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Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

EVALUATION OF THE REIMBURSEMENT FOR HEARING AIDS AND IMPLANTS IN HEARING LOSS





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Membership of a stakeholder group on which the results of this report could have an impact: Nicolas Baeyens (EDIC ASBL), Naïma Deggouj (ENT department of the university clinics of Saint-Luc, where hearing implant patients are treated), Leo De Raeve (All 4 cochlear implant companies sponsor ONICI annually to a limited extent to advertise their products on our website or in our newsletter), Mark Laureyns (AEA – European Association of Hearing Aid Professionals), Bob Lerut (Belgian ENT society, EAONO), Andrzej Zarowski (Belgian Association for Otorhinolaryngology, Head and Neck Surgery; Belgian Association for Audiology).

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
BAHA	Bone Anchored Hearing Aid
BCD	Bone Conduction Device
BCI	Bilateral Cochlear Implant
(BI)CROS	(Bilateral) Contralateral Routing of Offside Signals
CHA	Conventional Hearing Aid
CHL	Conductive Hearing Loss
CI	Cochlear Implant
CUA	Cost-Utility Analysis
CVC	Consonant vowel consonant
dB	Decibel
ENT	Ear-Nose-Throat
EPS	Echantillon Permanent – Permanente Steekproef
EQ-5D	EuroQol Five Dimensions
HL	Hearing Loss
HTA	Health Technology Assessment
HUI-3	Health Utilities Index 3
Hz	Hertz
ICER	Incremental Cost-Effectiveness Ratio
IMA-AIM	Intermutualistisch Agentschap – Agence Intermutualiste
MEI	Middle Ear Implant
MHL	Mixed Hearing Loss
MZG-RHM	Minimal Hospital Data
nHL	Normal Hearing Level

pBCD	Percutaneous Bone Conduction Device
PTA	Pure Tone Audiometry
SF-36	Short Form 36
SIN	Speech In Noise
SNHL	Sensorineural hearing loss
SNR	Speech-to-noise ratio
SPL	Sound Pressure Level
SRT	Speech Reception Threshold
SSD	Single Sided Deafness
tBCD	Transcutaneous Bone Conduction Device
TCT	Technische Cel – Cellule Technique
TTO	Time Trade Off
UCI	Unilateral Cochlear Implant
VAS	Visual Analog Scale
WTP	Willingness-To-Pay
QALY	Quality-Adjusted Life Years

SCIENTIFIC REPORT

1 INTRODUCTION

1.1 Context, aim and research questions

The World Health Organisation (WHO) estimated in 2018 that around 6% of the world population suffers of disabling hearing loss (i.e. hearing loss of >40 dB in adults and >30 dB in children). Hearing loss starts mostly in adulthood (92%) and often (33%) above the age of 65 years.[1] Two thirds of the burden of disease locates in developing countries and it has been increasing progressively since 1986.[2] Also in 2018, the WHO made a call for action towards all its Member States to integrate strategies for ear and hearing care within the framework of their primary health care systems. Preventing and/or tackling hearing loss is fundamental for the patient (cognition, work, social environment, etc.), but also for the society.[1] In many patients, hearing loss is not sufficiently treated because of several reasons such as people not realizing they have a hearing problem (preventive screening tests could be helpful), esthetical reasons (big devices or devices not attractive), insufficient benefit of the device (patients will switch the device off or leave it out), not meeting the patients' expectations (patients expected to 'hear' better or differently, good counselling is therefore important), not comfortable to wear, expensive non-refunded devices or accessories, etc. Non (optimal) treatment of hearing loss leads to e.g. social deprivation, reduced language development, and could enhance dementia. For these reasons, it is important to prevent hearing loss, but also in case of hearing loss to detect it in an early stage and treat it adequately and accordingly.

Rapid advances in technology have led to many (new) treatment options for different types (e.g. sensorineural, conductive, mixed, unilateral, bilateral) and severities, i.e. mild to profound/deafness, of hearing loss. Besides ear surgery and the conventional hearing aids (CHAs), several implants are now available, such as bone conduction devices (BCDs), middle ear implants (MEIs), cochlear implants (CIs) and auditory brainstem implants. While most people can be helped with conventional hearing aids, some do not benefit enough or cannot wear these devices (e.g. because of anatomical or skin-related issues), and in those cases implants could be considered. We

discuss the causes, severities and different types of hearing loss, together with the different hearing solutions more in detail in chapter 1 of this report.

In Belgium, the RIZIV-INAMI (National Institute for Health and Disability Insurance (NIHDI)) sets the reimbursement fees and the conditions as to who is eligible for reimbursement of the different treatment options for several pathologies including hearing loss. In case of hearing loss, two different commissions within RIZIV-INAMI focus on the reimbursement indications of the different therapies for hearing loss: one commission on the non-implantable hearing devices and one commission on the hearing implants. Of note, as BCDs have an implantable as well as non-implantable part, indications for BCDs are overlapping both commissions. Besides the device, the reimbursement indications take also into account other factors such as the types of hearing loss, population, severity of hearing loss, etc. The current reimbursement indications on hearing aids and implants are listed in chapter 3. As hearing technology evolves rapidly RIZIV-INAMI regularly gets new demands from manufacturers, clinicians and patients to broaden or adjust the reimbursement criteria. In this context, RIZIV-INAMI submitted a study proposal for **an analysis of the current reimbursement criteria and organisational structures especially towards the hearing implants** (such as: are there other indications that should be reimbursed?; are there any overlaps?; are there other devices that should be reimbursed?; could the organisation of care towards the hearing implants be improved?).

Based on the clinical background (chapter 1), the current reimbursement criteria (chapter 3) and the interviews with the experts and stakeholders, we focused on the following research topics:

- The active transcutaneous bone conduction devices.
- A second cochlear implant in adults with bilateral severe-profound hearing loss.
- A cochlear implant in adults and children with single sided deafness.

The specific research questions, concerning these three main topics, are listed in the beginning of the clinical and economic chapter (chapter 4 and chapter 5, respectively). These topics will be consequently discussed in these chapters, and where possible we provide data on costs and expected volumes for budget impact estimations (chapter 6). We looked also to the reimbursement situation in other countries for these topics (chapter 7).

Next to these three main research topics, all options for improvement that are brought up by the experts and stakeholders during the interviews are listed and discussed in chapter 8.

1.2 Methods and report outline

In order to get an understandable view of the hearing aids and hearing implants we provided an overview on the clinical background in chapter 1. Consequently, we listed the reimbursement criteria in Belgium for hearing aids and implants in chapter 3. Together, we consulted and interviewed stakeholders and clinical experts to identify their requests towards improvements for reimbursement, possible overlaps and hiatus in the reimbursement criteria.

Interviews

The interviews took the format of semi-structured interviews. They were conducted face-to-face or telephonically. We interviewed the following respondents:

- RIZIV/INAMI (n=4)
- ENT specialists (n=10, from 7 hospitals), two of them (1 NL and 1 FR) were appointed by the Belgian professional association for ENTs
- Audiologists/speech therapists/clinicians working in a rehabilitation center (n=5, 5 centers)
- Representatives of patient organisations (n=4, 3 organisations)
- Representatives of manufacturers (n=9, 6 companies and beMedTech)
- Representative of the sickness fund (n=1)

The interviews were conducted with one or multiple respondents from the same organisation at a time. The names of the interviewed persons are mentioned in the colophon of this report.

Mostly based on the input from these interviews and the current reimbursement rules, we considered 3 main topics (i.e. active transcutaneous bone conduction devices, a second cochlear implant in adults with bilateral severe-profound hearing loss, and a cochlear implant in adults and children with single sided deafness) that were discussed throughout the report.

However, we established a full list of options for possible improvement (chapter 8), containing all suggestions raised during the interviews. This list does not only pertain to changes in reimbursement indications for implants that are currently already reimbursed, but also to expansion of reimbursement to new implants, as well as to changes in reimbursement level and the organisation of care. These other options were briefly discussed and evaluated when possible.

Expert meeting

In a second stage, a draft version of the report was sent to the expert group. The experts were asked to send their comments either by mail, telephone or during the video-conferencing meeting. Comments from the expert round were incorporated into the draft and this resulted in a final version of the report.

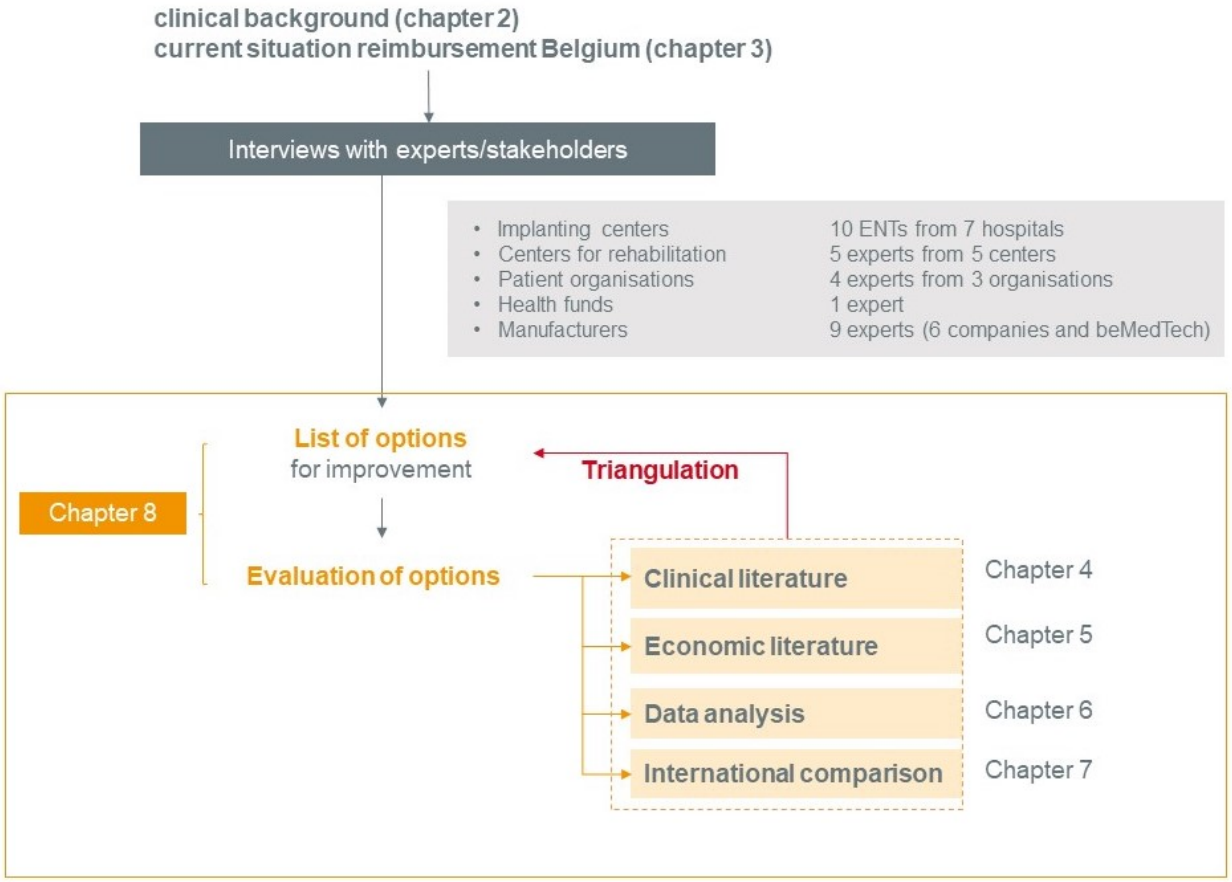
Evaluation and report outline

In order to evaluate each of the options in **chapter 8**, we assembled input from different angles, wherever this input was of relevance and available:

- Introduction (**chapter 1**)
- Clinical background (**chapter 2**)
- Current reimbursement in Belgium (**chapter 3**)
- Clinical evidence (**chapter 4**)
- Economic evidence (**chapter 5**)
- Data analysis (**chapter 6**)
- International comparison (**chapter 7**)

The methods used for these separate chapters are described more in detail at the beginning of each chapter.

Figure 1 – Methodological approach and report outline



2 CLINICAL BACKGROUND

In this chapter we will give some background information on the pathology, causes and types of hearing loss. We provide some information on the hearing devices and implants and list the indications and treatment options.

2.1 Pathology and causes of hearing loss

Hearing works through sound waves entering the ear, moving down the auditory canal of the ear, hitting the eardrum and making it vibrate. These vibrations are then passed to three bones i.e. 'the ossicles' in the middle ear. The ossicles amplify the vibrations, which are then picked up by small hair-like cells in the cochlea. These move as the vibrations hit them, and the movement data is sent through the auditory nerve to the brain. The brain processes the data, which a person with functional hearing will interpret as **sound**.[3]

Sound waves and thus hearing loss are characterized by frequency and intensity. The 'frequency', expressed in **Hertz (Hz)**, corresponds to the amount of vibrations per second. The higher the frequency the higher the sounds. The 'intensity' (amplitude or loudness), in **decibel (dB)**, corresponds to the volume of the sound evoked by the vibration amplitude. The higher the amplitude, the louder the sound.

According to the definition of the WHO, **disabling hearing loss** refers to a hearing loss (HL) > 40 dB in the better hearing ear in adults and a HL > 30 dB in the better hearing ear in children. A person who is not able to hear as well as someone with normal hearing (with hearing thresholds of 25 dB or better in both ears) is said to have **hearing loss (HL)**. Hearing loss may be mild (> 40 dB in adults or > 30 dB in children), moderate (up to 70 dB), severe (up to 90 dB), or profound (> 90 dB). It can affect one ear or both ears, and leads to difficulty in hearing conversational speech and sounds in general.[1]

Hard of hearing refers to people with hearing loss ranging from mild to severe. People who are 'hard of hearing' usually communicate through spoken language and can benefit from conventional hearing aids (CHAs), bone conduction devices (BCDs), and other assistive devices as well as captioning since they have a reduced ability to hear sounds in the same way as other people. People with more significant hearing loss as well as deaf people may benefit from cochlear implants (CIs). **Deaf** people mostly have profound hearing loss, which implies very little or no hearing (the term '**profound deafness**' is used in case the patient is unable to detect sound at all). They often use sign language for communication, as they cannot understand speech through hearing, even when sound is amplified.[3]

The timing of hearing loss can be **congenital** (hearing loss being present at or acquired soon after birth, can be (non)-hereditary or induced by certain complications during pregnancy and childbirth such as maternal rubella, low birth weight, birth asphyxia, use of drugs during pregnancy), genetic or **acquired** (hearing loss at any age such as infectious diseases like meningitis; injury to head or ear; use of certain medication; excessive noise; ageing; wax or foreign bodies in ear canal).[1] Chronic ear infections such as chronic otitis media is the most common cause of hearing loss in children. The majority of congenital hearing loss is due to a genetic cause and genetics are likely to contribute a significant partition of post-lingual and adult-onset hearing loss as well.[4] Understanding these genes and mutations is not only important in the development of gene therapy but also in the understanding of the molecular mechanisms that influence hearing implant (especially CI) outcomes (i.e. see section on auditory neuropathy). Nowadays, more than 500 genes are discovered that could influence hearing loss which illustrates the complexity.[5]

2.2 Types of hearing loss

Basically, there are three main types of hearing loss[3, 6]: sensorineural hearing loss; conductive hearing loss; mixed hearing loss. A further distinction can be made between uni- and bilateral hearing loss and pre- and post-lingual deafness. We describe this typology below as well as the case of auditory neuropathy.

2.2.1 Sensorineural, conductive and mixed hearing loss

Sensorineural hearing loss (SNHL) is caused by dysfunction of (the sensory organ in) the inner ear i.e. (the hair cells in) the cochlea, the auditory nerve, or brain damage. The most frequent cause of sensorineural hearing loss is the damage of hair cells in the cochlea (e.g. with ageing hair cells lose some of their function and hearing deteriorates, by long-term exposure to loud noises, gene mutations).

If the vibrations are not passing through from the outer ear to the inner ear (not reaching the cochlea due to e.g. excessive earwax, glue ear, aural atresia, cholesteatoma, chronic otitis media, malfunctioning ossicles), there is **conductive hearing loss (CHL)**. It is the most common type of hearing loss in children especially caused by build-up of fluid behind the ear drum. It occurs in an air-bone gap > 10 dB when air-conduction threshold > 20 dB while the bone conduction threshold < 20 dB. The maximum air-bone gap possible is about 65 dB.

Mixed hearing loss (MHL) is a combination of conductive and sensorineural hearing loss. Often there is initially conductive hearing loss and through aging the patient develops also sensorineural hearing loss. It occurs when the bone conduction threshold is > 20 dB and the air-bone gap > 10 dB.

2.2.2 Bilateral and unilateral hearing loss

Hearing loss can occur at both ears (**bilateral**) or in one ear (**unilateral**) ranging from mild hearing loss up to deafness. A specific form of unilateral hearing loss is **single sided deafness (SSD),** which is profound unilateral (single sided) sensorineural hearing loss (> 90 dB PTA) or non-functional hearing in one ear, with normal hearing in the other ear.[6] Persons with SSD are unable to spatially separate sources (squelch effect), to double auditory input (summation effect), and the head creates an auditory shadow that blocks sound from reaching the hearing ear (head shadow effect: attenuates high frequency components of sounds at the ear contra-lateral to their source). When also mild to moderate hearing loss is present at the better ear, the patient suffers **asymmetrical hearing loss**.

2.2.3 Prelingual and postlingual deafness

Treatment of hearing loss and its outcomes will depend on **when the hearing loss developed** (timing) i.e. prelingual or postlingual. In the **prelingual phase** (before the age of 3), the auditory cortex is highly plastic and during this phase **speech** (uttering and understanding) as well as **binaural hearing** (necessary to localize sound and perceive speech in noisy environment) is developed. People who developed a normal binaural hearing enjoy certain advantages such as a better speech-to-noise ratio (SNR), the summation effect (improved speech perception through the identification of identical signals arriving in both ears), and a better processing of the input sound signal by the brain from both ears.

