.

In contrast, active BCIs use an implanted transducer to deliver vibratory stimulation directly to the skull in response to input from an external sound processor. These systems preserve skin integrity and avoid the soft tissue attenuation seen in passive transcutaneous devices. Sound is captured by the external processor, converted to digital signals, and transmitted through the skin to the implanted receiver, which then generates mechanical vibrations via electromagnetic (e.g. MED-EL Bonebridge System) or

piezoelectric (e.g. Cochlear Osia System) stimulation. As vibration originates within the implant, signal loss through soft tissue is minimised, allowing greater efficiency and enabling the use of lower magnetic force to reduce skin-related complications.

Table 7 provides a comparison of different BCHD systems available in Australia. The application specifically nominated active BCIs – the Bonebridge System (MED-EL) and the Osia System (Cochlear) – as direct comparators. The bone conduction fitting range for the Bonebridge System is up to 45 db HL, while the Osia System accommodates thresholds up to 55 dB HL. In comparison, passive percutaneous BCIs have a higher fitting range, accommodating bone conduction thresholds up to 55–65 dB HL, depending on the sound processor used. In contrast, passive transcutaneous systems typically have a more limited fitting range, generally suitable for thresholds up to 30–35 dB HL, due to attenuation of signal transmission through the skin and soft tissue.

Table 7 Comparison of bone conduction hearing devices

Feature	Non-surgical passive BCHD (headband/ softband or adhesive)	Percutaneous passive BCI (abutment)	Transcutaneous passive BCI (magnetic)	Active BCI
Implantation required	No	Yes	Yes	Yes
Skin penetration	No	Yes (through abutment)	No	No
Signal transmission	Through soft tissue via band pressure or adhesive interface	Direct mechanical coupling to bone	Magnetic coupling through intact skin	Implanted transducer directly stimulates bone
Surgical complexity	None	Minor	Minor	Moderate (deeper implantation)
Maintenance burden	Low	High (daily hygiene and skin care)	Low	Low
Suitable option for	Mild MHL, mild to severe CHL, often used for age <5 years or non-surgical candidates of any age; temporary or trial use	Mild to severe MHL/CHL, age ≥5 years, suitable skin requiring high audiological gain	Mild MHL, mild to severe CHL, age ≥5 years prioritising intact skin and aesthetics	Mild to severe MHL/CHL, age ≥5 years needing higher gain and intact skin
Limitations	Not suitable for permanent use in adults	Patients with poor skin health, cosmetic concerns	Thick soft tissue may reduce performance	Skull thickness, surgical/ anatomical limitations
Example devices	Cochlear Baha Softband; Oticon Ponto Softband; MED-EL ADHEAR	Cochlear Baha Connect; Oticon Ponto Abutment	Cochlear Baha Attract; Oticon Ponto with magnet	MED-EL Bonebridge, Cochlear Osia; Oticon Sentio

BCHD = bone conduction hearing device; BCI = bone conduction implant; CHL = conductive hearing loss; MHL = mixed hearing loss.

Regulatory status

The Bonebridge System (MED-EL) and the Osia System (Cochlear) are the only active transcutaneous BCI systems registered in Australia for MHL and CHL (Table 8).

Recently, the TGA approved a third active transcutaneous BCI, the Sentio System (Oticon Medical).

The Bonebridge and Osia Systems are indicated for individuals aged 5 years and older while the Sentio System is indicated for individuals aged 12 years and older.

Table 8 ARTG summary for active transcutaneous bone conduction hearing systems

System	Bonebridge	Osia	Sentio
Sponsor	MED-EL Implant Systems Australasia Pty Ltd	Cochlear Ltd	Oticon Medical (a Division of Audmet Australia)
Manufacturer	Med-EL Elektromedizinische Geraete Gesellschaft m.b.H.	Cochlear Ltd	Oticon Medical AB
ARTG ID	389050 – BCI 602 Kit 353072 – Samba 2 BB Audio Processor[a] 329049 – BCI 602 Lifts[b]	444958 – Cochlear Osia OSI300 Implant[c] 444959 – Osia 2(I) Sound Processor[d] 375451 – Osia Fitting Software 2 375452 – Cochlear Osia Smart App	488205 – Sentio Ti Implant Kit 488206 – Sentio 1 Mini Sound Processor
ARTG start and effective dates	ARTG ID 389050: 24 May 2022[e] ARTG ID 353072: 14 January 2021 ARTG ID 329049: 22 January 2020	ARTG ID 444958 &444959: 28 March 2024 ARTG ID 375451 & 375452: 29 September 2021	ARTG ID 488206 & 488205: 8 May 2025 (start) 20 May 2025 (effective)
Product category	Medical Device Class III	Medical Device Class III	Medical Device Class III
GMDN	61176 Implantable vibrator bone-conduction hearing implant system 62209 Bone-conduction hearing implant system sound processor	64989 Bone-conduction hearing implant system vibrator assembly 47374 Cochlear implant system sound processor 60211 Hearing aid fitting/ programming application software	61176 Implantable vibrator bone-conduction hearing implant system

ARTG = Australian Register of Therapeutic Goods; BCI = bone conduction implant; dB = decibels; GMDN = Global Medical Device Nomenclature; ID = identification number.

a. The predecessor sound processor (Samba BB Audio Processor) is also included in the ARTG (ID 270912).

b. BCI 602 Lifts (1 mm) are not mandatory for BCI 602 implantation. Whether to use them is the surgeon's individual decision, which should be based on the anatomical situation of the particular patient.

c. The predecessor implant (Cochlear Osia OS100 Implant) is also included in the ARTG (ID 389472).

d. The predecessor sound processor (Osia 2 Sound Processor) is also included in the ARTG (ID 375450).

e. Original ARTG ID 329050 had start date 22 January 2020 before reclassification from active implantable medical device (AIMD).

Source: ARTG Public Summaries, accessed 11 June 2025.

Current funding of the comparator procedure and device

Implantation of a BCI is funded on the MBS under items 41603, 45794 and 45797 for one-step and two-step procedures. The MBS item descriptors and fees are shown in Appendix B, Box 4, and utilisation is shown in Appendix B, Figure 5.

The Bonebridge and Osia systems are listed on the PL (Table 9).

Table 9 PL listings for Bonebridge and Osia active transcutaneous bone conduction hearing systems

System	Bonebridge System	Osia System
Sponsor	MED-EL Implant Systems Australasia Pty Ltd	Cochlear Limited
Product Group	02.01.04 – Implantable Bone Conduction Hearing System	02.01.09 – Implantable Piezoelectric Bone Conduction Hearing System (all components)
PL Billing Codes	US026, US027, US030	QQ642

System	Bonebridge System	Osia System
Sponsor	MED-EL Implant Systems Australasia Pty Ltd	Cochlear Limited
PL total Benefit	$196 + $2,222 + $6,808 = $9,226	$14,369

PL = Prescribed List.

Source: Prescribed List of Medical Devices and Human Tissue Products, Part A, effective 01 July 2025.

As with AMEIs, individuals under 26 years of age, as well as other eligible HSP participants (refer to 'Population' section), may receive financial support for audio processor maintenance – including battery replacement, repairs and upgrades – through the program's CSO component. The cost of surgery and implanted components is not covered under the program.

Outcomes

The outcomes relevant to the assessment of implantation of an AMEI versus implantation of a BCI are summarised in Table 10. The safety and effectiveness outcomes should be explicitly assessed in relevant subgroups:

- Type of hearing loss – mixed or conductive, mild or moderate or severe, unilateral or bilateral
- Age – children >5 years, adolescents, adults, older adults (e.g. aged >70 years).