Thus, the benefit of implantation during the prelingual phase in case of (sensorineural) deafness or hearing loss will be higher. In fact, if children with prelingual sensorineural deafness are given cochlear implants in infancy (critical window between 12 months and 3yr), they can acquire oral language successfully. In children with unilateral deafness an **aural preference syndrome** could be developed i.e. the developing auditory pathway reorganizes to prefer the hearing ear leaving the deafened ear weakly represented in the auditory system.[7] When the ear with hearing loss is adequately stimulated during the prelingual phase, binaural hearing can be adequately restored.

The benefit of an implant for adults, who are deaf from birth and have not developed binaural hearing or normal speech, will be limited.[8, 9]

However, children or adults who lost their hearing suddenly or progressively (e.g. meningitis, trauma) in the **postlingual phase**, spoken language and binaural hearing were acquired during the sensitive period and can be restored by stimmulating the deafned ear(s). Thus they are eligible to have an implant fitted within a few months.[6, 9, 10]

2.2.4 The special case of auditory neuropathy

Auditory neuropathy is defined as hearing loss in individuals with normally functioning outer hair cells. These receptors are not important for real-time hearing, which is an essential role of the inner hair cells. Due to the wide array of physiologic defects in the auditory system that can cause auditory neuropathy, the more broad term **auditory neuropathy spectrum disorder (ANSD)** is used. It includes lesions affecting the auditory synapse (auditory synaptopathy: presynaptic - inner hair cell or postsynaptic - spiral ganglion) or nerve (auditory neuropathy: spiral ganglion cell bodies and proximal axons). Auditory neuropathy spectrum disorder can be caused by genetic lesions (13 known genes) but can be also caused by environmental factors (e.g. hyperbilirubinemia, thiamine deficiency, hypoxia, noise-induced, age related). Of all people with hearing loss, 1.2% - 8.4% is caused by auditory neuropathy spectrum disorder.[4]

The clinical presentation is characterized by individuals who suffer hearing loss showing normal oto-acoustic emissions or cochlear microphonics, indicating normal cochlear function, together with abnormal transmission of auditory signal from the synapse to the brain (altered auditory brainstem responses). In fact, the inner hair cells and outer hair cells function irrespective of transmission of neural signal, and therefore these lesions result in **auditory dyssynchrony**. Individuals will have difficulty with temporal processing of sound resulting in impaired speech perception and sound localization.

It is important to differentiate two groups i.e. **(i) patients in whom auditory neuropathy spectrum disorder occurs prelingual (e.g. neonates)** and **(ii) patients in whom auditory neuropathy spectrum disorder occurs in the postlingual period.**

2.2.4.1 Auditory neuropathy spectrum disorder in the prelingual phase (neonates and toddlers)

In a population with **prelingual auditory neuropathy spectrum disorder** such as neonates and toddlers, the hearing threshold might improve over time leading towards commonly noted spontaneous remissions.[11] To illustrate: in a group of 75 children, one in five showed some threshold recovery to a level of hearing that allowed adequate speech understanding and language development without a hearing prosthesis.[12] Moreover, 32.7% complete and 9.3% partial recovery was noted at the retest at 4 to 6 months. Thus, some of the children develop relatively normal auditory brainstem responses, indicating the possibility of the development of normal neural function. Yet, these positive findings should be nuanced. After all, children continue to experience difficulties with detecting speech-in-noise (SIN) and cannot be seen as having acquired fully normal hearing.[11]

In Belgium, screening with the automatic auditory brainstem response test and oto-acoustic emission test is consistently done in neonates between 2 and 4 weeks of age, as part of a universal neonatal screening program for hearing loss executed by ‘kind&gezin (K&G) / Office de la Naissance et de l'Enfance (ONE). When the screening result shows the auditory brainstem responses are altered or absent, it is important to verify if oto-acoustic emissions and/or cochlear microphonics are present. If that is the case, it might indicate that the neonate suffers from auditory neuropathy spectrum disorder. The interviewed experts indicate that these tests should be at least repeated 2 times more (e.g. after 3-6 months and at 1y of age), in order to verify if the hearing of the neonate does not recover spontaneously before thinking on advanced therapy, in this case a CI. Thus, implanting a CI before the age of 12 months is not recommended. A negative consequence is that the CI could be placed too late (e.g. average age: 3.3y in auditory neuropathy spectrum disorder, compared to average age of 1.9y in sensorineural hearing loss).[11] The fluctuating character of auditory neuropathy spectrum disorder makes it difficult to balance between the possibility of spontaneous remission and implanting a CI as soon as possible (‘the earlier the better’). However, the opinion of the interviewed experts seems to be in line with the available evidence. When multiple tests, during this prelingual phase, point out the child is suffering from auditory

neuropathy spectrum disorder CI seems to be indicated and could be implanted within the prelingual development time-frame.

2.2.4.2 *Auditory neuropathy spectrum disorder in the postlingual phase (children and adults)*

In postlingual auditory neuropathy spectrum disorder in children and adults, the patient will indicate that (s)he "does not understand anymore what has been said". The results of a tonal audiometry, can be still moderate to good, but the scores on the speech in noise tests are (very) low. Children do not progress with speech understanding and language development as would be expected from their (aided) hearing threshold levels.[11] Adults, are especially hindered in activities of daily living since they do not understand anymore what has been said.

Conventional hearing aids that amplify sound may have limited benefit because of the inability to effectively transmit the neural signal from the cochlear to the brain (due to defective synaptic function or neural conduction). In recent literature, the effectiveness of a cochlear implant is subject of investigation. Positive results of a CI were seen for children with auditory neuropathy spectrum disorder as in children with sensorineural hearing loss: improved hearing skill performance such as sound- and speech localization.[13, 14] However, robust evidence is absent to generally support the effectiveness of a CI in auditory neuropathy spectrum disorder. A returning conclusion is that the 'hearing loss category' auditory neuropathy spectrum disorder is far too heterogeneous (i.e. isolated auditory neuropathy without other confounding issues vs. many co-morbidities and/or anatomical abnormalities) to make definitive statements about outcomes with CI.[11, 13, 15]

A more nuanced perspective and selection of the patients, depending on the exact site of lesion causing hearing loss, is needed to understand the outcomes of CI in auditory neuropathy spectrum disorder.[4] For example, Shearer et al., 2019 found that good results with a CI are achieved in individuals with postlingual auditory neuropathy spectrum disorder with lesions that primarily affect the cochlear sensory system and synapse. In those cases the CI bypasses the lesions (Figure 2). Yet, poor performance was observed for a CI in lesions that affect the auditory nerve. This is probably because neural transmission of the electrical signal from the CI is affected. Therefore, the authors propose that in the future, description of auditory neuropathy spectrum disorder patients should be based on the molecular site of lesion typically derived from genetic evaluation (synaptopathy vs. neuropathy) as this might have implications for expected CI outcomes.

For these reasons, in case auditory neuropathy spectrum disorder occurs in the postlingual period, careful counselling of the patient is needed together with the selection of possible poor and good performers before cochlear implantation.[4]

Figure 2 – Overview of the peripheral auditory system with special attention to cochlear implant physiology

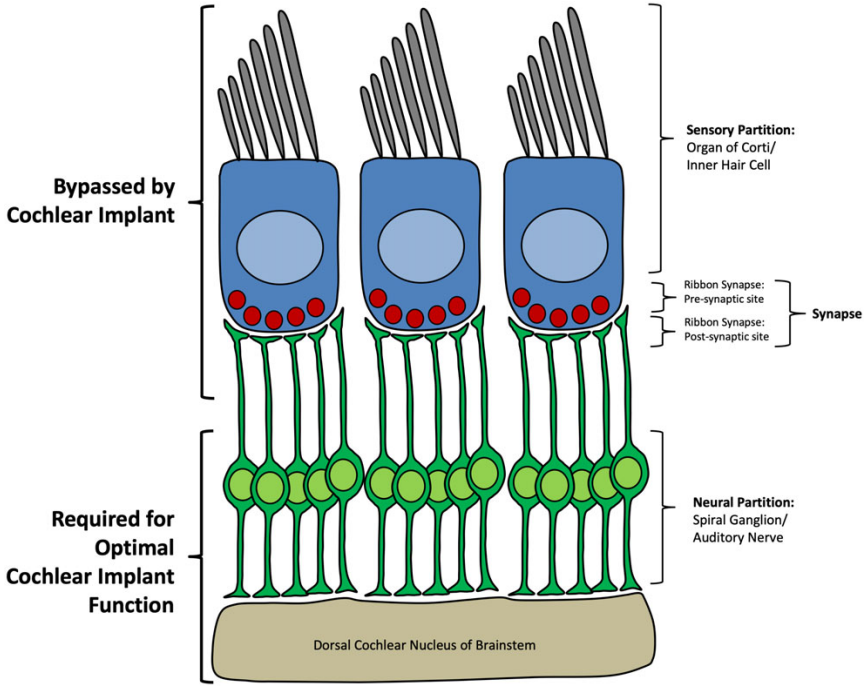


Figure retrieved from Shearer and Hansen 2019[4]

- **When auditory neuropathy spectrum disorder is suspected in the prelingual period, at least multiple tests should be executed during this phase to verify if CI is indicated, as auditory neuropathy can resolve spontaneously.**
- **Currently, the hearing loss category auditory neuropathy spectrum disorder is far too heterogeneous to make definitive statements about outcomes with CI.**

- **Therefore, a more nuanced perspective based on the site of lesion (the cochlear sensory system and synapse lesions but not in case of lesions of the the auditory nerve) in order to estimate the effect of CI in auditory neuropathy spectrum disorder (selection of poor and good performers) is needed.**

2.3 Categorisation of hearing devices: hearing aids and implants

2.3.1 Conventional hearing aid (CHA)

A conventional hearing aid is a small electronic device that is worn in or behind the ear. It makes some sounds louder so that a person with hearing loss can listen, communicate, and participate more fully in daily activities. It can help people hear more in both quiet and noisy situations.[16] A hearing aid consists of three basic parts: a microphone, an amplifier, and a speaker. The sound is cached by the microphone, which converts the sound waves to electrical signals and sends them to an amplifier. The amplifier increases the power of the signals and then sends them to the ear through a speaker. There is also an energy source present.

Monophonic equipment refers to the fact that the hearing aid is at one ear, while in **stereophonic** equipment, both ears have an aid.

There are two electronics used to process the sound i.e. **analogue** (the sound is processed as an electrical impulse) or **digital** (the sound is translated in digital characters by the hearing aid and transduced in an understandable signal for the listener). The majority of the hearing aids make use of digital processing. In Belgium, it is a condition for reimbursement, thus little analogue hearing aids are still on the market.

There are two main categories of hearing aids with many variants [16] ranging from **behind the ear to completely (invisible) in the ear canal**.

Besides the CHAs, there are also the **(Bilateral) Contralateral Routing Offside Signals ((BI)CROS)** hearing aids. These hearing aids are especially useful for people with non-treatable hearing loss/deafness at one ear. In a CROS device, the sound is caught (through a microphone) at the inaccessible ear and transferred to the accessible ear where there is a conventional hearing aid, without influencing the hearing of the healthy ear In case the best ear does not function well, the sound could be also caught by a second microphone with BICROS.[17]

2.3.2 Bone conduction hearing device (BCD)

Until recently, Bone Anchored Hearing Aid (BAHA) was the most used term to describe a hearing aid with bone conduction, and especially percutaneous bone conduction devices (pBCD). However, BAHA is also a brand name (by the Cochlear manufacturer, i.e.BAHA connect (pBCD) and BAHA attract (a transcutaneous bone conduction device) and since more manufacturers started to produce hearing aids with bone conduction, the term Bone Conduction hearing Devices (BCD) is increasingly used and will be further used throughout the report.[16] Note that in the data analysis in Belgium, still the term BAHA is use (with or without bone anchoring) making differenciation in data between the different types of BCD impossible.

A BCD is a small device that is attached to the bone behind the ear. The device transmits sound vibrations directly to the intact/working inner ear (cochlea) through the skull, bypassing the outer and middle ear (e.g. ossicular chain and the round window membrane). There are different types of BCDs. On the one hand, there are **non-implantable BCDs** (vibrations are transmitted through the skin), often used in children when the bone-thickness does not yet allow implantation or used as try-out model during a trial period to see if BCD implantation is useful for the patient. There are many different types, but the headband BCD such as the softband is commonly used. When the bone-thickness allows implantation and the try-out with the headband BCD had favourable results, a BCD can be implanted.

Implantable BCDs (consisting out of an implantable part and a non-implantable part (sound processor)) can be classified into ‘percutaneous’ or ‘transcutaneous’. There are ‘active’ and ‘passive’ devices.

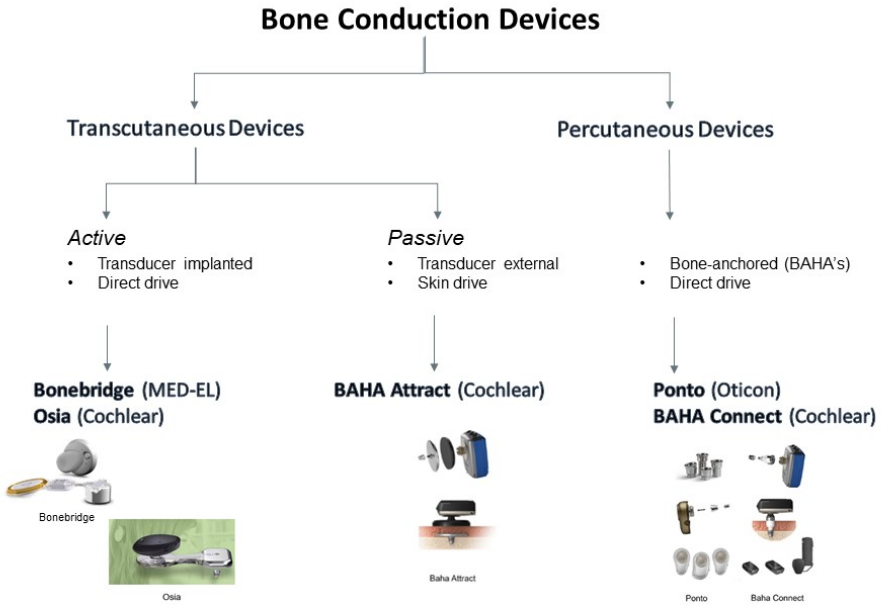
- In percutaneous BCDs (pBCD) such as Baha Connect and Ponto, the abutment (end of a metal screw drilled into the bone = osseointegration) sticks out through the skin and an external audio processor is attached to it. Therefore, the skin is often irritated, since there is a permanent wound, and even chronic skin pathologies can occur. Note that the pBCDs are the ‘real’ bone anchored devices also often referred to as BAHAs.

- For these reasons, the trend exists to opt for a **transcutaneous** BCD (tBCD), since the skin remains intact as it heals over the metal plate and the sound processor is held in place using strong magnets (see Appendix 1.1).[18]
    - Currently there is only one **active** transcutaneous BCD (the Bonebridge) on the market. There is an Food and Drug Administration (FDA) clearance for Osia (Cochlear) and the device is not (yet) on the Belgian market. The semi-implantable Bonebridge consists of an external part i.e. the audioprocessor (Amadé or Samba BB) that picks up sound and generates **signal** that is transmitted to the implantable part. The implantable part (with a receiving coil, a holding magnet, electronics, and a floating mass transducer) that accepts the signal and the floating mass transducer generates the **vibrations** (= active implant) that is applied directly to the bone (= direct drive).
    - In **passive** transcutaneous BCDs (BAHA attract), the external part i.e. the audioprocessor picks up sound and generates **vibrations** that is applied onto the skin. The sound processor needs a transducer (external) that adds to the size and weight. The implantable part mainly consists of a magnet that holds the vibrating audioprocessor in plase and generates skin pressure (= passive implant). the transcutaneous osseointegrated (with anchors to the bone instead of an abutment) implantable unit consist mainly out of a magnet (skin heals over the magnet plate) to keep in place an external audioprocessor that drives sound vibrations into the skull through the skin (skin-drive) Therefore they can be limited in acoustic power at high frequencies.

An overview of the different types of implantable BCDs is given in Figure 3

.

Figure 3 – Most common implanted bone conduction devices (BCDs) in Belgium.



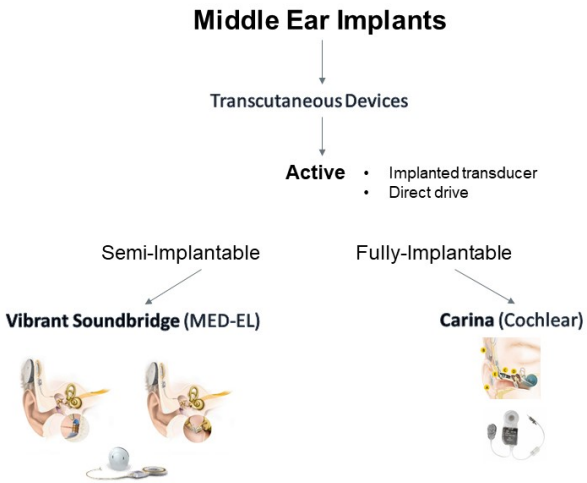
Pictures retrieved from Kozslowski et al.[19], except for Osia (not on Belgian market, FDA clearance) and Bonebridge.