PASC advised that the assessment should include consideration of differential outcomes by MHL/CHL, hearing loss severity, age groups and longitudinal outcomes (device, patient-related) as individuals age, if the evidence is available.

Table 10 Outcomes relevant to the assessment of the proposed intervention

Outcome type	Outcome
Safety	Intraoperative and postoperative complications Device-related adverse events (e.g. extrusion, malfunction, processor issues, infection) Revisions, device explants or reimplantation (reoperations due to device failure or patient intolerance) Long-term implant durability (≥5 years)
Effectiveness	Audiological outcomes • effective gain • functional gain • speech recognition scores (e.g. WRS, SIN test) • speech reception threshold in noise (e.g. SRT 50 test) • sound localisation tests Patient-specific outcomes • hearing-specific quality of life (e.g. APHAB, SSQ) • health-related quality of life (e.g. HUI3, EQ-5D) • patient satisfaction

Outcome type	Outcome
Healthcare resources	Device costs (internal and external components) Procedure duration and costs Maintenance/replacement costs (internal and external components) Costs associated with changes in clinical management (testing required before the procedure; follow up ENT and audiology visits) Costs associated with management of adverse events, revision surgery and explantation
Cost-effectiveness	Cost per QALY gained Cost per unit/point improvement (based on audiological or patient-reported outcome thresholds) – only if utilities/QALYs are not well established in the proposed population
Total Australian government healthcare costs	Total cost to the MBS Total cost to other government health budgets (including the Australian Government HSP) Total cost to the PL

APHAB = Abbreviated Profile of Hearing Aid Benefit; ENT = ear, nose, throat; EQ-5D = EuroQol 5-dimension; HUI3 = Health Utility Index Mark 3; HSP = Hearing Services Program; MBS = Medicare Benefits Schedule; PL = Prescribed List of Medical Devices and Human Tissue Products; QALY = quality-adjusted life year; SIN = Speech in Noise; SRT = Speech Reception Threshold (50% of spoken words); SSQ = Speech, Spatial and Qualities of Hearing Scale; WRS = Word Recognition Score.

This list of outcomes in Table 10 expands on the 4 key audiological outcomes proposed in the application:

- **Functional Gain** refers to the difference in hearing thresholds measured in sound-field audiometry with and without the hearing device in place. It is calculated by subtracting aided thresholds from unaided thresholds across key frequencies (typically 0.5, 1, 2, and 4 kHz). Functional gain reflects the overall benefit provided by the device in improving audibility, though it is influenced by environmental factors and the individual's own auditory responses.
- **Effective Gain** is defined as the difference between the aided free-field threshold and the bone conduction threshold of the unaided ear. It is often used in the evaluation of implantable hearing devices to quantify how effectively the device compensates for the sensorineural component of hearing loss. A smaller effective gain (i.e. closer match between aided threshold and bone conduction threshold) suggests more efficient transmission of sound to the cochlea.
- **Word Recognition Score** (WRS) measures an individual's ability to correctly identify and repeat phonetically balanced monosyllabic words presented 'in quiet' at a fixed sound pressure level (SPL), commonly at 65 dB SPL or at the individual's most comfortable listening level. It is expressed as a percentage of correctly repeated words and provides information on speech discrimination ability. WRS is typically assessed unaided and/or aided and is a key outcome in evaluating the functional benefits of hearing interventions.
- **Speech Reception Threshold (SRT) in Noise** refers to the minimum signal-to-noise ratio (SNR) at which an individual can correctly repeat 50% of presented speech material (e.g. sentences or words) when background noise is present. SRT 50 evaluates hearing performance under realistic listening conditions and is a sensitive measure of device performance in complex acoustic environments. Lower values indicate better performance.

Although standard audiological assessments provide objective measures of hearing performance, they do not reflect how individuals experience their hearing in everyday environments. Patient-reported outcomes provide a complementary perspective on treatment benefit. Instruments such as the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial and Qualities of Hearing Scale (SSQ) offer validated, structured tools to quantify subjective improvements in hearing-related functioning.

Health-related quality of life (HRQoL) instruments (e.g. EuroQol 5-dimension [EQ-5D]; Health Utility Index Mark 3 [HUI3]) are informative for the economic evaluation and allow for broader assessment of how hearing improvement translates to general physical, emotional, and social well-being.

Patient satisfaction surveys and global rating scales provide additional insight into how users value the hearing device, their willingness to use it regularly, and the extent to which it meets their expectations — all of which are important for long-term device acceptance and adherence.

Assessing the rate of device revisions and explantations is crucial for evaluating the long-term safety and durability of implanted devices. Revisions may be required due to medical complications such as infection, device migration, or coupling failure, or due to technical issues such as device malfunction or failure of the external processor to communicate effectively with the internal component. Explantation, while less common, may be necessary in cases of irreversible complications, non-responsiveness, or patient dissatisfaction with auditory outcomes.

Revision and explantation procedures can contribute to increased costs, hospital utilisation, and patient morbidity, and may adversely affect patient confidence in the intervention.

Device longevity and the need for revision are particularly important in children and adolescents, who may rely on the implant for many decades.

PASC advised that the assessment should include the full downstream costs following delivery of both the proposed service and the comparators, encompassing subsequent testing, follow-up services and care, and any optimisation requirements of the device post-implant, including revision surgery and replacement devices.

Clinical management algorithms

Clinical management prior to implantation of an AMEI

In the Australian clinical setting, individuals considered for an AMEI typically follow a multidisciplinary care pathway, ensuring that all conventional treatment options have been trialled or deemed unsuitable prior to implantation.

Patients commonly first present with hearing loss to either a general practitioner (GP) or an audiologist. The GP may initiate initial management or refer the patient to an ENT specialist for further investigation. Audiologists conduct a comprehensive diagnostic assessment, including pure tone audiometry (air and bone conduction thresholds), tympanometry, and speech discrimination testing.

Referral requirements for audiology services in Australia vary by funding source. Medicare-funded diagnostic audiology services require a referral from a medical practitioner. In contrast, services provided under the HSP, National Disability Insurance Scheme (NDIS), or privately funded care generally allow direct access without a GP referral.

Initial management prioritises the least invasive and most accessible interventions. This may involve medical or surgical treatment of reversible middle ear pathology (e.g. tympanic membrane perforation or otitis media with effusion), and/or a trial of hearing amplification using conventional air conduction or bone conduction hearing aids.

ENT specialists are responsible for confirming the diagnosis and underlying cause of the hearing loss, assessing suitability for surgical intervention (e.g. tympanoplasty or ossiculoplasty), and coordinating necessary imaging and multidisciplinary care. Where required, high-resolution computed tomography (CT) of the temporal bones is used to assess ossicular integrity, mastoid pneumatisation, round and oval window patency, and any anatomical contraindications. Magnetic resonance imaging (MRI) may also be requested when inner ear or retrocochlear pathology is suspected.

If conventional treatments do not provide sufficient benefit, are not feasible, or are contraindicated due to anatomical, medical, or dermatological factors, the patient may be considered for an implantable hearing device such as an AMEI.

A formal multidisciplinary assessment is undertaken to determine candidacy for AMEI implantation. This includes a detailed review of the patient's audiological profile, imaging findings, and broader clinical considerations such as age, communication needs, previous middle ear surgery, and patient expectations.

Patients and/or their caregivers are counselled about the potential risks and benefits of implantation, device use and maintenance, and the differences between alternative interventions. This process may also include consideration of whether unilateral or bilateral implantation is appropriate based on the severity and symmetry of hearing loss and functional needs. Multidisciplinary team discussions ensure that timing and sequencing of any required treatment for the underlying ear pathology is completed prior to surgery.

The application stated that healthcare resource use prior to implantation is comparable for AMEIs and active transcutaneous BCIs. However, a radiologist is recommended as part of the multidisciplinary team to assess anatomical suitability for implantation. Radiological input is essential to identify anatomical contraindications – such as facial nerve dehiscence, aberrant vascular structures, or limited middle ear space – prior to surgery. This supports appropriate patient selection and enables safe and effective surgical planning.

Follow up after implantation of an AMEI

Following surgical implantation of an AMEI, patients in Australia typically follow a postoperative care pathway designed to support wound healing, device function, and long-term hearing outcomes. Care is delivered through both hospital-based ENT services and community audiology clinics.

Activation of the audio processor occurs approximately 4 to 6 weeks after surgery. The external audio processor is fitted, and initial programming is undertaken by an audiologist.

Ongoing audiology review involves hearing assessment, device adjustment, and outcome monitoring 3 times in the first 12 months after activation, and annually thereafter. These services may be delivered by hospital-based or community audiologists, depending on the patient's location and referral pathway.

Postoperative care in paediatric patients typically involves ENT surgeons, paediatric audiologists, and allied health professionals including speech pathologists. Speech and language development is actively monitored, and therapy is provided where needed. In some cases, magnet strength adjustments or external processor upgrades may be required during development. Individuals under 26 years of age may be eligible for financial support for such services under the CSO component of the HSP.

Access to postoperative services, including audiology and speech therapy, may be supported via telehealth for patients in rural or remote areas.[12]

The application claimed there is no difference in healthcare resource use after implantation of an AMEI or an active transcutaneous BCI; however, this claim requires verification during the assessment process.

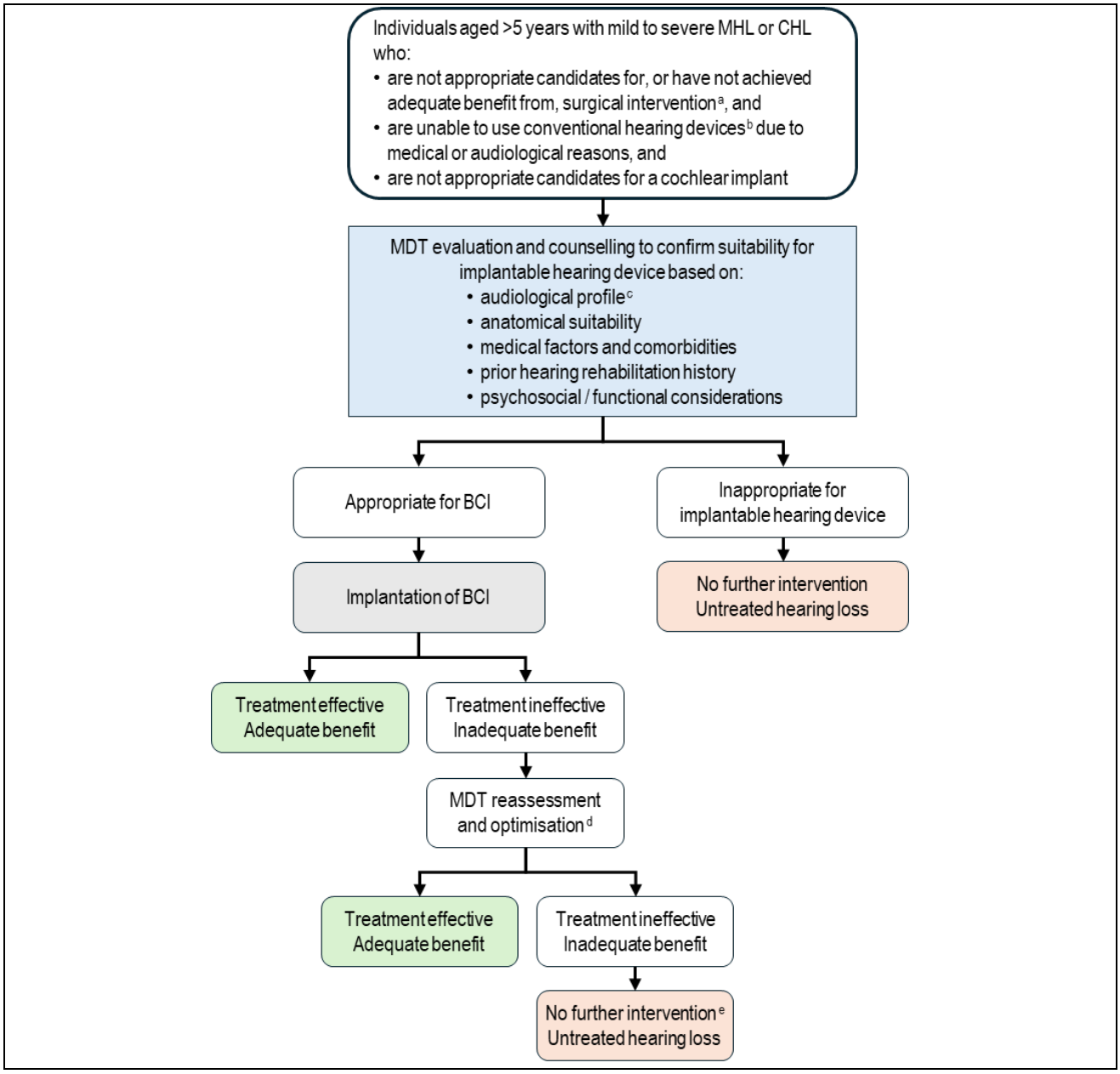
Clinical management algorithms

A simplified version of the current clinical management algorithm for the proposed population is shown in Figure 2. The decision to implant a BCI is made by a multidisciplinary team who consider the patient's clinical profile and functional needs. Explantation of a BCI is uncommon but may be required due to medical complications, device-related issues or insufficient clinical benefit. For patients who derive inadequate benefit from BCI as a result of progressive changes in hearing status, cochlear implantation is described in clinical practice as a recognised management option (Brkic et al. 2019).

At present, AMEI implantation is funded for individuals with SNHL only. AMEI implantation in individuals with CHL or MHL is uncommon but may be accessed through limited public hospital funding or self-funded by patients (not shown in Figure 2).

[12] MBS Telehealth Services, factsheet for audiology and otolaryngology MBS telehealth (video and phone) services, accessed 13 June 2025.

Figure 2 Current clinical management algorithm for the proposed population



BCI = bone conduction implant; BCHD = bone conduction hearing device; CHL = conductive hearing loss; MDT = multidisciplinary team; MHL = mixed hearing loss; MRI = magnetic resonance imaging.

a. Surgical intervention includes repair and/or reconstruction of the middle ear.
b. Conventional hearing devices include air conduction hearing aids and non-implantable BCHDs (headband/softband or adhesive).
c. May include a trial of a non-implantable BCHD, where appropriate, to assess the potential benefit prior to considering an implantable option.
d. MDT may reassess any/all of the following: device fitting, settings and coupling; skin and soft tissue issues; device positioning or osseointegration; changes in hearing status; patient adherence or difficulties with device use. Revision surgery is infrequent and typically only required in the event of complications or device-related issues.
e. Explantation is uncommon but may be required in specific clinical scenarios. In cases where removal is not indicated, the device may be deactivated and left in situ. Where a BCI no longer provides adequate benefit due to progressive sensorineural hearing loss or presbycusis, the MDT may consider a cochlear implant.
Note: Although not shown, implantation of an AMEI in the proposed population is occasionally funded via public hospitals or self-funded by patients.

A simplified version of the proposed clinical management algorithm is shown in Figure 3. MBS listing of AMEI implantation in the target population would offer an alternative to BCIs and provide an option for

individuals who are not appropriate candidates for a BCI and would otherwise remain with untreated hearing loss.