2.3.3 *Middle ear implant (MEI)*

There are mainly two different types of middle ear implants (MEIs): the **semi-implantable** MEI such as the Vibrant Soundbridge (VSB) and the **fully implantable** MEI such as the Esteem or Carina (Figure 4). Although they work differently than the conventional hearing aids, the MEIs are developed to increase the transmission of sound vibrations entering the inner ear.[16] Patients with radical cavities have often had multiple middle ear surgeries with inadequate results and therefore have difficulties wearing conventional hearing aids because of placement loss of the ear mold. In these cases, a MEI solves both: no need for an ear mold and the inner ear is directly stimulated. The floating mass transducer is a small device attached to one of the bones of the middle ear (i.e. 'ossicles), the oval window membrane or the round window membrane (the surgical technique is called vibroplasty).[20] Rather than amplifying the sound traveling to the eardrum, the MEI moves these ossicles or membranes of the inner ear directly. Both the conventional hearing aids as well as the MEIs have the net result of strengthening sound vibrations entering the inner ear so that they can be detected by individuals with sensorineural hearing loss, as well as conductive and mixed hearing loss.[16]

- **Semi implantable MEIs (Vibrant Soundbridge):** A partially implanted MEI consists of an externally worn sound processor and an internal vibrating ossicular prosthesis, kept at place with a magnet. Speech is processed in the sound processor, which transmits the signal transcutaneously to the internal receiver unit. The signal then travels to the electromagnetic floating mass transducer where vibrational energy is realized and either the osccicular chain or inner ear is stimulated directly, depending on transducer's placement. The battery can be changed or upgraded easily, but cosmetically there are visible components.
- **Fully implantable MEI (Carina):** A fully implanted MEI is placed completely into the middle ear. Therefore it is cosmetically invisible. The sensor, using the motion of the incus, sends electric impulses to the speech processor, which modifies the signal. The modified signal is sent from the speech processor to the driver, which vibrates the stapes. The disadvantage is that battery change is only possible by surgery and there could be body sound problems with microphones under the skin. Since May 2020, the Carina is not on the Belgian market anymore.

Figure 4 – Most common implanted middle ear implants (MEIs) in Belgium.



Note: since May 2020 Carina is not available anymore on the Belgian market.

2.3.4 Cochlear implant (CI)

A **cochlear implant** (CI) contains an external microphone and speech processor (including a battery and a transmitter) worn just behind the ear that converts sound into electrical stimuli. These stimuli are captured electromagnetically by a surgically implanted antenna, and directed to the internal electrodes, which stimulate the auditory nerve.[9, 10] The CI bypasses damaged portions of the ear and directly stimulates the auditory nerve.[10, 21]

'Fitting' versus 'Rehabilitation'

With **fitting** of a CI is understood the programming or mapping of the device. It creates a set of instructions (code) that defines the specific characteristics used to stimulate the electrodes of the implanted array.

Often rehabilitation is wrongly seen as a synonym of fitting, however, **rehabilitation** is a broad term that considers auditory training and a multidisciplinary approach of several health care practitioners and could include fitting together with speech therapy (articulation, etc.), psychology (With a CI, patients often expect to hear immediately better, but in fact, they experience to hear worse after implantation. Sounds created by CI are different than natural sounds, therefore patients with CI need to learn how to hear with it.), audiologist (auditory training, etc.), social nurse/worker (who can advise on transportation, accessibility, reimbursement, etc.) and other relevant professions. In case of BCD or MEI, rehabilitation is not required as these implants produce a more natural sound.

With the 6th state reform in 2014, payment and organisation of fitting and rehabilitation for CI has been transferred from the federal (RIZIV-INAMI) to the federated level. Until end 2018 RIZIV-INAMI continued the operational work, from then on the regions took over.

2.3.5 Auditory Brainstem Implant

Auditory Brainstem Implants are fully implanted in the brainstem in case of retrocochlear (neural) hearing loss. It is taken in consideration when the patient cannot benefit from any other hearing device or implant such as a cochlear implant, mainly because there is no (accessible) cochlea or in absence of a nervus cochlearis.[4]

2.4 Indications and treatment options by pathology

For the demarcation of indications for each of the devices described in section 2.3 many different sources of literature are available such as guidelines, clinical literature, manufacturer's websites, CE marking, FDA approvals and reimbursement criteria in other countries. In chapter 3 we give an overview of the indications for reimbursement applied in Belgium. In this section, a brief overview will be given of the treatment options i.e. applied devices by pathology. Of note: Assistive listening devices are useful for all types of hearing loss.

2.4.1 Sensorineural hearing loss (SNHL)

Sensorineural hearing loss is often treated with hearing devices. In mild to moderate sensorineural hearing loss, amplifying sound with **conventional hearing aids** is primarily useful to improve the hearing and speech comprehension. The so called **super power conventional hearing aids** might partly compensate for severe sensorineural hearing loss (≥ 70 dB). But there are limits to the amount of amplification and if the hair cells are too damaged, even large vibrations will not be converted into neural signals. So in profound hearing loss, the conventional hearing aids are often ineffective.[16]

When a conventional hearing aid does not help sufficiently or cannot be worn (Textbox 1) a **BCD** can be considered..

In case of mild to severe sensorineural hearing loss, also a **MEI** might be useful under certain circumstances: maximal hearing loss at the middle ear of 65 dB HL (0.5 kHz) to 85 dB HL (4 kHz).

In the case of profound unilateral or bilateral sensorineural hearing loss (≥ 70 dB HL at the cochlea), a **CI** is the preferred treatment to restore hearing.[22]

Textbox 1 – Reasons for which an air conduction or bone conduction hearing aid cannot be worn

When air conduction (conventional) hearing aid cannot be used, or does not give sufficient improvement:

Problems with: chronical eczema, chronical psoriasis, chronical otitis media, chronical otitis externa, dermatosis, excessive production of ear wax, other.

Medical or anatomic causes which hamper the use of a conventional hearing aid:

Agnesia or microtia of the outer ear; Aplasia, congenital atresia, otospongiosis or uncommon morphology of the middle ear; Stenosis of the ear canal; Multiple ossiculoplastia on the middle ear without audiological result; Otorroe; Cochlear ossifications, absence of cochlear development; Other

When bone conduction hearing aids cannot be used, or does not give improvement:

Problems with: chronic eczema, chronic psoriasis, skin irritation (around abutment), the skin (that prohibit wearing the audioprocessor), bone weakness (quality, too thin, etc.), headache, exostosis, other

2.4.2 *Conductive hearing loss (CHL)*

Conductive hearing loss (depending on the cause) can be treated **medically or surgically** (removal and/or treatment for tumours, antibiotics for infections, removal of earwax build-up, elimination of fluid in middle ear, abnormal bone growth, removal of foreign objects, etc.) and in combination with a hearing device.

A **BCD** is indicated to restore hearing in this pathology (≥ 30 dB HL at the middle ear) as it especially overcomes the conductive hearing loss by transferring sound vibrations directly to the cochlea bypassing outer and middle ear. Especially for those suffering from inoperable conditions, these hearing aids can eliminate the need for the damaged/malformed parts of the ear

Another possible treatment is the use of a **MEI**. This option is especially applied when a conventional hearing aid or BCD is not appropriate (e.g. skin irritations, infections) or does not give enough benefit. It is especially useful when a maximal of 45 dB HL (0.5 kHZ) to 65 dB HL (4 kHz) is present.[22]

2.4.3 *Mixed hearing loss (MHL)*

Conductive hearing loss can be primarily treated **medically or surgically** (removal and/or treatment for tumours, antibiotics for infections, removal of earwax build-up, elimination of fluid in middle ear, abnormal bone growth, removal of foreign objects, etc.) and in combination with a hearing device. Often a **conventional hearing aid** is considered to overcome the sensorineural hearing loss. In case conventional hearing aids are not indicated or there is still significant conductive hearing loss, a **BCD** can be chosen. For a BAHA device, an average bone conduction threshold ≤ 65 dB should be considered, while for an active tBCD a ≤ 45 dB bone conduction threshold at the affected ear or ≤ 20 dB at the contralateral ear is considered. Another possible treatment is the use of a **MEI**. This option is especially applied when a conventional hearing aid or BCD is not appropriate (e.g. skin irritations, infections) or does not give enough benefit..[22]

2.4.4 *Single sided deafness (SSD) and asymmetrical hearing loss (AHL)*

In case of SSD and AHL, a **CROS device** is the first option of treatment. It focusses on the principle of redirecting sound to the hearing ear and thus overcoming the head shadow effect. However, it is poorly accepted (10-20%) due to the occlusion of the better hearing ear and insufficient benefit. The second option to overcome the head shadow effect is with a **BCD** worn as a non-implantable solution or implanted into the skull to activate the hearing ear via bone vibration. In studies comparing CROS with BCDs in SSD, nearly 90% of the patients opt for a BCD.[2] A BCD is especially indicated with unilateral severe to profound sensorineural hearing loss with air and bone conduction thresholds ≥ 70 dB at all frequencies in the affected ear and normal hearing in the contralateral ear. For a BAHA device, a bone conduction threshold ≤ 20 dB should be considered. In the 2000s, FDA approval for the active tBCD was obtained for SSD, and could be considered. The last option is the only treatment focussing on trying to revive the deafened ear and thus restore binaural hearing by using a **CI** (normal anatomy of the cochlea should be present) in SSD. This is a topic of ongoing research. As in SSD tinnitus is often present in the deaf ear, a CI might be the indicated treatment.[23]

3 REIMBURSEMENT OF HEARING AIDS AND IMPLANTS IN BELGIUM

With this chapter we aim to list the current reimbursement criteria for hearing aids and implants in Belgium. Together with the content from the expert interviews, we aim to indicate possible options to be considered for reimbursement.

3.1 Decision-making at RIZIV-INAMI

Two consultation bodies at RIZIV-INAMI are competent for the decision-making on devices for hearing solutions. On the one hand, *the agreement committee of audiciens and insurance institutions (overeenkomstencommissie audiciens / commission de conventions audiciens)* is responsible for the decision-making on conventional hearing aids and the non implantable part of the BCDs. On the other hand, *the Committee for The reimbursement of Implants and Invasive Medical Devices)(Commissie tegemoetkoming implantaten en invasieve medische hulpmiddelen (CTIIMH) / Commission de remboursement des implants et des dispositifs médicaux invasifs (CRIDMI))* is responsible for the (reimbursement of the) implants (see Table 1) (the implantable part of a BCD, CI and MEI) as well as their accessories. [24] [25] Note that the reimbursement of the non-implantable part of a BCD (the sound processor) falls under the competence of the agreement committee of audiciens and insurance institutions while all decisions concerning the reimbursement of the implantable part of a BCD is treated by CTIIMH. The fact that these 2 committees have a different composition and treat the 2 parts of a single device separately from each other, poses problems and could be the reason why the reimbursement for this device is not aligned with the reimbursement for the other hearing solutions.

Table 1 – Competent consultation bodies at RIZIV-INAMI

	Agreement committee of audiciens and insurance institutions	Commission for the reimbursement of implants and invasive medical devices
Domains	• Conventional hearing aids • Sound processor of BCD (non-implantable part)	• CI • MEI • Anchoring system of BCD (implantable part)
Members	• CEUPA (umbrella organisation of the professional organisations for audiciens) • Sickness funds • Representative of the control service of RIZIV-INAMI	Members with decision power: • Universities • Sickness funds • Physicians • Hospital pharmacists Members with advising role • Hospital managers • Fabricants, importers and distributors • Minister of budget and Minister of Health and Social Affairs • Federal Agency for Medicines and Health Products • Dienst voor geneeskundige evaluatie en controle (DGEC) / Service d'évaluation et de controle médicaux (SECM)

CI: cochlear implant, MEI: middle ear implant, BCD: Bone conduction device

3.2 Reimbursed devices

An overview of the suppliers and manufacturers of the available conventional hearing aids and the non-implantable part of BCDs is given in Appendix 2.1.[26]

Table 2 gives an overview of the implants mainly used in Belgium and whether they are reimbursed. Only the Bonebridge (an active transcutaneous BCD) is not yet reimbursed.

Table 2 – Summary of used devices in Belgium

Type of device	Subcategory	Brand (specified versions) (manufacturer)	Reimbursed or not	Reimbursement level
Bone conduction implants	Percutaneous bone conduction devices	Baha connect (Baha 5, Baha 5 power, Baha 5 super power) (Cochlear) Ponto (Ponto Wide implants and BHX implants, sound processors Ponto Plus, Ponto Plus Power, Ponto 3, Ponto 3 Power, Ponto 3 SuperPower, Ponto 4) (Audmet)	Yes	Implant: 100% Sound processor: partly
	Passive transcutaneous bone conduction devices	Baha attract (Cochlear)	Yes	Implant: 100% Sound processor: partly
	Active transcutaneous bone conduction devices	Bonebridge (implant BCI 602, sound processor Samba, Amadé) (MED-EL) Osia (Cochlear)	No (no reimbursement file submitted for Bonebridge; file submitted for Osia)	
Middle ear implants	Semi-implantable MEIs	Vibrant soundbridge (implant VORP 503, sound processor Samba, Amadé) (MED-EL)	Yes, since 2015	Implant : 100% Sound processor : 100%
	Fully implantable MEIs	Carina (Cochlear)	Yes, since 2020 – no longer on the market since May 2020	
Cochlear implants		MED-EL : implants: Synchrony, Synchrony 2, Synchrony pin 2, concerto, concerto pin; sound processors: Opus, Rondo, Sonnet, Sonnet EAS, Sonnet 2, Sonnet EAS 2, Rondo 2) Advanced bionics: implants: HiRes Ultra, HiRes Ultra 3D, HiRes 90K Advantage ; sound processors: HiFocus Mid-Scala, SlimJ, Hifocus 1J, Hifocus Helix) Cochlear: implants: Nucleus Profile Plus CI600 Series Implant, Nucleus Profile CI500 Series Implant, Nucleus CI24RE Series Implant; sound processors: Nucleus 7 CP1000 Sound Processor, Nucleus Kanso CP950 Sound Processor) Audmet: implants: Digisonic SP Classic, Digisonic SP Evo, Neuro ZtiCla, Neuro ZtiEvo; sound processors: Saphyr CX, Saphyr SP, Neuro One, Neuro 2) Neurelec*: implants: Digisonic SP Classic, Digisonic SP Evo; sound processors: Saphyr CX, Saphyr SP	Yes	Implant: 100% Sound processor: 100%

** Reimbursement file will be submitted by Neurelec for new implants Neuro ZtiCla, Neuro ZtiEvo and new sound processor Neuro 2.Source: RIZIV/INAMI*[27]

Note that the reimbursed CIs also include electro-acoustic stimulation (EAS) systems, which consist of an electro-acoustic component coupled to a CI processor. Until recently the electro-acoustic system has been very limited applied in Belgium because of the strict reimbursement criteria for CI. Since the system requires a level of residual hearing, it is a solution especially for patients with severe hearing loss (70 dB – 90 dB) and less for profound hearing loss (> 90 dB). With the new reimbursement criteria for CI in bilateral hearing loss, it is expected that the electro-acoustic system will be applied more in the near future as to protect residual hearing (at low frequency levels) so that patients could still hear naturally basal sounds.

3.3 Reimbursed indications

3.3.1 Conventional hearing aids

The reimbursement criteria for conventional hearing aids are described in article 31 (based on the Royal Decree of 25°November°2018 and entered into force on 1°February°2019) concerning the nomenclature of the audiciens (S-list).[24]

Hearing loss

The **general rule** is that a patient is entitled to reimbursement of a hearing aid when the hearing loss of the (best or worst) ear is ≥ 40 dB, assessed by tonal audiometry (the average of the measurements at a frequency of 1, 2 and 4 kHz).

Hearing aids can also be reimbursed (**exceptions**) when the hearing loss is < 40 dB during tonal audiometry (the average of the measurements at a frequency of 1, 2 and 4 kHz) in the following cases:

- The patient is < 18y old and has permanent (≥ 3 months) hearing loss in which the hearing loss has a negative influence on the speech- or language development or there is a link between the hearing loss and reduced scholary performance. The prescribing ENT specialist describes in the medical file of the patient, the permanent hearing loss and the influence of it on speech- and language development or the association between hearing loss and reduced scolary perfomance.
- The patient has an average hearing loss of ≥ 40 dB with tonal audiometry at the average of three of the following frequency zones: 250, 500, 1 000, 2 000 or 4 000 Hz.
- Based on the tonal audiometry, the air-bone gap is ≥ 30 dB at the average of three of the following frequency zones: 250, 500, 1 000, 2 000 or 4 000 Hz. The air-bone gap is independent of the hearing loss through air conduction.
- The patient is < 65y old and scores 3 dB lower than the normative value during a speech in noise test. The normative value is dependent of the specific speech list, normative for speech audiometry in noise. This rule applies also for patients over 65y in case the rule was applicable before their 65th birthday. In case of stereo adjustment, when at least for one ear one exception is applicable, the nomenclature code for exceptions applies.

In case of (BI)CROS montage, the worst ear should be evaluated to assess hearing loss. The extra reimbursement fee for (BI)CROS adjustment is only applicable with a monophonic device.

Hearing gain

The **general rule** implies that the hearing aid should provide a hearing gain of ≥ 5 dB against the vocal index or 5% gain in speech intelligibility without noise.

- A test with monophonic equipment includes a measurement done in free field without and with monophonic equipment.
- A test with stereophonic equipment includes a binaural measurement done in free field without and with stereophonic equipment. The test report of the stereophonic device should indicate an objectified and more accurate localisation of the sound source (expressed in percentage or degree) in comparison with the monophonic device. There need to be an improvement of at least 10° or 10% with a location test of the stereophonic device compared to the monophonic device. It

should be shown with a broadband signal (e.g. speech, noise) or high frequency (≥ 1 000 Hz) narrowband signal.