For the proposed population, selection between a BCI and an AMEI is individualised and informed by various clinical and patient-specific factors, such as audiological profile, anatomical suitability, and previous surgery or pathology (Table 11). Additional considerations include the presence of chronic skin conditions that may contraindicate BCIs, the individual's lifestyle and preferences, as well as the expertise and experience of the surgical team. BCIs are generally considered the preferred first-line implantable hearing device in individuals with MHL/CHL due to their less invasive surgical approach and broader clinical familiarity. Implantation of an AMEI following inadequate benefit from a BCI is not described in clinical practice guidelines, and there is currently limited clinical evidence to support its use in this context.

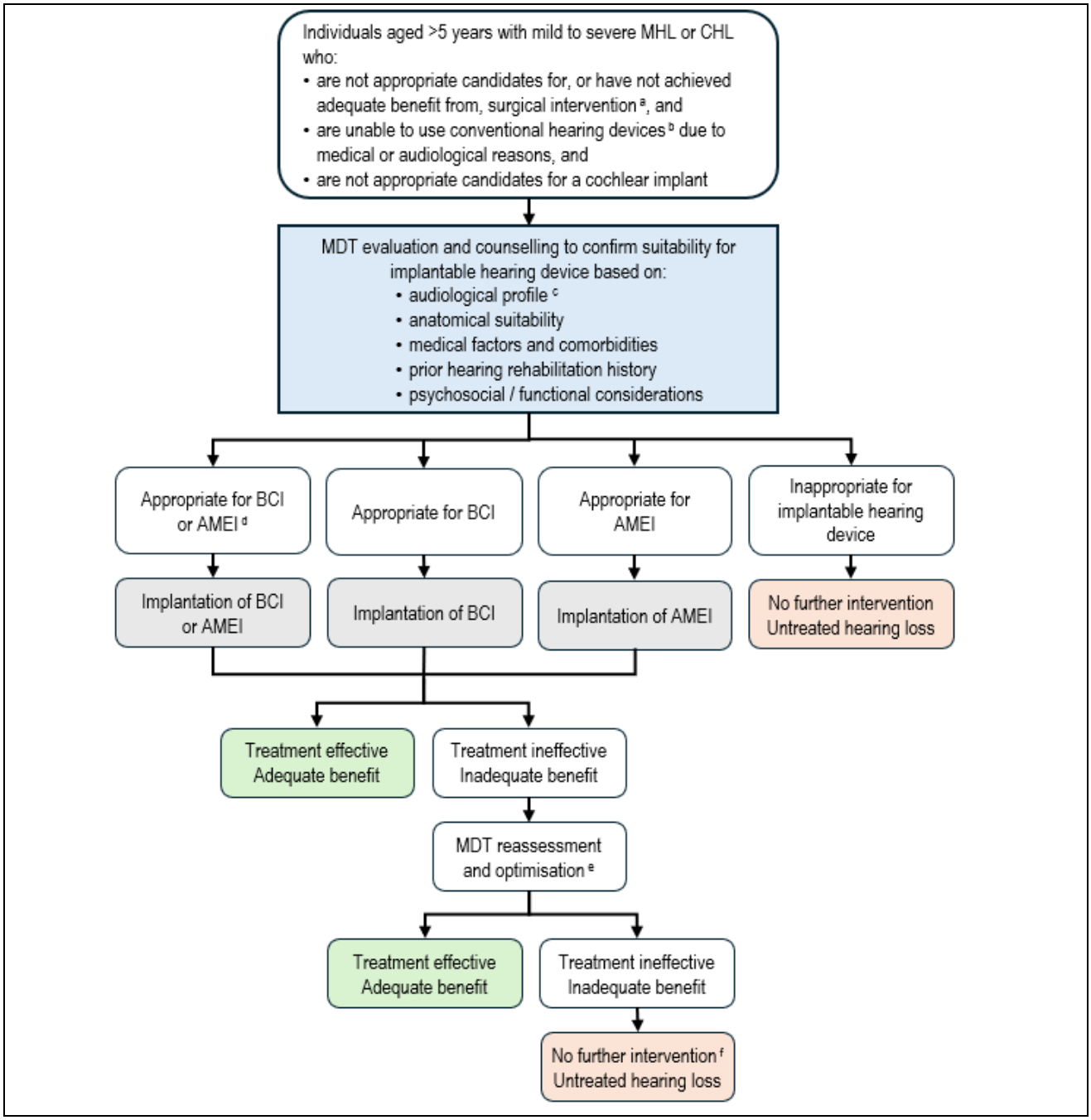
Final candidacy decisions are made by a multidisciplinary team to ensure that the selected implant aligns with the patient's clinical profile and functional needs.

Table 11 Key factors in deciding between BCI or AMEI implantation in individuals with MHL or CHL

Category	Factor	BCI preference	AMEI preference
Audiological profile	Bone conduction thresholds	Typically ≤45–65 dB HL	Similar, but AMEI may be preferred if more precise coupling improves outcomes
	Cochlear reserve	Good	Adequate
	Speech discrimination	Not impaired	Better preserved speech discrimination favours AMEI
	Aided benefit with non-implantable BCHD trial	Benefit demonstrated with softband or headband	No or poor benefit from BCHD trial, or discomfort
Anatomical suitability	Skull bone thickness	Thin or irregular bone may preclude BCI	Does not rely on skull bone thickness
	Middle ear status	Atresia or chronic drainage (no viable middle ear)	Intact middle ear anatomy or remnant structures suitable for coupling
	Temporal bone/ mastoid condition	Requires flat bone bed for implant	Requires middle ear access and space for transducer placement
	Round or oval window visibility	Not relevant	Required for transducer coupling if using those sites
Previous surgery or pathology	Canal or middle ear pathology	External canal atresia, chronic otorrhoea	Failed tympanoplasty or ossiculoplasty
	Scarring from past surgery	Scarred middle ear limits AMEI use	Scarred skull site limits BCI use
Patient factors	Skin condition	Good skin tolerance	Dermatitis, infection risk favours AMEI
	Lifestyle	Less surgical complexity and quicker recovery	More natural hearing experience, but more complex surgery
Device and system factors	MRI compatibility	More systems are now MRI-safe; BCI implants are conditionally MRI compatible up to 3.0 Tesla	Vibrant Soundbridge VORP 503 implant is conditionally MRI compatible up to 1.5 Tesla
	Surgical expertise and experience	Shorter procedure, broader availability	Specialist surgical centres with ENT implant expertise

AMEI = active middle ear implant; BCHD = bone conduction hearing device; BCI = bone conduction implant; dB HL = decibels hearing level; ENT = ear, nose and throat; MRI = magnetic resonance imaging.

Figure 3 Proposed clinical management algorithm for the proposed population



AMEI = active middle ear implant; BCHD = bone conduction hearing device; BCI = bone conduction implant; CHL = conductive hearing loss; MDT = multidisciplinary team; MHL = mixed hearing loss; MRI = magnetic resonance imaging.

a. Surgical intervention includes repair and/or reconstruction of the middle ear.

b. Conventional hearing devices include air conduction hearing aids and non-implantable BCHDs (headband/softband or adhesive).

c. May include a trial of a non-implantable BCHD, where appropriate, to assess the potential benefit prior to considering an implantable option.

d. BCIs may be preferred for their less invasive surgical approach and greater clinical familiarity. AMEIs may be preferred for their broader fitting range, which offers more flexibility for patients who later develop age-related progressive sensorineural hearing loss.

e. MDT may reassess any/all of the following: device fitting, settings and coupling; skin and soft tissue issues or inflammation; device positioning; changes in hearing status; patient adherence or difficulties with device use. Revision surgery is infrequent and typically only required in the event of complications or device-related issues.

f. Explantation of a BCI is uncommon but may be required in specific clinical scenarios. In cases where removal is not indicated, the device may be deactivated and left in situ. Explantation of an AMEI may involve greater surgical complexity due to the need to access and manage components located within the mastoid and middle ear structures. Where a BCI or AMEI no longer provides adequate benefit due to progressive sensorineural hearing loss or presbycusis, the MDT may consider a cochlear implant (Brkic et al. 2019; Barbara et al.2021; Knölke et al. 2025). Implantation of an AMEI after explantation of a BCI may be considered in exceptional cases; however, such practice appears to be rare, not reported in the available clinical literature, and is not established as standard clinical care.

PASC considered that the proposed clinical management algorithm positions AMEIs alongside BCIs and questioned whether, in practice, AMEIs are more likely to be offered to patients who are unsuitable for BCIs. The applicant's clinical expert advised that some patients are more appropriately managed with a BCI, others with an AMEI, and a subset may be suitable for either; in the latter case, device selection is determined through shared decision-making with the patient and/or caregivers following counselling on risks and benefits. PASC noted that the positioning of AMEIs within the treatment pathway is critical for defining the clinical claim and informing the economic evaluation. For patients eligible for both devices, BCIs represent the appropriate comparator, whereas for patients who are unsuitable for BCIs, the relevant comparator is no further intervention (i.e. untreated hearing loss). This distinction is expected to determine the scope of the clinical evidence base and the structure of the cost-effectiveness modelling.

Proposed economic evaluation

Based on the applicant's clinical claims of **superior effectiveness** and **non-inferior safety** of implantation of an AMEI compared with the main comparator – an active transcutaneous BCI – in the proposed population,[13] a cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) is appropriate (Table 12). A CUA is likely to be more informative as the findings of a CEA (e.g. cost per unit/point improvement in audiological or patient-reported outcome) is more difficult to interpret.

For individuals within the proposed population who are not appropriate candidates for a BCI, the appropriate comparator is no further treatment (i.e. untreated hearing loss). The applicant's clinical claims in relation to this secondary comparator are **superior effectiveness** and **inferior safety**. In this case, a CUA is likely the appropriate economic evaluation.

Table 12 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	**? Likely CUA (secondary)**
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	**CEA/CUA (main)**
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis.
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis.
a. Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations.
b. An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

The evidence base for the effectiveness and safety of partially implantable AMEI consists predominantly of prospective and retrospective single-arm case series and case reports involving children, adolescents,

[13] Confirmed at the pre-PASC meeting held on 24 June 2025.

and/or adults across a range of underlying ear pathologies. In these studies, audiological or patient-reported outcome measures collected at baseline are used to demonstrate the effectiveness of the device at follow up.

While randomised controlled trials are lacking, a small number of non-randomised comparative studies have evaluated the effectiveness and/or safety of the Vibrant Soundbridge System against BCIs (for example, Távora-Vieira et al. 2023) or specifically against active transcutaneous BCIs, in particular the Bonebridge System (for example, Liu et al. 2024; Vickers et al. 2023). However, not all comparative studies are restricted to the proposed population (for example, Vickers et al. 2023 compares longer-term safety but includes patients with any type of hearing loss).

PASC noted that the available evidence is heterogeneous and generally of low quality, which may limit the extent to which the clinical claims can be substantiated against the primary comparator, active BCIs. PASC also noted that the PL benefit for the Vibrant Soundbridge System is higher than that for the active BCIs currently listed on the PL (the Bonebridge and Osia systems). In this context, PASC considered that an economic evaluation using the secondary comparator – no further intervention (untreated hearing loss) – would be informative, particularly if AMEIs are positioned for individuals who are contraindicated for, or unsuitable for, active BCIs.

Proposal for public funding

The MBS item descriptor and fee recommended by PASC is shown in Box 1.

Box 1 MBS item for implantation of an AMEI recommended by PASC

Category 3 – THERAPEUTIC PROCEDURES
MBS item AAAAA Active middle ear implant, partially implantable, insertion of, via mastoidectomy, for patients with: (a) mixed or conductive hearing loss; and (b) stable (less than 10 dB variations over 2 years for adults) pure tone bone conduction threshold levels; and (c) not appropriate candidates for, or have not achieved adequate clinical benefit from, surgical repair or reconstruction of the middle ear; and (d) conventional hearing aids are contraindicated, not tolerated, or provide insufficient clinical benefit; and (e) absence of active middle ear infections or retrocochlear pathology Multiple Operation Rule (Anaes.) (Assist.)
Fee: $2,189.60 **Benefit:** 75% = $1,642.20

AMEI = active middle ear implant; MBS = Medicare Benefits Schedule.

Proposed MBS item descriptor

The proposed descriptor refers to insertion of an AMEI via vibroplasty, which the applicant states is the terminology that has been widely adopted in the literature to describe specific surgical techniques involving the coupling of the Vibrant Soundbridge FMT to middle ear structures. The descriptor for MBS item 41618 for MEI implantation in patients with SNHL is device-agnostic and refers to insertion of an MEI

via mastoidectomy (Appendix B, Box 3).[14] The applicant has agreed to consistency in terminology of the surgical technique across the 2 MBS items.[15]

The proposed item descriptor is simplistic when compared to the descriptor for MBS item 41618 (Appendix B, Box 3) and the descriptor proposed in the Final Protocol for MSAC Application 1364 for AMEI implantation in patients with CHL and MHL (Appendix A, Box 2). The current proposed descriptor does not specify eligibility criteria for AMEI and also lacks definitions for what constitutes a lack of success or adequate benefit from prior surgical intervention or BCHDs,[16] and does not detail the reasons a patient may be unable to wear conventional hearing aids.

The applicant stated that determination of candidacy for implantation of an AMEI should be at the discretion of the multidisciplinary team.[15] This team would typically comprise an ENT surgeon/otologist, audiologist and radiologist.

The proposed MBS item is intended to be used per ear, not per procedure.

PASC noted the inclusion of eligibility criteria regarding the population in the descriptor for MBS item 41618 (for MEI in individuals with SNHL) and advised that the proposed descriptor for individuals with mixed or conductive hearing loss should also include a similar level of detail in defining the appropriate patient population, including the use of speech discrimination thresholds. PASC further agreed that the inclusion of an upper age limit would only be warranted if clinical evidence demonstrated that AMEI implantation is unsafe or clinically inappropriate in individuals above a defined age threshold.

The Final Protocols for MSAC Applications 1364 and 1365 proposed a separate MBS item for AMEI explantation and revision surgery. According to the Public Summary Document (PSD) for MSAC Application 1365, the Evaluation Subcommittee (ESC) considered that a separate item for revision surgery was not necessary based on reported revision rates for AMEI in patients with SNHL, which ranged from 1.4% to 15.6% between studies, with an average of 2.82%. The applicant advised that revision and explantation rates for AMEIs in patients with MHL or CHL are expected to be similar to those observed in patients with SNHL.[17] As such, a separate MBS item for revision or explantation may not be required, provided this is confirmed in the clinical evaluation.

PASC noted that revision rates are a specified outcome for the assessment and will inform consideration of whether the service should be restricted to a once-per-lifetime provision. PASC considered that while such a restriction may be appropriate, it would preclude access to revision procedures under the MBS. By contrast, MBS item 41618 does not impose such a limit, thereby allowing clinically necessary revision surgeries to be claimed under the same item.