In the following cases (**exceptions**) the added value of the device can be indicated otherwise:

- For children < 6y old or with a mental age of < 6y old (proof should be kept in the medical file), a speech audiometry test and localisation test are not needed. The hearing gain should be objectivated by the audicien with the use of an observation test or another appropriate test.
- For patients 6-18y old with a permanent hearing loss < 40 dB a speech audiometry in noise can be conducted. The test is conducted in free field, with a noise level of 60 dB sound pressure level (SPL), with noise from the same speaker. Improvement of 2 dB signal-noise ratio (SNR) for 50 % score or 10 % in speech intelligibility on SNR of the speech reception threshold (SRT).
- If in case of medical reasons (speaking a foreign language is not a medical reason) a speech audiometry is not possible, a tonal audiometry in free field should be conducted. Based on this test, on the same frequencies as the measurement of hearing loss, an average minimum gain of 10 dB should be shown.

Contralateral device

In **general**, a reimbursement fee for a contralateral device is given to switch from a monophonic towards a stereophonic device if the following three conditions are fulfilled:

- The ear complies with the requirements for hearing loss and hearing gain (as described above)
- At the moment of providing the monophonic device, the entitled person did not comply with the reimbursement criteria for a stereophonic device.
- The contralateral device is given at least one year and maximum 4 years after the monophonic device.

An **exception** is made for patients who meet the reimbursement conditions for a CI, who already had a monophonic device and have to choose between a CI and a CHA for the other ear. In this case, after motivation of a multidisciplinary team, the patient can be reimbursed for a switch from a monophonic to a stereophonic device. Also, in case a patient with a stereophonic device decides to renew only one (monophonic) hearing aid before the standard renewal term because of deterioration of at least 20 dB. This patient can get reimbursement for renewal of the other hearing aid until at least 4 years after delivery of the new monophonic device.

Renewal terms

In **general**, the reimbursement for monophonic or stereophonic hearing aids can be allowed after

- 3y for children who were at the time of the previous delivery < 18y old, and
- 5y for adults who were at the time of the previous delivery > 18y old.

Exceptions are that

- the delivery of a contralateral aid does not influence the renewal term, **and**
- if before the age of 3 a first aid is delivered, an additional aid can be requested of another type for children < 6y old.

The reimbursement for monophonic or stereophonic aids can be renewed if:

- there is, minimum at one ear, a deterioration of at least 20 dB on the average of 3 out of 5 frequency zones (250, 500, 1 000, 2 000, 4 000 Hz) compared to the hearing loss at the time of the previous delivery; **and**
- if the patient, due to medical reasons, needs to switch from a hearing aid with air conduction towards a bone anchored hearing aid (or vice versa).

General criteria for reimbursement of conventional hearing aids (exceptions listed above):

- Hearing loss: ≥ 40 dB PTA (average of measurements at 1, 2, and 4 kHz).
- Hearing gain: ≥ 5 dB against the vocal index or 5% gain in speech intelligibility without noise.
- Contralateral hearing aid (stereophonic):
  - The second ear complies with the requirements for hearing loss and hearing gain.
  - At the moment of providing the monophonic device, the entitled person did not comply with the reimbursement criteria for a stereophonic device.
  - The contralateral device is given 1yr-4yr after the monophonic device.

3.3.2 *Implantable part of the bone conduction devices*

The Royal Decree of 26°November°2015 stipulates no criteria related to the reimbursement of the implantable part of the reimbursed bone conduction devices.[28]

3.3.3 *Middle Ear Implants*

The conditions for reimbursement (concerning indications / centre's / implants) and the nominative list with all implants that are approved for reimbursement are decided on by the CTIIMH within the RIZIV/INAMI and are available in the list of reimbursed implants and invasive medical devices.[29]

An active MEI is defined as a medical device with the purpose of compensating hearing loss by transducing sound waves to electrical signals and conduct the vibrations towards one of the ossicles, the oval window or round window.

The kits for active MEIs should contain at least:

- For all implants: all components necessary for the implantation
- For the implants with implanted microphone: a charger for the rechargable battery of the microphone and a remote control for the patient
- For the sound processor: a remote control for the patient

The general condition of the patient should allow the implantation of the middle ear implant and the sustainable and optimal use of the aid. The indications are listed in Table 3. Basically it considers the same criteria as CHA's AND compliant with CE marking AND solid motivation why CHA's are not doable.

Note that there is reimbursement for only one ear (no reimbursement for the contralateral ear in case of bilateral implantation).

Table 3 – Indications for reimbursement of the MEI

General indications	Additional indications in case of sensorineural hearing loss	Additional indications in case of conductive or mixed hearing loss
Age as stated in CE marking for the aid (user manual), AND	Intact ear drum and ventilated middle ear, **AND**	**Or** BCD not indicated for medical or anatomical reasons†, **or** measurements in free field with a bone conduction simulator show a gain of < 5 dB against the vocal index or < 5% gain in speech intelligibility test without noise, **AND**
Minimal bilateral hearing loss in each ear, based on tonal audiometry, of ≥ 40 dB as average value on three out of five frequency zones i.e. 250, 500 1 000, 2 000, and 4 000 Hz, AND	Tonal air conduction thresholds are the once indicated in the CE marking of the implantable device as stated in the user manual, **AND**	In case of preceding reconstructive middle ear surgery with elimination of the pathology, but with limited hearing by a difference in air- and bone conduction threshold (air-bone gap) ≥ 30 dB, **AND**
Or a trial period of ≥ 3 months with a conventional hearing aid£ in the ear to implant that points out that the patient does not experience sufficient advantage, **or having a medical or anatomic pathology that hinders wearing a conventional hearing aid*, AND**	The difference between air- and bone conduction thresholds (the "air-bone gap") is not bigger than 10 dB for each of the frequencies 500, 1 000, 2 000, 4 000 Hz at the implantable ear	Bone conduction thresholds are the once indicated in the CE marking of the implantable device as stated in the user manual.
Auditory tests indicating a stable hearing loss during at least a 2 year period (< 15 dB HL difference at the average of 3 of the 5 following frequencies: 250, 500, 1000, 2000, 4000 Hz) should be kept in the medical record of the patient		
The absence of active middle ear infections at the implantable ear, AND		
The absence of skin problems, which limit wearing the audio processor, AND		
The absence of chronic diseases of the inner ear such as dissiness or Menière disease.		
Absence of every contraindication noted in the user manual of the implantable device following CE marking.		

**Possible reasons the person is not able to wear a conventional hearing aid or the patient does not experience sufficient advantage: chronic eczema, chronic psoriasis, chronic otitis media, dermatosis, excessive production ear wax, etc.*

£Medical reasons why a trial period with a conventional hearing aid is not necessary: agenesis or microtia of the external ear, aplasia, congenital atresia, otospongiosis or unusual morphology of the middle ear, stenosis of the ear canal, multiple ossiculoplasties on the middle ear, without audiologic results, etc.

†Contra-indications to wear a BCD in case of mixed or conductive hearing loss: not able to place BCD due to bone thickness or bone quality, exostosis, etc.

dB: decibel, HL: hearing loss, nHL: normal hearing level, CVC: Consonant vowel consonant, SPL: sound pressure level, BCD: Bone conduction device

No supplementary indications for fully implantable devices.[29]

In case of a non-implantable sound processor there are supplementary indications:

- **OR** the air- or bone conduction thresholds are the ones stated by the CE marking of the implantable device are covered by the use of the implant in combination with the external sound processor; AND there should be a phoneemscore at 70 dB SPL without the use of a CHA or sound ampifier ≥ 50 %. This should be shown by speech audiometry based on monosyllabic lists (type consonant-vowel-consonant (CVC)).
- **OR** the air- or bone conduction thresholds are the ones stated by the CE marking of the implantable device are covered by the use of the implant without the external sound processor; **AND**
  - **OR** the hearing gain is limited by feedback problems or interferences with internal sounds with the implantated sound processor;
  - **OR** the hearing gain is limited AND there is an improvement of at least 10% in speech intelligibility testing at 70 dB SPL by using the external sound processor. This should be tested by speech audiometry in free field based on monosyllabic lists (type CVC) executed in quiet or noise.

Request procedures and request forms

The request for reimbursement is done before or after the implantation by the ENT who performed the implantation by filling out the request form (C-I-07 (new implant) or C-I-08 (replacement), C-I-13 (new external sound processor), C-I-14 (replacement external sound processor)) and by submitting it to the College of Medical doctors-directors. The decision of the college is reported simultaneously to the hospital pharmacist, the advising specialist and the ENT specialist.

A device to be considered for reimbursement should be:

- **OR** FDA with PMA approved
- **OR** have one or more publications in a peer reviewed journal (at least 200 patients) for that type of hearing loss (at least 20 patients), in which its clinical effectiveness is shown.

Rules for replacement

Reimbursement for replacement of the sound processor of MEI can only be obtained at least 5 years after implantation or replacement and when the previous device is broken.

Reimbursement of the implantable part of MEI can only be obtained at least 10 years after reimbursement of implantation or replacement.

A MEI can be implanted in all 3 types of hearing loss (i.e. sensorineural, conductive and mixed).

General criteria for reimbursement:

- Bilateral hearing loss in each ear age following CE marking: ≥ 40 dB PTA at ≥ 3 frequencies: .25, .5, 1, 2 and 4 kHz.
- Trial period with CHA indicates no sufficient advantage or skin problems (unable to wear CHA).
- No active middle ear infections, chronic diseases of the middle ear, skin problems or other contra indications as stated in the user manual of the implantable device (CE marking).

Extra criteria for sensorineural hearing loss:

- Intact ear-drum and ventilated ear.
- Air conduction: indicated in the CE marking of the implantable device (user manual).
- Air-bone gap ≤ 10dB for each frequency (.5, 1, 2, and 4 kHz).

Extra criteria for conductive and mixed hearing loss:

- Bone conduction: indicated in the CE marking of the implantable device (user manual)
- Air-bone gap ≥ 30 dB (in case of preceding surgery)
- Contra-indication for BCD or not sufficient gain from BCD

3.3.4 Cochlear Implants

The reimbursed indications and conditions (on nursing unit and implant), as well as procedures and rules related to the reimbursement of a CI are listed in the nomenclature list and the nominative list of the RIZIV/INAMI.[30]

The Belgian reimbursement criteria for CIs in bilateral hearing loss or deafness have been enlarged in 2019. With these adjustments, the threshold audiometric value was lowered from ≥ 85 dB to ≥ 70 dB HL.[30] Full details on the most recent criteria are listed in Table 4.

Table 4 – Indications for reimbursement of a cochlear implant.

Patient with bilateral hearing loss; for the first ear
The assessments indicate the existence of hearing loss at both ears, in compliance with all of the following conditions: • The average air conduction threshold with tonal and/or behaviour audiometry under headphone is ≥ 70 dB at ≥ 3 of the following frequencies: 500, 1 000, 2 000, and 4 000 Hz. In case of absence of hearing at one or more frequencies, a threshold of 120 dB HL needs to be used for calculation, AND • A BERA test indicates a threshold of peak V ≥ 75 dB nHL, AND • With patients ≥ 6 years, without the use of a suitable hearing aid or amplifier, the phoneme score should be ≤ 50% at 70 dB SPL via speech audiometry in free field based on monosyllabic lists (CVC type).
Patient with asymmetrical bilateral hearing loss
The assessments indicate the existence of hearing loss at the best ear, in compliance with all of the following conditions: • In case of tonal and/or behaviour audiometry under headphone is ≥ 60 dB HL at ≥ 3 of the following frequencies: 500, 1 000, 2 000, and 4 000 Hz. In case of absence of hearing at one or more frequencies, a threshold of 120 dB HL should be used for calculation, AND • A BERA test indicates a threshold of peak V ≥ 65 dB nHL. The assessments indicate the existence of hearing loss at the most deteriorated ear, in compliance with all of the following conditions: • In case of tonal and/or behaviour audiometry under headphone is ≥ 85 dB HL at ≥ 3 of the following frequencies: 500, 1 000, 2 000, and 4 000 Hz. In case of absence of hearing at one or more frequencies, a threshold of 120 dB HL should be used for calculation, AND • A BERA test indicates a threshold of peak V ≥ 90 dB nHL, AND • With patients ≥ 6 years, without the use of a suitable hearing aid or amplifier, the phoneme score should be ≤ 30% at 70 dB SPL via speech audiometry in free field based on monosyllabic lists (CVC type). The implantation of the CI should be executed within 3 years after the determination of hearing loss of at least 60 dB HL at the best ear and before the age of 12. The nomenclature numbers are only applicable for the most deteriorated ear.
Patient with bilateral hearing loss and threatening bilateral ossification; for the first ear
The assessments indicate the existence of hearing loss at both ears, in compliance with all of the following conditions:

- The average air conduction threshold with tonal and/or behaviour audiometry under headphone is ≥ 70 dB HL at ≥ 3 of the following frequencies: 500, 1 000, 2 000, and 4 000 Hz. In case of deafness on one or more frequencies, 120 dB HL needs to be used for calculations, AND
- A BERA test indicates a threshold of peak V ≥ 75 dB nHL, AND
- There is fibrosis or threatening ossification.

Patient with auditory neuropathy; for the first ear

The assessments indicate the existence of hearing loss at both ears, in compliance with all of the following conditions:

- A BERA test at a threshold of 75 dB nHL, gives no response or abnormal bad synchronised responses for both ears, that cannot be explained by the space occupying processes in the bridge angle of a tumour located at the 8th nerve (an acoustic neuroma), AND
- For patients old enough to conduct speech audiometry (≥ 6 years), the average air conduction threshold with tonal and/or behaviour audiometry under headphone of both ears is not in compliance with the results of the speech audiometry, AND
- There is remaining function of the outer hair cells of the cochlea of at least one of both ears, based on oto-acoustic emission and/or cochlear microphone potentials, AND
- In patients with pre-lingual deafness there is a lag in speech development (shown with use of a hearing aid), AND
- In patients with post-lingual deafness and ≥ 6 years, without the use of a suitable hearing aid or amplifier, the phoneme score should be ≤ 50% at 70 dB SPL via speech audiometry in free field based on monosyllabic lists (CVC type).

Patient with OR bilateral deafness, OR bilateral deafness with threatening bilateral ossification, OR auditory neuropathy; for the contralateral ear

The patient received reimbursement for the first CI for bilateral deafness, or bilateral deafness with threatening bilateral ossification, or auditory neuropathy.

In case the patient received reimbursement for the first CI for asymmetrical bilateral hearing loss, it should be shown that the contralateral ear has evolved towards bilateral deafness (in congruence with the conditions listed above).

If the patient fulfils the criteria for bilateral hearing loss, (s)he can receive a CI for the contralateral ear up until the age of 12yr. After the age of 12, only the CI for the first implanted ear is reimbursed.

If the patient fulfils the criteria for bilateral hearing loss with threatening ossification OR auditory neuropathy, (s)he can receive a CI for the contralateral ear up until the age of 18yr. After the age of 18, no contralateral CI is reimbursed.

dB: decibel, HL: hearing loss, nHL: normal hearing level, BERA: Brainstem evoked response audiometry, CVC: Consonant vowel consonant, SPL: sound pressure level, CI: cochlear implant, Hz: Hertz, . With contralateral ear is meant the ear that receives as last the CI.

General criteria concerning the patient

There are general criteria a patient should fulfil to be eligible for reimbursement of the CI:

- The general condition of the patient should allow the implantation of the CI and the sustainable and optimal use of the device.
- Depending on the pathology, the age, the timing of hearing loss (pre-lingual or post-lingual) and the intended results of the implantation, the patient should be oriented towards follow up containing speech therapy or a multidisciplinary rehabilitation program. This should be discussed with the patient (or its authorized parent), before implantation.
- The speech therapist or the centre that is indicated for follow up should be presented to the patient.
- The multidisciplinary implant team of the nursing unit should be available to answer question of the patient concerning hearing rehabilitation, in consultation with the speech therapist or the centre.
- In case of mental retardation, psychological or psychiatrical problems, in children or adults, a psychological advice should be added to the request. Specifically, the familial context and the ability to participate in speech therapy or multidisciplinary rehabilitation of the patient should be judged.

Specific rules for reimbursement

For the first implantation and the implantation of the contralateral ear, the reimbursement should be provided if the implantation was conducted within 6 months after the approval of the advising specialist or College of Medical doctors-directors (sending date).

The approval of reimbursement expires on the birthday of the patient who reached the ultimate age stated in the nomenclature number within the 6 months period.

Rules for replacement

Reimbursement for renewal of the sound processor is possible after 3 years in children until the age of 8 and after 5 years above that age.

Reimbursement for the replacement of the implantable parts can be provided minimum 10 years after the implantation of the ear.

Request procedures and request forms

In case of the first implantation

The request for reimbursement is done by the ENT specialist who is part of the team who performed or will perform the implantation in that specific nursing unit. Through the request for reimbursement forms, the expected personalized end-results of the speech therapy or multidisciplinary rehabilitation should be indicated in the request for reimbursement form.

Depending on the reimbursement procedure, the advising specialist or the College of Medical doctors-directors shares his/its motivated decision within 45 days after receiving the request for reimbursement form. This decision is immediately and at the same time shared with the hospital pharmacist and the ENT specialist who submitted the form.

In case of auditory neuropathy for the first ear the request form should contain the expectations towards speech understanding of the patient after CI, specifically if there are indications towards post-synaptic neuropathy.

In case speech audiometry of the patient ≥ 6 years old is not executable e.g. in case of mental retardation (not a contra-indication for CI), the reason should be explicitly given on the request form and motivated through a psychiatric or psychologic report.

In case of a replacement

In case the replacement was of an implant that was not reimbursed by the compulsory insurance, the document of the first implantation should be used to show that the first implantation was eligible for reimbursement, and the C-Form-I-12 should be filled out by the ENT specialist who is part of the team who (will) execute(d) the replacement and submitted to CTIIMH.

The process of timing and the communication of the decision is similar to the one described above (in case of the first implantation).