[14] The Final Protocol for MSAC Application 1365 referred to the procedure as vibroplasty but did not use this terminology in the proposed MBS item descriptor. According to the Public Summary Document (PSD) for MSAC Application 1365.1, MSAC recommended modification of wording from 'insertion of, including mastoidectomy' to 'insertion via mastoidectomy' given that a partial or complete mastoidectomy is required for the procedure.
[15] Discussed at the pre-PASC meeting held on 24 June 2025.
[16] At the pre-PASC meeting held on 24 June 2025, the applicant clarified that the term 'bone conduction device' was intended to encompass non-implantable BCHDs (headband/softband or adhesive), not BCIs.
[17] Discussed at the pre-PASC meeting held on 24 June 2025.

Proposed MBS item fee

The fee proposed in the application is based on the existing MBS item for implantation of a MEI via mastoidectomy for patients with SNHL (MBS item 41618, see Appendix B, Box 3). The applicant stated that the time and complexity involved in implanting an AMEI for MHL or CHL is comparable to that for SNHL.[17] However, the assessment will need to justify this claim, as more complex coupling strategies are often required in patients with MHL or CHL. These may necessitate additional surgical steps, which could contribute to increased operative time and complexity.

The fee is intended to cover intraoperative testing of the implanted components of the system.

A 75% benefit is appropriate as the proposed service is intended to be delivered in a hospital setting.

There are existing MBS items for ENT consultation, CT scan, audiometric testing and tympanometry prior to the proposed intervention. Likewise, there are existing MBS items for ENT/audiologist programming of the device after implantation, and for hearing assessment at follow up (refer to Appendix B for examples).

Summary of public consultation input

PASC noted and welcomed consultation input from 3 organisations and 1 individual health professional. The 3 organisations that submitted input were:

- Audiology Australia
- CICADA QLD
- Independent Audiologists Australia (IAA).

Consultation input was supportive of public funding for implantation of an AMEI for treatment of mixed and conductive hearing loss.

Consumer input

CICADA QLD shared the experiences of individuals living with mixed and conductive hearing loss, along with their families and carers. Input from CICADA QLD stated that for people with mixed and conductive hearing loss, especially those who cannot benefit from hearing aids, the impact extends well beyond hearing alone. It affects education, employment, relationships, and mental health, and these effects are deeply felt by individuals and their families.

Input reported that hearing loss often leads to withdrawal from social activities, sport, or volunteering due to embarrassment, fatigue, or the inability to keep up with conversations and can lead to dependence on others in unfamiliar or unsafe environments where hearing is critical (e.g. cooking, crossing roads, responding to alarms). Input stated that untreated or under-managed hearing loss is strongly associated with increased anxiety and depression, and reduced self-esteem.

Benefits and disadvantages

The main benefits of public funding reported in the consultation input included the ability to preserve the natural anatomy of the ear canal, avoid issues commonly associated with conventional hearing aids (e.g. chronic ear infections, occlusions), and provide true binaural hearing. The input also emphasised that AMEI would benefit patients for whom conventional amplification is either ineffective or contraindicated.

CICADA QLD input stated that benefits included improved hearing in noisy environments, less distortion and more natural sound compared to bone conduction and traditional aids, which directly improve individual's communication ability, daily functioning, mental health and overall health outcomes.

The main disadvantages of public funding identified in the consultation input were limited access to surgical services in regional and remote areas and the need for ongoing maintenance and upgrades.

Population, comparator (current management) and delivery

The consultation input broadly agreed with the proposed population. Audiology Australia emphasised the importance of age-specific evaluations as hearing loss impacts children differently than adults, and careful assessment is essential to ensure that the intervention is developmentally appropriate. Input highlighted the importance of including culturally informed strategies to facilitate access for First Nations people, who are more likely to experience long-standing ear disease and face greater barriers to accessing effective rehabilitation.

The consultation input agreed with the proposed comparators, however input noted that not all patients are suitable for or respond to current surgical treatments and have limited options for rehabilitation using available treatment options.

Other services identified in the consultation input as being needed to be delivered before or after the intervention included counselling and targeted training for both ENT surgeons and audiologists who form part of the multidisciplinary team for implantation of active middle ear implants.

MBS item descriptor and fee

The consultation input mostly agreed with the proposed service descriptor, with some input stating that it may be worth considering whether the service could be incorporated into the existing item number (i.e. 41618), to reduce administrative complexity. Audiology Australia stated that all preoperative and postoperative services were already part of standard care and MBS funded. IAA stated that an additional MBS item should be created for complex implant candidacy assessments and that postoperative audiological services should be clearly MBS supported.

The consultation input broadly agreed with the proposed service fee. Input stated that MBS funding for AMEI would reduce out-of-pocket costs for individuals who are currently self-funding the procedure due to long public hospital waiting lists or public hospitals not including this service.

Additional comments

The consultation input commented on the outcomes in the application, agreeing with those outlined in the PICO, but also adding that patient-reported outcome measures (PROMs) including peer and community integration were essential.

PASC noted that consultation feedback acknowledged the potential benefits of AMEI implantation in the target population, while also highlighting concerns regarding limited availability of surgical services in regional and remote areas, as well as the requirement for ongoing maintenance and upgrades of the external device. PASC advised that issues relating to patient out-of-pocket costs and equity of access for rural and remote populations should be addressed in the ADAR.

Next steps

PASC noted the applicant confirmed that an applicant-developed assessment report (ADAR) will be prepared.

Applicant Comments on Ratified PICO

Regarding the level of detail for the proposed item descriptor, the applicant considers that the AMEI descriptors are overly detailed and misaligned with those used for other hearing implants (CI/BCI). The applicant maintains that a simpler descriptor is appropriate, given the highly heterogenous audiological, anatomical, and aetiological conditions of the target population. Suitability for AMEI should thus remain at the discretion of an interdisciplinary team, supporting the need for a simpler descriptor.

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Appendix A Prior MSAC applications for implantation of a middle ear implant

Table 13 Summary of PICO elements in prior MSAC applications for implantation of active middle ear implants

Application	Population(s)	Intervention	Comparator(s)	Outcomes
1137	1. Patients with mild or moderate SNHL of any aetiology, who have failed all other conservative medical, pharmaceutical and behavioural treatments 2. Patients suffering from severe SNHL of any aetiology, who have failed all other conservative medical, pharmaceutical and behavioural treatments 3. Patients with mild or moderate MHL of any aetiology, who have failed all other conservative medical, pharmaceutical and behavioural treatments 4. Patients suffering from severe MHL of any aetiology, who have failed all other conservative medical, pharmaceutical and behavioural treatments 5. Patients suffering from established stabilised CHL of any aetiology, who have failed all other conservative medical, pharmaceutical and behavioural treatments	MEI (partially and fully implantable)	Population 1: BAHA Population 2: CI Population 3: BAHA Population 4: CI Population 5: BAHA	**Safety:** • complications and AEs • infection rates • taste disturbance • fibrosis • aural fullness • acoustic trauma • dizziness • damage to the middle ear • revision surgery, explant rate, device failure • mortality **Effectiveness:** • APHAB • client-orientated scale of improvement • functional gain • speech recognition • real ear insertion gain • sound-field assessment • speech comprehension scores • tympanometric and acoustic reflex measures • self-assessment scales/patient preference

Application	Population(s)	Intervention	Comparator(s)	Outcomes

1365	People with outer ear pathology that prevents the use of conventional hearing aids who meet all of the following criteria:
	• stable SNHL; AND
	• PTA4 below 80 dB HL with one of the following air conduction thresholds:
	  ○ mild hearing loss – 25 dB ≤ BE $HL_{0.5\text{-}4kHz}$ < 40 dB, or
	  ○ moderate hearing loss – 40 dB ≤ BE $HL_{0.5\text{–}4\ kHz}$ < 70 dB, or
	  ○ severe hearing loss – 70 dB ≤ BE $HL_{0.5\text{–}4\ kHz}$ < 95 dB, AND
	• speech understanding of >65% for word lists with appropriately amplified sound, AND
	• bilateral, symmetrical HL with PTA thresholds in both ears within 20 dB $HL_{0.5\text{-}4\ kHz}$ of each other, AND
	• normal middle ear with:
	  ○ no history of middle ear surgery, AND
	  ○ no history of post-adolescent, chronic middle ear infections, AND
	  ○ normal tympanometry, AND
	  ○ on audiometry, an air-bone gap of no greater than 10 dB $HL_{0.5\text{-}4\ kHz}$ at two or more frequencies, AND
	• no history of other inner ear disorders such as Meniere's disease.
		Vibroplasty (for implantation of an AMEI)[a]	No treatment	Same as Application 1137 but **excluding**:
				• real ear insertion gain
				• tympanometric and acoustic reflex measures

1365.1	Patients with stable SNHL with an outer ear pathology that prevents the wearing of a hearing aid and who have:
	• a PTA4 below 80 dB HL with one of the following air conduction thresholds:
	  ○ mild HL – 25 dB ≤ BE $HL_{0.5\text{-}4kHz}$ < 40 dB; or
	  ○ moderate HL – 40 dB ≤ BE $HL_{0.5\text{–}4\ kHz}$ < 70 dB; or
	  ○ severe HL – 70 dB ≤ BE $HL_{0.5\text{–}4\ kHz}$ < 95 dB; AND
	• have speech perception discrimination of ≥65% correct with appropriately amplified sound; and
	• bilateral, symmetrical SNHL with PTA thresholds in both ears within 20 dB $HL_{0.5\text{-}4kHz}$ of each other; 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 $HL_{0.5\text{-}4kHz}$ at two or more frequencies; and
	• no history of other inner ear disorders such as Meniere's disease.
		Insertion of partially implantable AMEI[a]	No treatment	Consistent with Application 1365

Application	Population(s)	Intervention	Comparator(s)	Outcomes
1364 (withdrawn)	People with CHL or MHL thresholds in the mild to moderate range, who cannot wear conventional hearing aids due to anatomical or medical reasons who meet the following criteria: • unsuitable or unsuccessful alternative treatments (e.g. middle ear surgery, ear reconstruction surgery, anatomical anomalies, chronic pathologies, previous repeated failed middle ear surgeries etc.) • mild to moderate hearing impairment as indicated by British Society of Audiology AC thresholds[b] • pure-tone bone-conduction threshold levels at or within the levels depicted in Figure 1. • stable (<10 dB variations over 2 years for adults) bone conduction thresholds within the shaded area in Figure 1 • speech audiometry curve adequate to the respective PTA • accessible round window or oval window and middle ear anatomy that allows the transducer to be placed on a suitable vibratory structure • absence of active middle ear infections • absence of retro-cochlear or central auditory disorders • speech perception discrimination of ≥65% correct with appropriately amplified sound.	Partially implantable MEI	BCI (percutaneous or transcutaneous)	Same as Application 1365 but **including**: • sound localisation testing • absence of clinical management, maintenance and replacement costs associated with external abutments

AC = air conduction; AE = adverse event; AMEI = active middle ear implant; APHAB = Abbreviated Profile of Hearing Aid Benefit; BAHA = bone anchored hearing aid; BCI = bone conduction implant; BE HL = better ear hearing level; CHL = conductive hearing loss; CI = cochlear implant; dB = decibels; dB HL = decibels hearing level; HA = conventional hearing aid; HL = hearing loss; MEI = middle ear implant; MHL = mixed hearing loss; PTA = pure tone average; PTA4 = 4-frequency pure tone average (typically 500, 1000, 2000, 4000 Hertz); SNHL = sensorineural hearing loss.

a. Proposed and final MBS item descriptor referred to mastoidectomy, not vibroplasty.

b. Mild hearing loss = 20 – 40 dB HL; Moderate hearing loss = 41 – 70 dB HL.

Source: MSAC Application 1137 Assessment report (department contracted), July 2010; MSAC Application 1365 Final Protocol, October 2014; MSAC Application 1365.1 Re-submission to MSAC (applicant developed), October 2015; MSAC Application 1364 Final Protocol, April 2015.

Box 2 Proposed MBS item descriptor in MSAC Application 1364 (withdrawn)

Category 3 – THERAPEUTIC PROCEDURES
MBS item YYYYY Middle ear implant, partially implantable, insertion of, including mastoidectomy, for patients with conductive or mixed hearing loss who meet all the criteria listed below: • ear pathology that prevents the use of a conventional hearing aid • unsuited or unsuccessful to alternative treatments (e.g. middle ear surgery, ear reconstruction surgery, or due to anatomical anomalies, chronic pathologies, or previous repeated failed middle ear surgeries etc.). • mild to moderate hearing impairment as indicated by BSA air-conduction thresholds • stable (less than 10 dB variations over two years for adults), pure-tone bone-conduction threshold levels • speech audiometry curve adequate to the respective PTA • accessible round window or oval window and anatomy that allows the transducer to be placed on a suitable vibratory structure • absence of active middle ear infections • absence of retro-cochlear or central auditory disorders • speech perception discrimination of ≥65% correct with appropriately amplified sound • adequate motivation and expectations (Anaes) **Fee:** $1,876.59 (based on mastoidectomy item at the time)

BSA = British Society of Audiology; dB = decibels; MBS = Medicare Benefits Schedule; MSAC = Medical Benefits Advisory Committee; PTA = pure tone average.

Source: MSAC Application 1364 Final Protocol, April 2015.

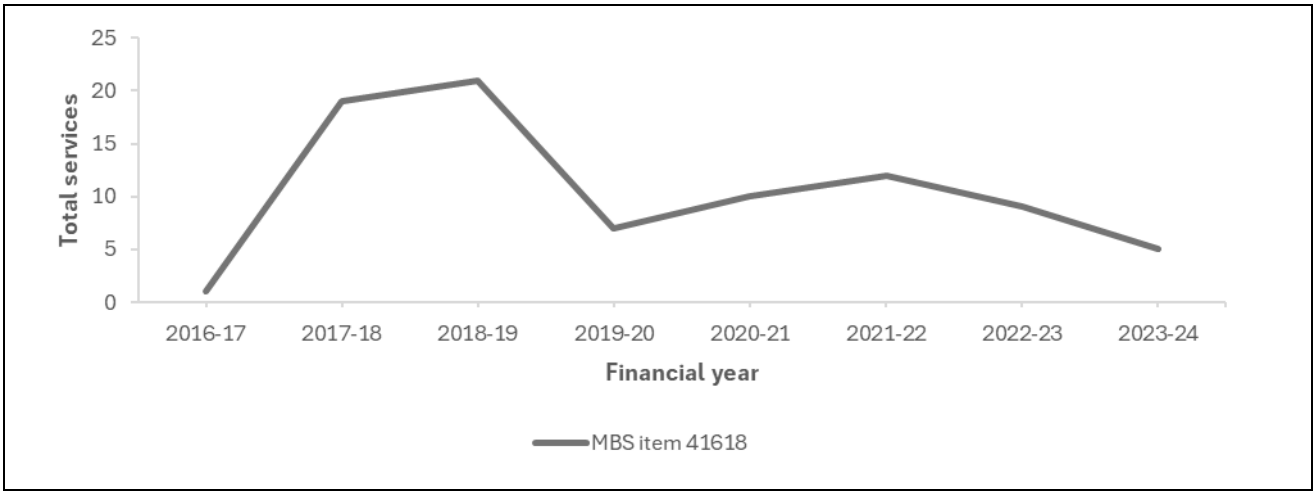
Appendix B Existing MBS items for implantation of hearing devices