Preliminary replacement within the guarantee terms described above (criteria concerning the implant) can be approved by the CTIIMH based on a motivated medical file and after the evaluation of the aid is not within the guaranty conditions.

CI is reimbursed for the following indications in Belgium (all conditions need to be fulfilled):

Criteria for CI in bilateral hearing loss:

- ≥ 70 dB PTA at ≥ 3 frequencies: .5, 1, 2 and 4 kHz in both ears
- BERA peak V ≥ 75 dB nHL
- Phoneme score at ≤ 50 %, at 70 dB SPL in quiet without hearing aids/amplification (≥ 6yr).

If the patient fulfils the criteria for bilateral hearing loss, (s)he can receive a first (unilateral) or a second (bilateral) CI up until the age of 12yr. After the age of 12, only the first CI is reimbursed.

Criteria for CI in asymmetrical hearing loss:

- Measured at the best ear:
  - 60 dB PTA at ≥ 3 frequencies: .5, 1, 2 and 4 kHz
  - BERA peak V ≥ 65 dB nHL
- Measured at the worst ear:
  - ≥ 85 dB PTA at ≥ 3 frequencies: .5, 1, 2 and 4 kHz
  - BERA peak V ≥ 90 dB nHL
  - Phoneme score at ≤ 30 %, at 70 dB SPL in quiet without hearing aids/amplification (≥ 6yr).

If the patient fulfils the criteria for asymmetrical hearing loss, (s)he can receive a first (unilateral) CI up until the age of 12yr. After the age of 12, no CI is reimbursed.

Criteria for CI in bilateral hearing loss and threatening ossification:

- ≥ 70 dB PTA at ≥ 3 frequencies: .5, 1, 2 and 4 kHz in both ears
- BERA peak V ≥ 75 dB nHL
- Fibrosis or threatening ossification

If the patient fulfils the criteria for bilateral hearing loss with threatening ossification, (s)he can receive a first (unilateral) or second (bilateral) CI up until the age of 18yr. After the age of 18, no CI is reimbursed.

Criteria for CI in auditory neuropathy:

- BERA peak V ≥ 75 dB nHL
- Speech audiometry ((≥ 6yr): average air conduction threshold with tonal and/or behaviour audiometry (headphone) of both ears is not in compliance with the results of the speech audiometry
- Oto-acoustic emissions and/or cochlear microphonic potentials present
- Prelingual deafness: lag in speech development (with use of hearing aids)
- Postlingual deafness: phoneme score at ≤ 50 %, 70 dB SPL in quiet without hearing aids/amplification (≥ 6yr).

If the patient fulfils the criteria for auditory neuropathy, (s)he can receive a first (unilateral) or second (bilateral) CI up until the age of 18yr. After the age of 18, no CI is reimbursed.

The following indications are currently not reimbursed in Belgium:

- Unilateral CI in children and adults (all ages) for single sided deafness
- Contralateral (second) CI in children (≥12 yr) and adults with bilateral hearing loss
- Unilateral (first) CI in children (≥12 yr) and adults with asymmetrical hearing loss
- Contralateral (second) CI in children and adults (all ages) with asymmetrical hearing loss.
- Unilateral and/or bilateral CI in adults (≥18 yr) for bilateral hearing loss with threatening ossification or auditory neuropathy.

3.3.5 *Exceptional reimbursement by Special Solidarity Fund*

In exceptional cases patients who do not meet the reimbursement criteria for CI have been reimbursed through the Special Solidarity Fund. In the previous years, requests have been approved for the following indications:

- Usher syndrome (contralateral CI after 12 years)
- Intracochlear schwannoma
- Children with unilateral or bilateral hearing loss after infection with CMV or meningitis and who do not meet the threshold hearing loss levels
- Bilateral hearing loss with progressive loss of vision (contralateral CI after 12 years).

3.4 Reimbursement fees and out-of-pocket expenditures

3.4.1 *Conventional hearing aids and the sound processor of bone conduction devices*

Reimbursement fees depend on the age of the patient (<18y, 18-64y, or ≥65y) and on the type of hearing aid:

- Monophonic (unilateral hearing aid)
- Stereophonic (bilateral hearing aid)
- Contralateral to convert a monophonic hearing aid to a stereophonic hearing aid

The fees can be combined with an extra fee for:

- a BCD that is bone anchored
- a BCD that is not bone anchored
- the microphone (wired or wireless) for a (BI)CROS adjustment

We refer to Appendix 5.1 (of the data analysis chapter) for the detailed reimbursement fees.

In case of a BCD the patient gets a base reimbursement for the hearing aid like for conventional hearing aids. On top of that, an additional reimbursement fee is provided, which is differentiated for bone conduction without bone anchored device (e.g. softband) and bone conduction with bone anchoring (see Table 5). Mind that especially in children, who cannot have an implanted bone anchored device, these reimbursement fees do not cover the price that is charged for the processor. In case the children are older, and the skull is thick enough to implant the BCD, the nomenclature fee and reimbursement is higher. Since it is a procedure, in some cases the hospitalisation insurance will cover some of the costs.

Table 5 – Summary of reimbursement fees for sound processor of bone conduction device (2020) from January 1 2020.

Age (y)	Base reimburement for the hearing aid	Extra reimbursement for the bone conduction		
		Bone conduction without bone anchoring	Bone conduction with bone anchoring (first device)	Bone conduction with bone anchoring (renewal device)
Monophonic				
< 18	€ 1 203,06	€ 99,66	€ 1 658,61	€ 1 092,69
18-64	€ 733,16	€ 99,66	€ 740,32	€ 443,13
≥ 65	€ 694,14	€ 99,66	€ 740,32	€ 443,13
Stereophonic				
< 18	€ 2 382,99	€ 199,32	€ 1 658,61	€ 1 092,69
18-64	€ 1 451,26	€ 199,32	€ 740,32	€ 443,13
≥ 65	€ 1 373,98	€ 199,32	€ 740,32	€ 443,13

The advisory retail prices for Baha 5, Baha 5 POWER and Baha 5 SUPERPOWER (including 6% VAT) range from around € 4 330 to € 4 540. In fact, the range of reimbursement for a specific medical device is based on a case-by-case analysis. This means that when the manufacturer submits a file for reimbursement of a device, every device/implant is looked at separately and the CTIIMH decides upon the level of reimbursement and reimbursement basis.

3.4.2 Implantable part of bone conduction devices

The implantable part of bone conduction devices is fully reimbursed, thus there is no out-of-pocket payment. We refer to Appendix 5.1 for the detailed fees. Mind that supplements for the medical act/hospital stay (procedure) can be billed.

3.4.3 Middle Ear Implants

The first middle ear implant is fully reimbursed, except in case of the replacement of the sound processor for which there is an out-of-pocket fee of up to € 1,00. We refer to Appendix 5.1 for the detailed fees.

3.4.4 Cochlear Implants

Both the implant and the procedure is reimbursed with zero co-payment when approved (nomenclature fees listed in appendix). Separate fees and reimbursement apply for the fitting and rehabilitation sessions. For CI extra costs are at charge of the patient, like an insurance for unforeseen damage or robbery (estimated at around €175/year) and battery costs - although most recent CIs work with rechargeable batteries. Other costs include potential co-payments for fitting and rehabilitation sessions, transportation costs towards the CI centre for the fitting and rehabilitation sessions, small reparation costs, etc.(Table 6).

Table 6 – Out-of-pocket expenditures for cochlear implants (prices are a rough estimation)

	With reimbursement by RIZIV/INAMI	Without RIZIV/INAMI reimbursement
Implanted device	€ 0	€ 11 000
Hospitalization	€ 300 for a two person bedroom (majority of this amount will be refunded in case of a hospitalization insurance)	
Sound processor (non-implantable part)	€ 150	€ 6 000
Replacement sound processor	Every 5 years - ±€150	No refund, expected lifespan 5-15 years
Supplementary insurance	€ 120 per year	
CI fitting	First 4 years: € 1.80/ hour After 4 years: € 35-55 per session	€ 35-70 per session
Auditory training	First 4 years: € 1.80 per session	No refund
Guarantee	By law depending on the manufacturer that the cochlear implant fulfils the expectations.	
Batteries	In case of disposable batteries: € 150 per year In case of rechargeable batteries, no supplementary costs (only when the rechargeable battery is broke)	

3.5 Conditions imposed to the implanting units

3.5.1 Middle Ear Implants

The MEI implant can only be billed to and reimbursed to the patient when placed and followed up in a nursing unit that complies to the following criteria: A specialized unit for otolaryngology that has a multidisciplinary team with at least 1 FTE speech therapist, 1 FTE audicien/audiologist, and 1 FTE ENT doctor. They are in charge of the clinical and audiometrical evaluation pre-implantation, the implantation, adjustment of the aid, and audiological and medical follow-up.

3.5.2 Cochlear Implants

Same conditions applied as for MEIs (see above). These services should provide assistance at all times.

3.6 Conditions for the implants

3.6.1 Middle Ear Implants

The implant is only reimbursed if it complies with one of the following criteria:

- approved by the FDA, or
- availability of one or more clinical studies published in a peer-reviewed journal with together at least 200 patients with similar indication, which shows its efficacy compared to other aids described in the nominative list.

The implant can be considered by the CTIIMH as a minor modification of an implant already on the normative list if:

- there is detailed and documented information that the implant is only a minor modification and does not concern a new implant, and

- there is information about the extent to which the slightly modified implant is reimbursed in other European countries. A change in electromagnetic mass is never considered as a minor change. In case the CTIIMH judges that the aid cannot be considered as minor modification, the CTIIMH should decide if this implant should be seen as 'modification or 'new aid'. For a change which is not considered 'minor', a report or scientific publication should illustrate the efficacy based on the implantation in at least 10 patients.

The implants listed in the nominative list have a guarantee of 10 years on the implantable part, and a 5 year guarantee on the non-implantable part (processor and battery holder).

3.6.2 Cochlear Implants

- The kit should at least contain the full hearing device or the non-implantable piece, 1 extra rechargeable battery, 1 charger for the rechargeable battery, 2 antennes (or 2 coils and 2 magnets), 5 cables and 12 earwires or wires or snugfits or formed earpieces.
- 10 year full guarantee at 100% on the implantable parts, and 3 year for the most important non-implantable parts (processor and battery holder).

For the CI kits for children ≥ 8 years old:

- The kit should at least contain the full hearing device or the non-implantable piece, 1 extra rechargeable battery, 1 charger for the rechargeable battery, 3 antennes (or 3 coils and 3 magnets), 7 cables and 12 earwires or wires or snugfits or formed earpieces.
- 10 year full guarantee at 100% on the implantable parts and 5 year at 100% for the most important non-implantable parts (processor and battery holder).

With contralateral ear is meant the ear that received as last the implant.

4 CLINICAL EVIDENCE

This chapter will provide an overview of the main results from the systematic clinical literature search concerning the three main topics.

4.1 Research questions

Taking into consideration the input from the experts and stakeholders, 3 main topics were considered and we stated the following research questions:

1. What is the clinical effectiveness of the active transcutaneous bone conduction implants?
2. What is the clinical effectiveness of bilateral cochlear implantation (compared to unilateral cochlear implantation) in bilateral hearing loss in adults?
3. What is the clinical effectiveness of cochlear implants and other hearing solutions in single sided deafness with or without tinnitus?
4. What is the clinical effectiveness of fully implantable middle ear implants and semi-implantable middle ear implants? *(Note that this was initially a research question, but since May 2020, the fully implantable middle ear implant is not anymore available on the Belgian market. We decided to leave it in the clinical part of the report but will not come back to it further in the report).*
5. What is the safety of hearing implants, and are there complications or adverse events reported?

4.2 Methodology

4.2.1 Search strategy

Instead of applying separate searches we decided to construct one general systematic search strategy. We formulated one generic PICO(S) for the literature search (Table 7):

- The population (P) in which we were interested are adults and children with unilateral or bilateral hearing loss (all types, all grades) or deafness (all types, all grades).
- The interventions (I) considered were: hearing implants i.e. bone conduction devices, middle ear implants, and cochlear implants.
- The comparators (C) are no treatment as well as treatment with one or more of the listed interventions, auditory brainstem implants, or (conventional) hearing aids. We decided not to search on comparator but to exclude articles during the screening process.
- Only systematic reviews, health technology assessments (including a systematic review, or review of reviews), review of reviews or meta-analyses were included as study design (S).
- We decided not to search on outcome (O) but to exclude articles during the screening process based on irrelevant (to this project) outcomes (e.g. articles that describe technical procedures, pathophysiology, assistive technologies, burden of disease, assessment) or to include articles assessing outcomes such as speech perception (in quiet and noise), sound localization, (subjective) quality of hearing, hearing specific quality of life, speech and language development.

The studies were selected on the following languages: English, Dutch, German, French, and Spanish. Since hearing technologies evolve very fast, the studies had to be published within the last 5 years (from 2014 to 2019).

Table 7 – Selection criteria of the systematic search based on the PICOs structure.

	Inclusion	Exclusion
Population (P)	Adults or children with unilateral, asymmetric or bilateral hearing loss (all types, all grades) or deafness.	Animals Adults or children without hearing loss Studies on populations with multiple or complex pathologies who might have hearing loss
Intervention (I)	Bone conduction devices (all types) Middle ear implants (all types) Cochlear implants	Interventions not related to hearing aids or implants to improve hearing.
Comparison (C)	No treatment Placebo devices (conventional) hearing aids (with or without (BI)CROS) Bone conduction devices Middle ear implants	

	Cochlear implants intervention Auditory brain stem implants	
Outcome (O)	Speech perception in quiet Speech perception in noise Sound localization (Subjective) quality of hearing Hearing specific quality of life Speech and language development Tinnitus Complications, safety, adverse events of the hearing implants	Articles that describe technical procedures Pathophysiology Assistive technologies Burden of disease Assessment
Study Design (S)	Systematic review Meta-analysis HTA (including systematic review) Review of reviews	

We constructed the search strategy using Medical Subject Headings (Mesh) and relevant keywords especially considering the population, the interventions and the study design. The search was conducted on 2019-09-10 in the following databases: the Cochrane Database of Systematic Reviews (Cochrane Library – Wiley), Embase (Embase.com), and Medline (OVID)(Appendix 3.1). Suggested references from different sources (external experts, exploratory searches in the bibliographical databases, and hand search of the key references) were added to the search results. All identified references were imported in Rayyan (https://rayyan.qcri.org/reviews/82698), and deduplication was manually executed. First, the retrieved articles were screened by one researcher (J.C.) based on the in- and exclusion criteria listed in Table 7 and labelled 'included', 'excluded' or 'tentative' based on title and abstract. Thereafter, the 'included' and 'tentative' articles were screened on full text. Then, the included articles were labelled by topic (research question). The results of the search are listed in section 4.3.

In case a review of reviews was retrieved, the search strategy and results were compared with our retrieved articles and selection criteria. If the review of reviews identified other reviews which were not retrieved by our search, these were verified and added if relevant, full text were searched and results discussed. Thus, the retrieved review of reviews are not summarized, instead they were used as a source to identify the included reviews.

In case only one review was found to answer a specific research question, the results of the review were summarized and discussed in order to answer the research question.

4.2.2 *Data to retrieve*

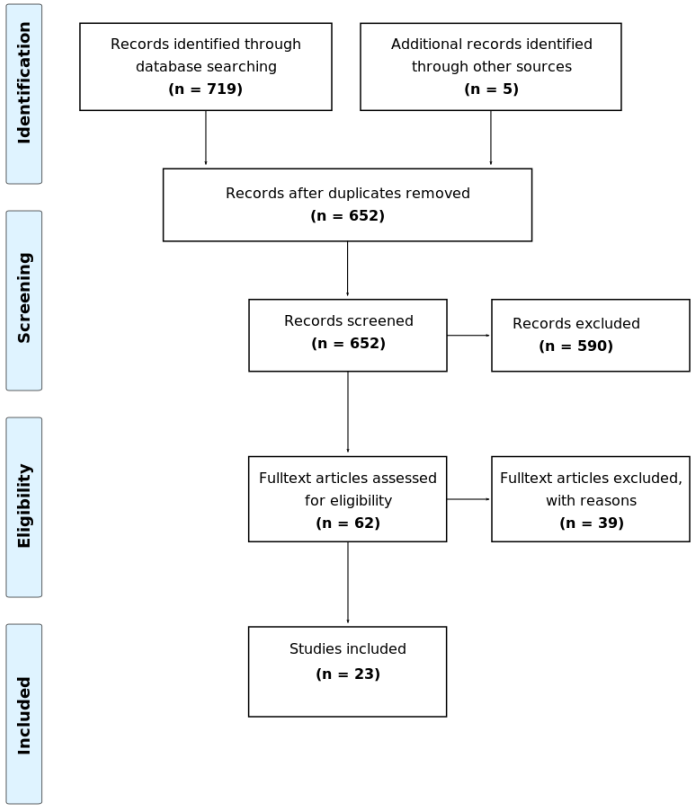
Depending upon the research questions, the following data were retrieved: author(s), year of publication, objectives of the study, number of articles included in the review (or number of reviews included in review of reviews), databases searched (e.g. name, number, search period), quality assessment (e.g. risk of bias, level of evidence, level of the recommendation), number of primary studies, description of the population (e.g. number of patients/ears, child/adult, age, type of hearing loss), general conclusions of the study, selected outcomes, and device types (and brand). It should be noted that we considered the devices (the implants) as a class of technology instead of reviewing the devices of individual manufacturers, implant models, or sound processors. If primary numeric data were not reported, descriptions such as 'no change', 'similar', 'improvement', or 'deterioration' were used. Various outcome measures were reported and for consistency, they were grouped into speech audiometry in quiet, speech audiometry in noise, sound localization, tinnitus, hearing-specific quality of life (e.g. patient satisfaction, subjective benefits of hearing), and speech and language development. Safety, adverse events, and/or complications concerning the hearing implants were listed.