Box 3 MBS item for implantation of a middle ear implant for patients with sensorineural hearing loss

Category 3 – THERAPEUTIC PROCEDURES **Group T8 – Surgical Operations** **Subgroup 8 – Ear, Nose And Throat**
MBS item 41618 Middle ear implant, partially implantable, insertion of, via mastoidectomy, for patients with: (a) stable sensorineural hearing loss; and (b) outer ear pathology that prevents the use of a conventional hearing aid; and (c) a PTA4 of less than 80 dB HL; and (d) bilateral, symmetrical hearing loss with PTA thresholds in both ears within 20 dB HL (0.5-4 kHz) of each other; and (e) speech perception discrimination of at least 65% correct for word lists with appropriately amplified sound; and (f) a normal middle ear; and (g) normal tympanometry; and (h) on audiometry, an air-bone gap of less than 10 dB HL (0.5-4 kHz) across all frequencies; and (i) no other inner ear disorders Multiple Operation Rule (Anaes.) (Assist.) **Fee:** $2,189.60 **Benefit:** 75% = $1,642.20

dB HL = decibels hearing level; kHz = kilohertz; MBS = Medicare Benefits Schedule; PTA4 = 4-frequency pure tone average (typically 500, 1000, 2000, 4000 Hertz).
Source: MBS Online, accessed 11 July 2025.

Figure 4 Total services for MBS item 41618, financial years 2016-17 to 2023-24



MBS = Medicare Benefits Schedule.
Source: Medicare Statistics from Services Australia, accessed 20 June 2025.

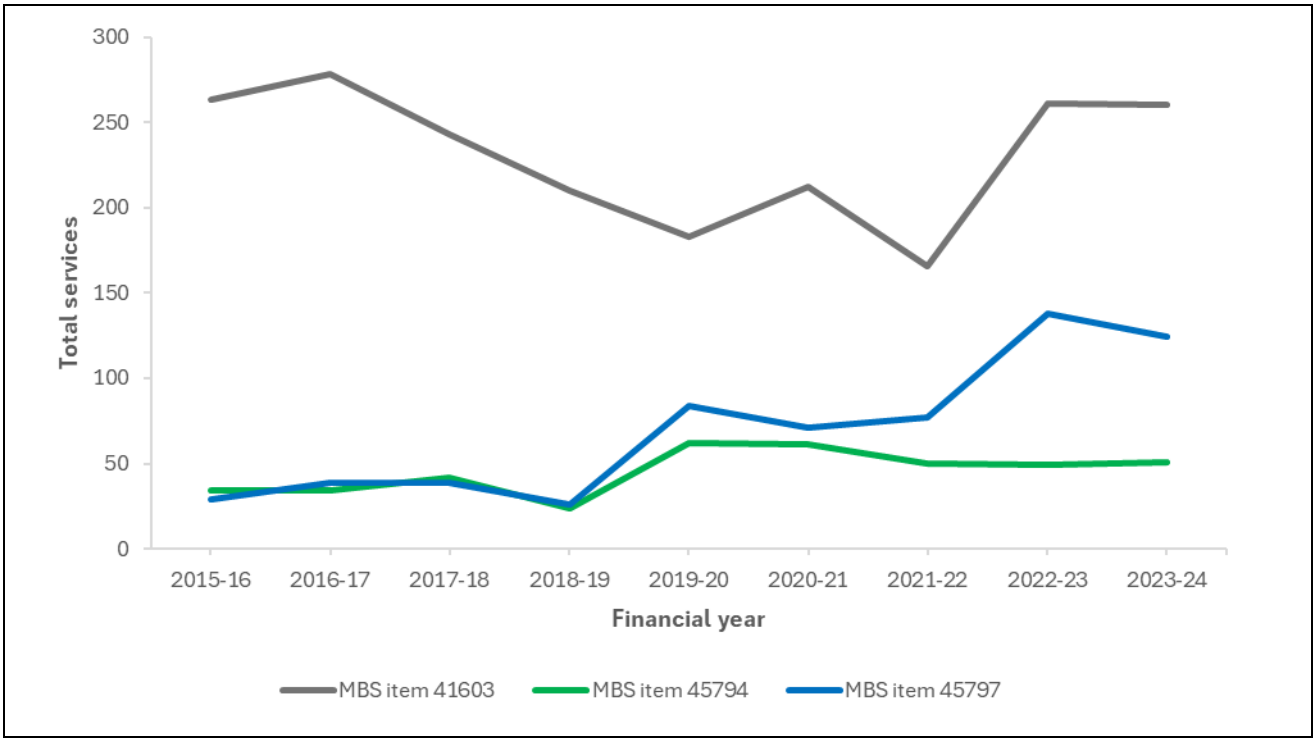
Box 4 MBS items for implantation of bone conduction hearing systems

Category 3 – THERAPEUTIC PROCEDURES **Group T8 – Surgical Operations** **Subgroup 8 – Ear, Nose And Throat**
MBS item 41603 Osseo-integration procedure—implantation of bone conduction hearing system device, in a patient: (a) with a permanent or long term hearing loss; and (b) unable to utilise conventional air or bone conduction hearing aid for medical or audiological reasons; and (c) with bone conduction thresholds that accord with recognised criteria for the implantable bone conduction hearing device being inserted; other than a service associated with a service to which item 41554, 45794 or 45797 applies (H) Multiple Operation Rule (Anaes.) **Fee:** $696.65 **Benefit:** 75% = $522.50
MBS item 45794 Osseo-integration procedure, first stage, implantation of fixture, following congenital absence, tumour or trauma, other than a service associated with a service to which item 41603 applies Multiple Operation Rule (Anaes.) **Fee:** $587.85 **Benefit:** 75% = $440.90 85% = $499.70
MBS item 45797 Osseo-integration procedure, second stage, fixation of transcutaneous abutment, following congenital absence, tumour or trauma, other than a service associated with a service to which item 41603 applies Multiple Operation Rule (Anaes.) **Fee:** $217.60 **Benefit:** 75% = $163.20 85% = $185.00

MBS = Medicare Benefits Schedule.

Source: MBS Online, accessed 11 July 2025.

Figure 5 Total services MBS items 41603, 45794 and 45797, financial years 2015-16 to 2023-24



MBS = Medicare Benefits Schedule.
Source: Medicare Statistics from Services Australia, accessed 20 June 2025.

Table 14 Example MBS items for audiometric testing and programming of hearing devices

Test	MBS item	85% benefit
Performed on behalf of a medical practitioner		
Air and bone conduction and speech discrimination audiogram	11315	$48.75
Impedance audiogram involving tympanometry	11324	$19.70
Programming an auditory implant or the sound processor, unilateral	11302	$190.90
Programming by video attendance of an auditory implant or the sound processor, unilateral	11342	$152.70
Programming by phone attendance of an auditory implant or the sound processor, unilateral	11345	$152.70
Performed by an eligible audiologist		
Air and bone conduction and speech discrimination audiogram	82315	$39.05
Impedance audiogram involving tympanometry	82324	$15.90
Programming an auditory implant or the sound processor, unilateral	82301	$152.70
Programming by video attendance of an auditory implant or the sound processor, unilateral	82302	$152.70
Programming by phone attendance of an auditory implant or the sound processor, unilateral	82304	$152.70

MBS = Medicare Benefits Schedule.
Source: MBS Online, accessed 11 July 2025.