Each research question will be discussed consequently. We will describe a short section on the articles included and each question is answered with the data retrieved from the studies.

4.3 Results of the systematic search

The literature search yielded 719 citations (Cochrane CDSR (n=19), Embase (n=54), Medline (n=359)). Five additional records were identified via handsearch. After deduplication (n=652) and first screening based on the in- and exclusion criteria listed in Table 7, 62 articles remained for full text evaluation. Ultimately, 23 articles (21 reviews, 1 HTA including a systematic review, 1 HTA including a review of reviews) were retained, answering the research questions (Figure 5).

Figure 5 – Four phase flow chart diagram of the selection process



4.4 Answering the research questions: results of the literature search

An overview and general description of the included studies is given in Appendix 3.2 (Table 59, Table 60). In these tables a description of the objectives, methods, search results, quality assessment and conclusions of the articles was given. Also a description of the primary studies, included population, intervention, comparator, and outcomes can be found there. An overview of the applied evaluation tools across the articles to measure the outcomes is given in Appendix 3.3 (Table 61).

Note that across this clinical part, all included studies represent a high heterogeneity in included populations and comparators. Moreover the quality of the studies was rather low, characterized by small sample sizes and heterogeneous assessment (there seem to be no universal standards on how to measure auditory performance (only audiometry is fully standardized)). All results presented in this chapter, should be interpreted with care and no hard statements can be drawn.

4.4.1 Clinical effectiveness of active transcutaneous bone conduction implants.

Existing pBCDs provide significant audiological gain but are often associated with skin complications. This has led to the development of passive tBCDs, however, audiological benefit may be compromised. An active tBCD, the Bonebridge, was introduced and first implanted in 2011 as part of a clinical trial and launched onto the EU market in September 2012. Two years after its initial launch it was already implanted in 200 centres around the world and received CE approval in 2014 for implantation in children aged 5 years and above.[2] In July 2018 FDA clearance was obtained for the active tBCDs in patients ≥ 12 years with single sided deafness, conductive or mixed hearing loss since a trend exists to move away from the pBCDs.

Of note, these results will partly overlap with the effectiveness of an active tBCD for SSD discussed in section 4.4.3.

Our search retrieved 3 citations describing the clinical effectiveness of active transcutaneous bone conduction implants. The 2020 Health Quality Ontario report was retrieved in which a review of reviews was conducted.[6] Only one review[2] was included that assessed the active tBCD in single sided deafness, conductive and mixed hearing loss. This review was also retrieved by our search and thus we decided to discuss the original review. The second citation is a recent review and meta-analysis by Magele et al. 2019 assessing the active tBCDs.[18] We will focus here on discussing the clinical effectiveness and subjective benefit of the active tBCD, while safety of the devices will be discussed in section 4.4.5.

Clinical effectiveness of the Bonebridge in SSD

Aided sound field thresholds (**audiometry**) of 20 dB to 40 dB with the hearing ear plugged were noted in 10 patients. The functional gain in 10 patients with SSD weighted via meta-analysis was 28.94 dB SPL [95%CI: 16.92; 40.96] represented by high heterogeneity (I^2=89.9%). Also for **speech recognition in quiet**, an improvement in word recognition (18% to 90%) and speech recognition thresholds (34.5 to 32.3 dB) was seen in this population. However, in a cohort group (7 studies, 78 subjects), meta-analysis[18] results showed the Word Recognition Score improved with 38.33% [95% CI: 8.42; 63.24] with high heterogeneity (I^2=88.9%) but this was a low result due to the SSD group reporting a word recognition score of 16% [95%CI: -17.26; 49.26]. Towards **speech perception in noise**, the Bonebridge showed to improve the signal-to-noise ratio by 1.3 to 2.5 dB (depending upon configurations) in 2 case series including 14 patients. Of note, an improvement of 2 to 3 dB in signal-to-noise ratio is stated to be clinically important. Data for meta-analysis could not be pooled but an improvement in speech understanding in noise was seen with the Bonebridge, especially when noise was presented from the normal hearing side and speech was provided on the deaf side. Towards **sound localization**, numbers are too small to draw conclusions or perform meta-analysis.[18]

Hearing specific quality of life was significantly improved with the Abbreviated profile of Hearing Aid Benefit (ease of conversation improved from 20% to 7%; background noise from 69% to 46% and listening in reverberant condition 43% vs 27%) in 10 patients. Improvements were also noted with the Glasgow Benefit Inventory and the Hearing Device Satisfaction Scale but no numeric data were shown. Many different tests were used describing a small study sample, therefore data could not be pooled but generally positive results were obtained.

Clinical effectiveness of the Bonebridge in conductive and mixed hearing loss

Functional gains in audiometry of 24 to 37 dB were reported in 7 studies (n=58) comparing Bonebridge to no treatment in adults and children.[2] This was in congruence with the mean functional gain of 32.7±16 dB reported in Magele et al.[18] and the weighted meta-analysis result of 30.89 dB SPL [95%CI: 27.53; 34.24]. It should be noted that the reported heterogeneity (I^2=87.9%) is high. An improvement of 10-15 dB in hearing threshold is considered clinically important. A sub-analysis of the functional gain in 30 patients with conductive hearing loss resulted in a gain of 39.48 dB SPL [95%CI: 35.25; 43.71] represented by low heterogeneity (I^2=26.9%) and in 58 patients with mixed hearing loss resulted in a functional gain of 29.08 dB SPL [95%CI: 26.32; 31.83] represented by low heterogeneity (I^2=0.0%). Significant improvement in **speech perception in quiet** (Freiburger disyllabic words improved 77% to 93% with the Bonebridge) were noted in five studies. A mean improvement of 19 to 36 dB was noted after receiving the Bonebridge in four studies by the 50% speech reception threshold. The mean WRS score reported by 27 studies improved with almost 60% (25.73±23.64% to 84.48±15.09%); the word recognition score improved with 56.73% [5%CI: 45.52; 67.94] with high heterogeneity (I^2=90.4) in the group with 57 patients suffering conductive hearing loss, while the word recognition score improved with 55.14% [95%CI: 21.67; 88.68] with high heterogeneity (I^2=92.1%) in 31 patients suffering mixed hearing loss.[18] **Speech perception in noise** showed aided signal-to-noise ratio values improved from -2 to -6.5 dB indicating no difference with preoperatively worn conventional hearing aids (3 studies, 23 patients). Meta-analysis data could not be pooled but in all studies for subjects with conductive or mixed hearing loss, an improvement in speech in noise understanding was observed with the Bonebridge. The mean aided signal-to-noise ratio values in 54 patients with conductive and mixed hearing loss ranged from +2.9 dB to -6.1 dB SNR, compared to +11.5 to -3.8 SNR unaided. If noise was presented from the front an average improvement of 5.5 dB SNR was reported. Overall, large variability was observed between individuals but results were always favouring the Bonebridge condition. **Sound localization** was only investigated in 4 adults, showing a variable performance. Numbers are too small to draw conclusions or perform meta-analysis.

Improvements in **hearing specific quality of life** (Glasgow Benefit Inventory, on average 32.4 ± 13.5) and higher **patient satisfaction** (Hearing Device Satisfaction Scale) were noted in one study and was high (79%) and stable over time. Two 12 to 18 and 24 months follow-up studies presented stable results in functional gain, word recognition score (even higher over-time), and speech reception threshold and therefore treatment with the Bonebridge demonstrated to show stable results in conductive and mixed hearing loss. Many different tests were used describing a small study sample, therefore data could not be pooled but generally positive results were obtained.[18]

Improved audiometric thresholds and intelligibility for speech in quiet and noise, is reflected in high levels of subjective satisfaction reported by the users of a Bonebridge via several questionnaires in all three types of hearing loss. Nonetheless, the limitations of the research should be emphasized: testing methodologies and language varies (important for the results of word recognition scores) across study sites in various countries; the level of evidence was low comprising mainly cohort and case-control studies leading to potentially biased conclusions. Therefore, caution in drawing conclusions in the overall performance of the device of treatment has to be taken. Based on current evidence, we cannot conclude that the Bonebridge is better than an alternative device but it can be a valuable treatment option.

In literature, the only active tBCD that was assessed is the 'Bonebridge'. Since December 2019, FDA clearance for reimbursement was obtained for another active tBCD named 'Osia' (Cochlear manufacturer). Preliminary literature is being published.[31, 32]

4.4.2 *Clinical effectiveness of bilateral CI (compared to unilateral CI) in bilateral hearing loss in adults.*

Our search did not retrieve reviews investigating the clinical effectiveness of bilateral CI in bilateral hearing loss in adults, however we retrieved an HTA investigating this topic i.e. the 2018 Health Quality Ontario report 'Bilateral cochlear implantation: A health technology assessment'. A systematic literature review was conducted on bilateral cochlear implantation in adults and children from inception to March 2017.[33] To scope their search they conducted also a search of available systematic reviews and found only systematic reviews published before 2014 (thus our search did not retrieved those reviews). The clinical effectiveness of bilateral CI in bilateral hearing loss in children (since bilateral cochlear implantation in children up till 12 year with bilateral severe-profound hearing loss is already reimbursed in Belgium) was not part of our research question and will not be discussed.

From the initial 1 718 publications, the authors retrieved 24 articles of which 10 described bilateral CI in an adult population.

There were 3 randomized controlled trials (RCTs) of which 2 reported on the same trial (n=38) comparing bilateral CI and unilateral CI in adults with severe bilateral SNHL. The other trial randomized 24 adults with severe bilateral SNHL in which 12 adults received a bilateral CI at the start of the study while the other 12 adults had to wait 6 months (wait-list control). The other studies were prospective observational studies in which 6 compared bilateral CI with unilateral CI with or without hearing aids in the non-implanted ear, using patients as their own controls. The last prospective observational study was a cohort analysis of a RCT (the one which included 38 patients) that compared simultaneous bilateral CI with unilateral CI in separate groups. The sample size across the observational studies ranged between 15 and 40 adults and the majority reported on follow up at several time points the first year of implantation.

Of note, the test measures used across the studies differ largely (different tests, test configurations, outcome measures, ranges of follow up, etc.) making direct comparison between studies very difficult. There was heterogeneity in methods, study design, patient characteristics (e.g. imbalanced patient characteristics included in the observational groups), reporting of results, and ears implanted. Moreover, when patients with bilateral CI serve as their own control by switching of one CI it does not represent true unilateral hearing. This should be taken into account when interpreting the summarized results.

The RCTs showed no significant difference for **speech perception in quiet** at 12 and 24 months of follow-up, in contrast, the patients with bilateral CI performed significantly better compared to patients with unilateral CI at 1 to 12 months of follow up in the observational studies (GRADE: low-moderate). In the RCTs a significant improvement was seen in patients with bilateral CI (compared to unilateral CI) of **speech perception in noise** when noise came from different directions but only in the worst hearing situation. Almost all observational studies reported a significant benefit, which was sustained over time (GRADE: moderate). All studies (RCT: n=2; Observational: n=3) that reported on **sound localization**, showed that patients with bilateral CI were better able to locate sounds from various directions compared to patients with a unilateral CI (GRADE: high). The speech, spatial and quality of hearing questionnaire was used by five of the studies (RCT: n=3, Observational: n=2) to assess the **subjective benefits of hearing**. Speech perception under different sound environments and better sound localization with bilateral CI was noted (GRADE: moderate). Towards 'quality', the results were inconsistent. One observational study showed that patients with bilateral CI performed better towards ease of communication, background noise, and reverberant listening conditions compared to patients with unilateral CI. No significant difference in aversiveness to sounds was noted. Moreover, one observational study used the Oldenburg inventory and showed that patients with bilateral CI performed significantly better than patients with unilateral CI towards hearing in noise, quiet, and sound localization. The majority of reported results (RCT: n=3, Observational: n=2)

on **quality of life** showed no significant difference between bilateral and unilateral CI. The reported effects of bilateral CI in **tinnitus** were inconsistent as decrease of tinnitus after the second CI, no significant difference, and also increase of tinnitus after the second CI were noted (GRADE: low).

When comparing bilateral CI to unilateral CI in adults with severe to profound sensorineural bilateral hearing loss was found:

- **High level of evidence for improvements in sound localization.**
- **Moderate level of evidence for improvements in speech perception in noise and subjective benefits of hearing.**
- **Low to moderate level of evidence for speech perception in quiet.**
- **Low level of evidence for tinnitus and quality of life (inconclusive results).**

4.4.3 Clinical effectiveness of cochlear implant and other hearing solutions in single sided deafness with or without tinnitus

We will discuss this research question in 3 steps. First we will discuss the effectiveness of current reimbursed therapies, after we will list the results for the effectiveness of CI in SSD, and finally we will discuss the effect of CI on tinnitus in SSD.

4.4.3.1 The effectiveness of current reimbursed therapies in SSD

Nine reviews described the effectiveness of currently reimbursed therapies (i.e. CHA, CROS hearing aid, frequency modulation and/or BCD) for adults and children with SSD. Of note, only data defined as 'SSD' or 'unilateral sensorineural hearing loss' are retrieved and described in Appendix 3.4 (Table 62).

Outcomes for non-surgical interventions: CHA, CROS hearing aid, and/or frequency modulation.

One review[34] included five studies accounting for 32 patients in which **objective and/or functional outcomes** of conventional hearing aids (n=3) and/or frequency modulation/CROS (n=2) in SSD were described. Concerning conventional hearing aids no benefit or harm was seen in functional and objective outcomes (including Bamford-Kowald-Bench (BKB) scores, audiometry, and sound localization) in one study while two others reported some improvement specifically for 'hearing in noise' and 'sound localization'. Improvement was reported in the functional CHILD score (measurement of communication needs in home environment) by one study (average improvement CHILD-child 1.25 and CHILD-parent 1.18). Concerning the CROS hearing aids, results were inconclusive since one study reported on worsened objective auditory outcome scores especially in noisy environments, while another study indicated CROS could improve objective outcomes in specific classroom settings. Benefits of frequency modulation systems on objective measures were reported in two studies and these systems have shown to be beneficial especially in classroom settings.(Table 8)

Another review[35] indicated that the outcomes for **speech perception in noise** varied across studies, configurations, and conditions and no uniform improvement was seen. Inconclusive results were reported for **sound localization** as improvements, deficits and no differences were noted.[35, 36] **Quality of hearing** was improved with CROS.[35]

Table 8 – Effect of aided (non-surgical interventions) versus unaided conditions on hearing outcomes.

	CHA	CROS	Frequency Modulation
Objective outcomes	=/+	-/+	+
Functional outcomes	+		
Speech perception in noise		-/+	
Sound localization		-/+	
Quality of hearing / QoL		+	

+: improvement, -/+: inconsistent results, =: no change, =/+: no change to small improvement, CHA: Conventional hearing aids, CROS: Countralateral routing off signals, QoL: Quality of Life.

Outcomes for surgical intervention: BCD

Four reviews described **objective audiometry measures** of which two for passive tBCDs i.e. Sophono and BAHA[34, 37] and two for an active tBCD i.e. Bonebridge in children and/or adults with SSD[2, 18]. All tBCDs improved objective audiometry measures including pure-tone average (PTA), speech recognition threshold (SRT), hearing in noise test (HINT) scores, and word recognition scores (WRS). Implantation of BAHA and Sophono both resulted in objective improvement but the BAHA had a greater audiological benefit (Table 9).

Studies[2, 18, 35, 36, 38, 39] showed some improvements in **speech perception in noise** (tested in various configurations of spatially separated speakers) as either the speech-in-noise ratio (SNR) in dB at which 50% of speech was understood correctly, or the total percentage of correctly repeated words. However, the effectiveness of the devices depended on where noise originated i.e. the best results were achieved when noise was presented at the hearing ear and speech or sound was presented at the deaf ear.

Considering the **sound localization**, no (significant) improvements were reported which was expected since BCDs do not restore binaural hearing necessary to locate the direction of sound.[18, 35, 36, 38, 39]

The CHILD score, a **functional auditory measures**, improved applying a passive tBCD[34]

The reviews[2, 18, 35, 36, 38-40], describing **quality of hearing and hearing-specific QoL,** showed overall (little) improvement in subjective benefits of hearing and patient satisfaction with BCDs. Similar results were achieved for the different aided conditions.

Table 9 – Effect of aided (BCD) versus unaided conditions (or CHA*) on hearing outcomes.

Author, year	Type of device	Objective audiometry	Functional audiometry	Speech perception in noise	Sound localization	Satisfaction / QOL
Appachi et al., 2017	Passive tBCD (Sophono & BAHA Attract)	+	+			
Cooper et al., 2017	Passive tBCD (Sophono & BAHA Attract)	+				
Kim et al., 2017	BAHA (not specified) and CROS			+	=	+
Peters et al., 2015	BCD (not specified) and CROS			=/+	=	+
Kitterick et al., 2015 & 2016	BCD (not specified, (non-) implanted)			+	=*	=/+
Liu et al., 2017	BCD (not specified)					+
Magele et al., 2019	Active tBCD (Bonebridge)	+		+	-/+	+
Sprinzl & Wolf-Magele, 2016	Active tBCD (Bonebridge)	+		=/+		+

+: improvement, -/+: inconsistent results, =: no change, =/+: no change to small improvement

Although not many objective differences are seen between CROS hearing aids and BCDs, the acceptance rate of a CROS was stated low (10-20%). This indicates that >80% of the target population opts for a BCD. In a study was reported that 63 out of 72 patients (88%) preferred to receive a BCD. A headband BCD trial is recommended before implantation. It is reported that 44-63% of patients chose for implantation afterwards. The acceptance rate for a BCD is 46.6%.[2, 18]

- **No conclusive results can be obtained for CHA or CROS. Frequency modulation seems to improve auditory outcomes especially in classroom settings.**
- **It was not possible to compare the effectiveness of the current therapies with each other however BCDs report, in general,more improvements of the outcomes than CHA and/or CROS.**

- **BCDs seem to improve objective audiometry outcomes in SSD.**
- **Limited effect of BCDs on speech audiometry outcomes (depending where the noise is localized) in SSD was seen.**
- **BCDs seem to have a medium-effect on subjective quality of life related to hearing loss outcomes.**
- **Similar results were reported for passive and active tBCDs. The BCD types investigated in the studies were often not defined making comparison between different BCDs difficult (e.g. active vs passive, transcutaneous vs percutaneous)**
- **As expected, no improvement was seen with the devices for sound localization as they do not restore binaural hearing.**

4.4.3.2 The effectiveness of cochlear implantation in SSD

Six reviews described the effectiveness of CI in SSD, for which only one review reported the outcomes in children.[41] We will give the overview for children and adults separately.

The effectiveness of cochlear implantation in SSD in children

Peters et al. (2016)[41] executed a systematic search in four databases (Pubmed, CINAHL, Embase and Cochrane) up until June 29, 2015 for children with unilateral hearing loss and cochlear implantation. Of the 296 unique articles, 5 studies including 31 children (under 18y, except for one) satisfied the eligibility criteria (Table 10). These articles were case reports or case series, characterized by small patient samples, heterogeneous findings, low-moderate directness of evidence and a high risk of bias. It was not possible to pool data (large clinical heterogeneity among studies: age of patients, type of hearing loss, etiology of deafness, duration of deafness, implant types, test conditions, outcome measures, follow up duration, etc.) thus they provided a descriptive analysis. The review described the outcomes for every patient separately but we will provide here the general conclusions.

Speech perception in noise was measured in various configurations and with different tests (BKB-SIN, OIS, dB SNR, etc.) across the four studies and therefore difficult to make comparisons. However, all four articles measured at S_0N_0 (sound and noise presented from the front) and speech perception in noise in this configuration improved in most patients, but the difference was statistically significant in only one patient. Also **sound localization** was measured in 4 studies, again using different test configurations, but they all reported on a localization error or root mean square (RMS) as outcome measure (the difference in degrees between the sound source and the sound source indicated by the patient). All (except for one) patients performed better on sound localization after implantation, of whom only the improvement of the post-lingual group (n=9) was statistically significant. **Quality of life** (QoL) was measured with the child and parent versions of the SSQ preoperatively and 12 months post-implantation in one study. The QoL was improved in all patients, but only statistically significant for the post-lingual group (n=9). One study reported a non-significant improvement in CAP-II and SIR scores to assess the **speech and language development** (Table 11).

To date, only few original articles (with weak level of evidence i.e. case series or case reports) are available on this topic. Therefore, no firm conclusions can be drawn but based on the significant improvements observed for sound localization (in post-lingual children with SSD) and quality of life, CI may be an effective treatment option in children with unilateral hearing loss. It is clear that trials are needed to make definite statements on the effectiveness of CI in SSD in children.

At this moment, a multicentre study called 'CICADE' is ongoing between several Belgian research centres in which they investigate the effect of early CI in SSD on children's language development. The first outcomes of this study were already published in 2019 by Sangen et al. assessing six children with SSD and CI and twelve children with SSD without CI and 19 children with normal hearing. They found that the children, implanted at a very young age (between 8 and 26 months, in the prelingual phase), wear their device and appear to perform largely like their normal hearing peers concerning linguistic skills and cognitive milestones. The results in the children with SSD who did not opt for a CI were more diverse. Long term observation of the outcomes in these children (expected within 5 to 10 years) are needed to draw firm conclusions on the CI benefit in this population but preliminary results are promising.[42]

Table 10 – Description of the included studies in Peters et al. to assess the effectiveness of cochlear implantation in SSD and/or AHL.

Included studies	Design	Type hearing loss	Sample size	Reported outcomes
Arndt 2015 (overlapping patient population with Hassepasse 2013)	Prospective case series	Unilateral hearing loss	13 (of which 9 in the post-lingual group)	Speech perception in noise Sound localization Quality of life
Tavora-Vieira 2015	Prospective case series	Unilateral hearing loss	4	Speech perception in noise Sound localization
Plontke 2013	Case report	Unilateral hearing loss	1	Sound localization
Cadieux 2013	Retrospective case series	Asymmetrical hearing loss	5 (of which one patient was 19.8y)	Speech perception in noise Sound localization
Tzifa 2013	Retrospective case series	Asymmetrical hearing loss	8	Speech perception in noise Speech and language development

Table 11 – Effect of cochlear implantation on hearing outcomes in SSD in children

Outcome	CI
Speech perception in noise	+ (sound and noise presented from the front) -/+ (other configurations)
Sound localisation	+
Hearing specific Quality of Life	+
Speech and language development	+

+: statistical (non)-significant improvement, -/+: inconsistent results, CI: cochlear implant

The effectiveness of cochlear implantation in SSD in adults

Five reviews [43-47] described the effectiveness of CI in SSD in adults towards speech audiometry (i.e. speech in quiet and/or speech in noise), sound localization, and/or (subjective) hearing specific quality of life. The (amount of) included original articles, patients and results are listed in Appendix 3.4 (Table 63). The study designs of the articles included in the reviews were of low-moderate quality as only case reports, prospective/retrospective comparative research or case series were included, describing small sample sizes (ranging between 1 and 25). The authors indicate it was not possible to pool data because of the high heterogeneity across the studies (e.g. various testing methodologies, configurations, follow-up, and populations).

Speech perception in quiet improved significantly only listening with the implanted ear. No studies reported equivalent results when participants also had the use of their non-implanted ear.[43] This result, however, is considered less useful in daily life. **Speech perception in noise** was measured (across the studies included in the reviews) using different spatial locations of speech and noise stimuli across the studies and therefore the authors of the

reviews experienced difficulties to compare the retrieved data. Most studies reported results on the configuration in which noise and speech were presented at the front (S_0N_0), showing improvements with a CI, however statistical significant improvement was only reported in one study assessing 8 patients. A (significant) improvement in speech understanding when the sound is presented at the CI and the noise at the normal hearing ear ($S_{CI}N_{NH}$) was also seen. This is considered the most challenging situation in daily life. These results can be attributed to the head shadow effect, meaning that the auditory system is able to process binaural signals after CI.[47] In all other signal-noise configurations the results were contradictory and thus inconclusive.[43, 47] In general, there is a lack of evidence for the effects of CI use on speech perception in noise due to variations in testing methodologies across studies.

All studies reported on **sound localization**, all reporting on the localization error (mean difference in degrees between the location of the sound source and the source indicated by the patient) as the outcome measure, but using different test set-ups. Thus, looking at the original included studies, one study reported a significant reduction of the localization error after CI compared to the pre-implant condition (CROS, BCD or unaided). Another study tested at different time points and reported a reduction of the localization error in CI-on versus CI-off condition (without presenting statistics). One study assessed data of post-lingual deaf patients and pre-lingual deaf patients separately and showed that the localization error reduced significantly in the bimodal (CI + CHA) post-implant condition versus CHA-alone (better ear) in the post-lingual deaf patients. This improvement was not found in the pre-lingual deaf patients, indicating that the development of binaural hearing is needed to get benefit of a CI in SSD towards sound localization. In general, all reviews consistently showed an improvement in sound localization after CI.[43, 45-47] But because of the heterogeneity of the literature it remains unclear whether CI can improve the ability to localize sounds despite restoring bilateral input.

Hearing specific QoL and **subjective benefits of hearing** were assessed in the majority of the articles included in the reviews with the SSQ.[43-46] Significant improvements on subjective benefits of hearing measured by the SSQ, especially in the speech and spatial components were noted in CI implantation (compared to BCD, CHA and/or untreated). This was confirmed by a meta-analysis. In the post-lingual group, speech and spatial subsections significantly improved, while in the pre-lingual group only significant improvement was seen in the spatial subsection. The quality section improved in most studies but not significantly. In general, there is a lack of evidence for the effects of a CI on health-related QoL.

To conclude, across reviews, an overall improvement of speech perception in noise, sound localization and hearing specific QoL after CI was seen. However, because of the varied test configurations and heterogeneity in testing methodologies, it is difficult to draw definite conclusions.

Table 12 – Summarized effect of cochlear implantation on hearing outcomes in SSD in adults

Outcome	CI
Speech perception in quiet	-/+
Speech perception in noise	+ (sound and noise presented from the front) + (sound presented at CI and noise at the normal hearing ear) -/+ (other configurations)
Sound localisation	+
Hearing specific Quality of Life	+

+: statistical (non)-significant improvement, -/+: inconsistent results, CI: cochlear implant

Cochlear implantation in SSD might improve speech perception in noise, sound localization and hearing-specific quality of life. However, because of the varied test configurations and heterogeneity in testing methodologies, it is difficult to draw definite conclusions.

4.4.3.3 The effectiveness of cochlear implantation in SSD or asymmetrical hearing loss when tinnitus is present.

Note that we focus here on the most effective treatment for tinnitus in combination with single sided deafness or asymmetrical hearing loss, and not on tinnitus in general. For prevention, diagnosing and treatment of tinnitus, we refer to the publication of the Superior Health Council ('Hoge gezondheidsraad'/'Conseil Supérieur de la Santé') in 2017[48] and published guidelines.[49]

The effectiveness of CI in SSD and/or AHL was assessed in 5 reviews (Table 13).[44-47, 50]. These reviews included studies on SSD, SSD and AHL or AHL alone (Appendix 3.2). Different tests to assess tinnitus were applied and an overview is given in Appendix 3.3. However, the most commonly used tests to assess tinnitus were the Tinnitus Handicap Inventory (THI) and the Visual Analogue Scale (VAS). As seen in Table 13, most reviews included the same articles ranging from 30 to 161 patients in 5 to 13 studies. Thus similar results were represented across the reviews. The most recent review of Peter et al., 2019 included the most studies and patients.[50]

With the implantation of a CI, a general improvement of tinnitus was achieved in around 88% of the patients, of which more than half (53.7% - 68.4%) reported a complete suppression of the symptom (Table 13).[50] This was quantified by a 5.29 point decrease on the VAS.[44] In around 8% of the patients, tinnitus remained stable. A deterioration was seen in 2.5%-5% of the patients, but no cases of tinnitus induction were reported (Figure 6).[50] When the CI was switched off, tinnitus often reoccurs.[45, 50]

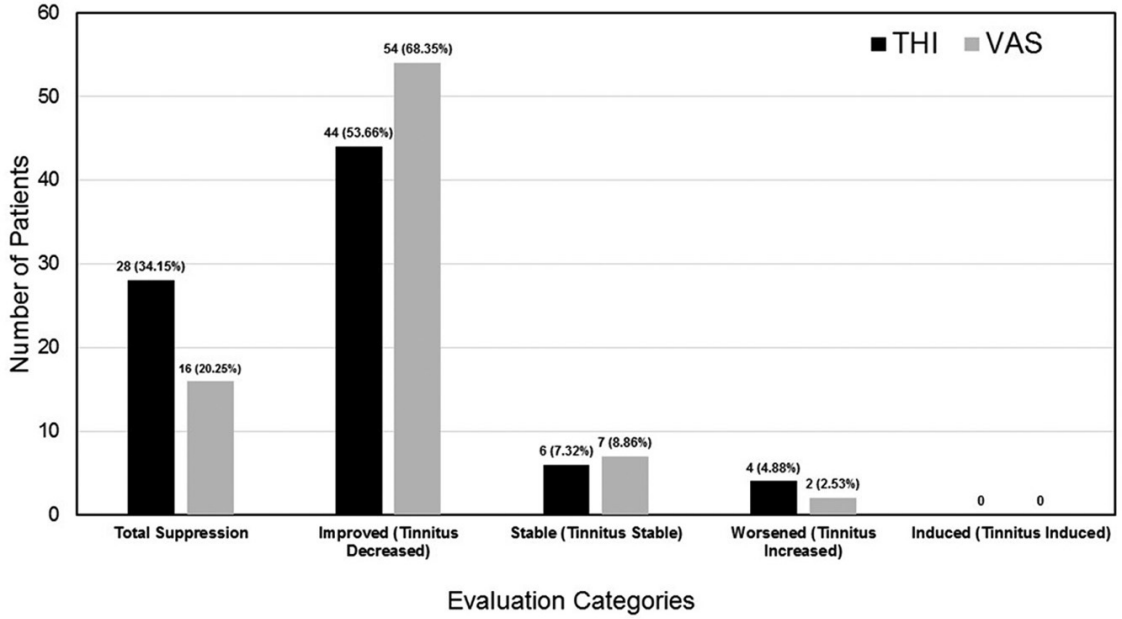
Although the reviews showed improvement of tinnitus with CI implantation, they fail to provide high level of evidence since the included trials were characterised by high heterogeneity and weak evidence scores (Appendix 3.2, Table 59). Also, meta-analysis was not always adequate as high heterogeneity (I^2 > 90%) was present and data could not be pooled.[50] Further (high-quality) prospective cohort studies are needed to draw firm conclusions.

Table 13 – Included reviews (articles & patients) comparing post- and pre-implantation tinnitus scores in patients with SSD or AHL.

Reviews	Articles (n), Patients (n)	Original articles	Results (comparing post- with pre-implant scores)
Vlastarakos et al., 2014[46]	8; 85	Arndt, 2010; Buechner, 2010; Punte 2013; Távora-Vieira, 2013; Van de Heyning, 2008; Vermeire, 2008; Ramos, 2011; one study not reported	Improvement was seen in 95.3% of the patients with complete suppression occurring in 34.1%.
Blasco & Redleaf, 2014[44]	5; 30	Arndt, 2010; Buechner, 2010; Távora-Vieira, 2013; Van de Heyning, 2008; Ramos, 2012	Overall improvement of tinnitus after CI was seen, except in one patient who did not experience any change in tinnitus after CI. A meta-analysis assessed the effectiveness of CI on tinnitus. The mean difference across 3 studies (n=22) demonstrated a 5.29 point (95% CI: -4.32, -6.27; p<0.001) reduction in tinnitus severity on the 10-point VAS, with a mild heterogeneity between the studies (I^2 = 28%).
van Zon et al., 2015[45]	6, 69	Arndt, 2010; Buechner, 2010; Punte 2013; Mertens, 2013; Távora-Vieira, 2013; Van de Heyning, 2008	A general improvement of tinnitus was seen. When the CI was switched off, tinnitus reoccurred (2 studies).
Cabral et al., 2016[47]	7, 98	Arndt, 2010; Ramos, 2012; Buechner, 2010; Távora-Vieira, 2013 & 2015; Punte 2013; Mertens, 2013; Van de Heyning, 2008	Five studies presented statistically significant reductions of tinnitus.
Peter et al., 2019[50]	13; 161	Arndt, 2010; Buechner, 2010; Punte, 2013; Távora-Vieira, 2013; Seo, 2015; Ramos, 2012; Holder, 2017; Macias, 2015; Dillon, 2017; Friedmann, 2016; Härkönen, 2015; Kitoh, 2016; Ahmed, 2017	Seven studies using the THI reported a low post-implantation score range (2.6-35.2) compared to the pre-implantation score range (25.4-79.6). All studies (n=6) except one, that reported on the VAS, had a low post-implantation score (1.2-5.7) compared to the pre-implantation score (5.0-8.5). The effect on tinnitus i.e. total suppression (34.2% and 20.3%), tinnitus decrease (53.7% and 68.4%), tinnitus stable (7.3% and 8.9%), tinnitus increased (4.9% and 2.5%), and tinnitus induced (0%) for the THI and VAS respectively (Figure 6). After switching off the CI (3 studies), the tinnitus perception returned to a level approximately similar to their respective pre-implantation stage.

CI: cochlear implantation, VAS: Visual Analogue Scale, THI: Tinnitus Handicap Inventory

Figure 6 – Quantitative effects of tinnitus after cochlear implantation.



Number of patients from all the studies categorized into different outcome classes. The calculation was based on the studies, which used the Tinnitus Handicap Inventory (THI) and/or Visual Analog Scale (VAS) questionnaires.[50]

The rationale behind the possible positive effects of CI on tinnitus suppression is not fully clear yet but it could be multi-factorial and explained by different mechanisms.[50] In some patients, an immediate improvement of tinnitus after the first activation of the CI was seen. This could be accompanied with a reoccurrence of the tinnitus symptoms when the CI was switched off.[46] This suggests an acoustic masking effect on tinnitus due to increased auditory input.[50] But tinnitus suppression can also be achieved by direct electrical stimulation of the cochlear nerve (as already noted in non-deaf subjects). Furthermore, on the long term, it is assumed that the CI induces a restoration of central auditory pathways and an induction of neuroplasticity which may then affect the tinnitus perception over-time. This could explain late-onset tinnitus improvement after CI activation. Typically, tinnitus returns after removal of the speech processor but, in some cases, with some latency, which could be attributed to mechanisms of residual inhibition. Moreover, as non-auditory areas of the brain are also involved, increased psychological health and well-being with a CI could influence tinnitus perception.[50]

Of note, tinnitus perception seems to remain stable or even worsen in some patients with cochlear implantation. For this, current hearing implants are not indicated for the symptom 'tinnitus' solely, but tinnitus can be a supplementary reinforcing indication besides severe/profound hearing loss

to opt for a CI.[49, 51] Thus, it remains important to inform and select possible candidates very carefully. Before considering cochlear implantation, a try out with a conventional hearing aid can be done in a person suffering from tinnitus (no negative adverse events were seen)[52], since the natural amplification could be sufficient to supress the symptom.[53-55]

- **A general improvement of tinnitus was noted after implantation of a CI in SSD or assymetrical hearing loss.**
- **There are patients in whom tinnitus was worse after cochlear implantation.**
- **Good selection of the patients and adequate information (to have realistic expectations) is necessary.**
- **Applying cochlear implants (or other hearing aids) to relieve tinnitus is only indicated when meaningful hearing loss is also present.**
- **Try out with a conventional hearing aid can first be considered, however this is not possible in severe hearing loss.**

4.4.4 Clinical effectiveness of fully implanted middle ear implants and traditional semi-implanted MEIs

Note that since May 2020 the fully implantable MEI is not anymore on the Belgian market. Since this research question was already outlined in the clinical part, we decided to leave it here in case of future submissions of requests for reimbursements. However, this topic will not be described anymore in the other sections of the report.

Four reviews were included selecting the population not on type or degree of hearing loss but on device describing the Vibrant Soundbridge (n=3), the Soundtec Direct (n=1), the Esteem (n=2) and the Carina (n=1).[56-59] Two semi-implantable MEI, and two fully implantable MEIs. In Appendix 3.2 is seen that these MEIs were implanted in a very heterogeneous population e.g. different degrees and types of hearing loss. Moreover, a wide variety on testing tools were used and heterogeneous outcome measures were described in the original studies. Therefore the authors of the review experienced difficulties to compare the data based on functional audiometry and quality of life outcomes. For these reasons we will discuss the findings of these 4 reviews one by one.

In an adult patient population (n=679) with mild to severe sensorineural hearing loss who are unable to tolerate conventional hearing aids, Bruchage et al. (2017) estimated that the Vibrant Soundbridge provided a **functional gain** of 25-33 dB HL in sound field audiometry.[56] **The speech perception in noise** showed to be improved around 30% compared to the unaided condition or conventional hearing aids. Concerning **QoL and patient satisfaction**, the patients benefit from a Vibrant Soundbridge as well as from CHAs but the Vibrant Soundbridge was stated to be more comfortable, clearer in sound perception and with less events of unease. The authors concluded that the Vibrant Soundbridge is highly reliable device which significantly improves perception of speech in noisy situations with a high sound quality and can be a safe tool in surgically experienced hands (more on safety in 4.4.5).

Also Kahue et al reviewed the Vibrand Soundbridge (n=211), the Soundtec Direct (n=190) and the Esteem (n=102) in patients with sensorineural hearing loss.[58] Mind that the results listed are generalized for the 3 different MEIs, and did not indicate differences between the MEIs. Comparing the MEIs with the best aided/unaided condition, the **functional gain** (25.2 dB vs. 8.1 dB, respectively) and the **speech recognition** (44.8% vs. 9.2%, respectively) improved with the MEIs. Also **patient-perceived outcome measures** suggest that MEIs provide enhanced sound quality and eliminate occlusion effect.

Ernst et al.[57] identified in their review 36 publications on patients suffering from conductive or mixed hearing loss describing Vibrant soundbridge outcomes (n=294), BCD outcomes (n=666) and middle ear surgery with conventional hearing aid outcomes (n=43). It was seen that bone conduction thresholds were stable pre-/post- surgery indicating that the Vibrant Soundbridge does not harm inner ear function and that it leads to a **functional gain** of around 30 dB on average. Also **speech recognition** was

significantly improved compared to the unaided condition. The patients were **satisfied** which also remained stable over time. The authors summarized that the Vibrant Soundbridge proved to be safe and effective when compared to unaided or BCD situation, and provided more and consistent hearing gain compared to middle ear surgery with conventional hearing aids. Therefore they concluded that the Vibrant Soundbridge is effective for patients with various middle ear pathologies, particularly with mixed hearing loss and failed previous tympanoplasties when classical ossiculoplasty could not provide enough functional gain.

Two fully implanted MEIs i.e. Carina (n=110) and Esteem (n=134) were compared in 22 studies.[59] The authors indicated difficulties while comparing these two devices with comparing the outcomes for word recognition and sound intensities due to heterogeneity in measurement. Comparing conventional hearing aid outcomes were conflicting. However, it was seen that the MEIs showed improvements for all outcomes and quality of life compared to the unaided condition. The authors concluded that there are still problems to be solved concerning device functioning. Moreover, none of these studies represented high levels of evidence and the sample sizes were small. Of note, in 4.4.5 is seen that fully implanted MEIs provide more adverse events. The chirurgical procedure is very complex and if there are defects or the batteries need to be replaced, a new chirurgical procedure has to be executed.

- **Overall, functional gain, speech recognition and patient satisfaction are improved with MEIs compared to CHAs or unaided condition.**
- **The Vibrant Soundbridge, a semi-implanted MEI, was subject of investigation in most studies and showed improved speech perception in noise, qualityof life, and patient satisfaction compared to conventional hearing aids.**
- **Due to difficulties, no comparisons between the two fully implanted MEIs (Carina and Esteem) could be made.**
- **None of the retrieved reviews compared fully versus semi-implantable MEIs.**

4.4.5 Complications, safety and adverse events of hearing implants.

Eleven articles reported on complications, safety and adverse events after an implantation of a hearing device (Appendix 3.2). A more recent article was retrieved from the experts during the expert round and will be discussed in a separate section.[60] Three reviews reported on passive transcutaneous BCDs (tBCDs), two reviews reported on active tBCDs, and four reviews on active middle ear implants. Concerning percutaneous BCDs (pBCDs), one review[38] was included, although for us it was not clear if they reported on the BAHA connect (pBCD) or the BAHA attract (passive tBCD), it was decided to report it as pBCD as done in the Ontario report[6]. As in Ontario[6], no reviews discussing this topic were found, but the authors conducted a supplementary search identifying four observational studies[61-64] reporting on 500 (178 adults), 403 (168 adults), 2827 and 971 (233 adults) devices.

Furthermore, 3 studies included in Kitterick 2016[36] reported on complications and adverse events in BCDs. However, the BCD type was not defined as the review selected all types of BCD including headband, abutment, ear canal insertions, etc. Taking that into account, skin reactions around the side of the abutment were seen in 9 patients with soft-tissue surgery in 2 cases and relocation of the abutment in 1 case. Moreover, pain leading to non-use of the device (n=1), minor soft tissue changes (n=4) and one case of minor irritation after a dental mounted BCD trial was described.

Across all reviews reporting on complications, safety and adverse events of the hearing devices, the follow-up was relatively short, with reported averages around 12 months[18, 65] ranging between 2 and 65 months.[2, 18, 57, 59, 65]

4.4.5.1 Percutaneous bone conduction device

A complication rate of 5% and 17% was described in two studies included in the review of Kim et al.[38] The complications were minor events mainly due to skin reaction problems of soft tissue overgrowth above the abutment.

4.4.5.2 Passive transcutaneous bone conduction device

The overall complication rate described in the 3 reviews varied between 18.3% and 29%.[37, 65, 66] The majority, 13.1% to 25.5%, were minor adverse events i.e. minor soft tissue reactions including pain, erythema, necrosis, discomfort, and infection which may have reduced device usage but did not prevent the use of the device and resolved with conservative measures. Major adverse events prevent the use of the device entirely, require active medical or surgical management and/or explantation, e.g. in case of skin breakdown, severe headache, seromas/hematomas, wound infections, full-thickness skin ulcers, wound dehiscence, and pain/discomfort/tinnitus, and ranged up to 5.2%. No intra-operative adverse events were reported.

In general, the authors of the reviews rated the complication rate of tBCDs as low (keeping in mind that there is no validated scale defining which complications are clinically significant). The complication rate of tBCDs must be viewed in the context of pBCDs as soft tissue complications have in part driven the development and use of tBCDs. For patients who are more prone to infections due to underlying medical conditions or for patients in certain occupations and children (no daily skin maintenance, no fixture extrusion due to trauma, shorter time to processor use and lower revision surgery rates as well as skin complications), this lower rate of soft tissue reactions in tBCDs is a major consideration.[37] Although there is high frequency attenuation through soft tissue, lower rates of postoperative complications and the aesthetics of a tBCD may outweigh this limitation which can also be mitigated through careful patient selection.

Since most minor complications of tBCDs are linked to the magnet's strength, the studies advised to implement a wearing schedule for tBCDs (starting with the lowest magnetic strength at initial fitting, followed by a gradual increase in strength and duration of wearing) in order to reduce magnet-related (minor) skin complications.[37, 65, 66]

4.4.5.3 Active transcutaneous bone conduction device, the Bonebridge

The overall complication rate described in the 2 reviews varied between 6% and 9.4%.[2, 18] The majority, 5.1% to 7.7% were minor adverse events (treated conservatively) such as infection, headache, pain, tinnitus (resolving), hematoma, edema/erythema, seroma, inflammation due to magnet strength, and diziness/vertigo. Major adverse events, ranging from 0.9% to 1.7%, included ischemia of the earlobe, chronic fibrosis, mastoiditis, revision surgery and explantation on patient's request. Magele et al.[18] calculated that there are 7 major adverse events in 1000 subjects per follow-up year and 1 in 10 minor adverse events per year of follow-up. Also the rate of major adverse events is low, with one major incidence in 148.9 person-years. Due to its low complication rate, the Bonebridge is currently a viable device.

4.4.5.4 Active middle ear implants, partly and fully implanted devices

Overall adverse events for the Vibrant Soundbridge (VSB) were described in 3 reviews (reporting adverse events in 25 studies) and ranged from 16.3% to 39%, of which 4.6% to 36.4% minor adverse events (e.g. aural fullness or taste disturbances, pain, tinnitus (resolving), limited benefit, headaches, floating mass transducer extrusion, wound dehiscence, dizziness) and 2.6% to 11.7% major adverse events (e.g. implant failures, explantation due to conductor lead breakage, revision surgery).[56-58] The adverse events for the Soundtec were only reviewed in one study, describing three original articles, and ranged from 10% minor adverse events to 14.2% major adverse events (e.g. tympanic membrane perforation, and ear canal hematomas).[58] Since the safety of the VSB was already investigated in several studies (although of retrospective nature and limited follow-up), the authors stated the VSB to be safe in surgical experienced hands as a major concern in MEI surgery lays in the risk of hearing loss during ossicular loading and device coupling[58]. However, no statistically significant loss in air- or bone conduction was reported after surgery.

Concerning fully implantable devices i.e. Esteem[58, 59] and Carina[59], it was seen that general adverse events were high with reported percentage of 45.5% in Carina and 84.4% in Esteem. There were no surgical complications reported in Carina, but with the Esteem a rate of 20% was seen. More device adverse events were seen in Carina (31.8%) compared to Esteem (17.8%) but there were more revisions in Esteem (11.1%) compared to Carina (9.1%). Kahue et al.[58] described for the Esteem a minor complication rate of 45.1% and a major complication rate of 49% (e.g. due to surgical procedure, facial paralysis, pain, dizziness, tinnitus), which is considerably higher compared to the partly implanted devices. Device malfunctioning requiring explantation was only reported in the Esteem (10.8%) and in the VSB (3.3%). It should be kept in mind that the need for explantation will demand reconstruction of the ossicular chain. Otherwise, the hearing threshold will increase due to the overlapping of conductive hearing loss on a pre-existing SNHL. For Carina, despite of the events related to surgical procedure, many studies showed device malfunction or failure with a need for revision surgery or explantations. This fact may be due to charging issues.

Discussing the safety data between active MEIs is relevant when these devices cover the same indications such as the VSB (3562 cases) versus Esteem (56 cases) (both implanted by an antrotomy, posterior tympanotomy approach to the long process of the incus). The rate of surgery related complications implanting the device is ranging from 2-9% (e.g. complications occurring during routine middle ear surgery, taste disturbances, middle ear effusion, aural fullness, predominantly resolving over time) in the VSB, compared to 5-44% in the Esteem. Implant failures rates massively decreased with the second generation of VSB development to currently 2.6% of all devices, which is almost half compared to the Esteem data.

4.4.5.5 Cochlear implants

The overall complication rate was between 16% and 19.9%. Among these complications, 2.9% to 8.3% involved re-implantation (e.g. device failure, infection, trauma), 5%-10.2% were major adverse events (meningitis, surgery without re-implantation) or required revision surgery, and 5.6%-14.9% were minor adverse events (e.g. transient facial palsy, wound hematoma, tinnitus, infections, vertigo). The authors concluded that based on this available evidence, cochlear implantation is reasonable safe.[6]

Article retrieved during expert round

In the HTA Ontario report was stated that there is not sufficiently published on adverse events in hearing implants. Recently, the types and frequencies of adverse events associated with bone conduction implants and active MEIs, as reported in 234 included references was reviewed. One of the conclusions was that the reporting quality of adverse events associated with these devices is often very low (only 58% reporting on the actual number of ears with adverse events, 66% reporting on F/U time and only 19% on this standard deviation, 43% on the resolution of adverse events and 54% reported on adverse event specification). There were 204 different adverse events found across all devices of which the 5 most frequent were Holger's grade I (minor), Holger's grade II (minor), skin revision surgery because of skin overgrowth (major), Holger's grade III (major), and soft tissue / skin overgrowth (minor). Adverse events associated with BCDs and active MEIs are qualitatively different and not equally frequent among devices. Many publications lack rigor in reporting adverse events, and the resulting gap in data integrity precludes thorough statistical analyses of adverse events associated with these medical devices. This has immediate consequences on decisions made by patients, clinicians, health authorities or advisory bodies around the world. Future publications could thus benefit from minimum standards that are based on international consensus. The review concluded also that state-of-the-art implantable BCDs and active MEIs are a safe treatment option for hearing loss.[60]

- **Minor events (5-17% of the patients) were seen for pBCDs.**
- **For passive tBCDs, an event rate of 18-29% (majority were minor events) was seen. A 'wearing schedule' is adviced.**
- **A relatively low complication rate (6-9%) was seen with the the Bonebridge (MED-EL), an active tBCD.**
- **Generally high complication rates were reported for the fully implantable MEIs i.e. Carina (46%) and Esteem (84%). The reported complication rate (16-39%) for the semi-implantable MEI i.e. Vibrant Soundbridge was lower.**
- **One should keep in mind that implantation of fully implatable MEIs is much more complex, and that surgery has to be redone every time there is an error, refitting, battery change, etc.**
- **For the cochlear implants, relatively low rates of adverse events were reported < 20%, although almost 10% were major adverse events, and these devices were considered reasonable safe.**

5 ECONOMIC REVIEW AND COST-CONSEQUENCES ANALYSIS IN BELGIAN SETTING

This chapter will provide an overview of the main results from the economical (cost-effectiveness and cost-utility) literature search concerning the three main topics.

5.1 Literature search

5.1.1 Research questions

In parallel with the clinical literature review, we limited the research questions to those device/indication combinations that are currently considered most relevant by experts and stakeholders to widen reimbursement for. These are:

1. Active tBCD as an alternative to other BCDs or no treatment, in conductive and mixed hearing loss and SSD.
2. Bilateral CI in adults as bilateral hearing loss is currently treated by bimodal treatment (a unilateral CI in combination with an air conduction hearing aid) or by unilateral CI and one ear untreated.
3. CI for SSD, in adults and especially in children as in some patients unilateral hearing loss is now treated with a CROS or a BCD. However, in many patients it is left untreated.

Note that the reimbursement for the fully implantable MEI in comparison with the semi implantable MEI is not evaluated in this economic review since the fully reimbursed MEI is not anymore on the Belgian market. We decided to leave it in the clinical part to remain some background information for future applications.

5.1.2 Selection criteria

For the selection of relevant studies we screened on the basis of titles and abstracts. For the studies meeting the inclusion criteria (Table 14), we obtained full-text articles.

Table 14 – Inclusion criteria for economic literature search

	Inclusion criteria (for each research question)	Exclusion criteria
Population	1. Mixed and conductive hearing loss (unilateral or bilateral): adults and children 2. Bilateral hearing loss: adults 3. SSD: adults and children	All other
Intervention and comparator	1. Active tBCD, compared to other BCD or no treatment 2. Bilateral CI, sequential or simultaneous*, compared to unilateral CI 3. Unilateral CI, compared to other options or no treatment for SSD	All other
Design	Cost-effectiveness, cost-utility analyses	Cost-analyses, cost-benefit analyses, study protocols
Language	English, French, German or Spanish	Other languages
Publication type	Full-text publications	Abstracts, letters and editorials

*CI: cochlear implantation, SSD: Single sided deafness, tBCD: transcutaneous bone conduction device. *With simultaneous implantation is understood: both CI devices are implanted at the same moment (same surgery and narcosis). With sequential implantation is understood: both CI devices are implanted on different days (other surgery and narcosis).*

5.1.3 Search strategy

In a first step, we searched the websites of institutes conducting health technology assessments, including member institutes of INAHTA (International Network of Agencies for Health Technology Assessment) and other. For a full list of searched websites, see Appendix 4.1.1. In addition, we searched the CRD (Centre for Reviews and Dissemination) HTA database. We also checked the POP (Planned and Ongoing Projects) database of EUnetHTA (European Network for Health Technology Assessment) partners; the most recent version of this database dated from January 2020. We limited our search to reports from 2014 onwards.

Through this first step, we identified three HTA reports, listed in Table 15. The economic reviews from the two Health Quality Ontario reports were found to be the most recent and complete ones. In these reports an economic search was performed until the date of January 2018. We took the results from the searches in these reviews as basis and updated them in the second step of our search strategy.

Table 15 – List of retrieved HTA reports identified in CRD's HTA database and websites of HTA institutes

Research question	Retrieved reports
Bilateral CI in adults	• Estrada-Sabadell MD. Efectividad y coste-efectividad de los implantes cocleares bilaterales en niños y adultos. Agència de Qualitat i Avaluació Sanitàries de Catalunya. 2018.[67] • Health Quality Ontario. Ontario HTA Series. Bilateral cochlear implantation: HTA. Volume 18, Number 6. October 2018.[68]
CI in SSD **Active tBCD in SSD / conductive and mixed hearing loss**	• Health Quality Ontario. Ontario HTA Series. Implantable Devices for Single Sided Deafness and Conductive or Mixed Hearing Loss: HTA. March 2020.[6]

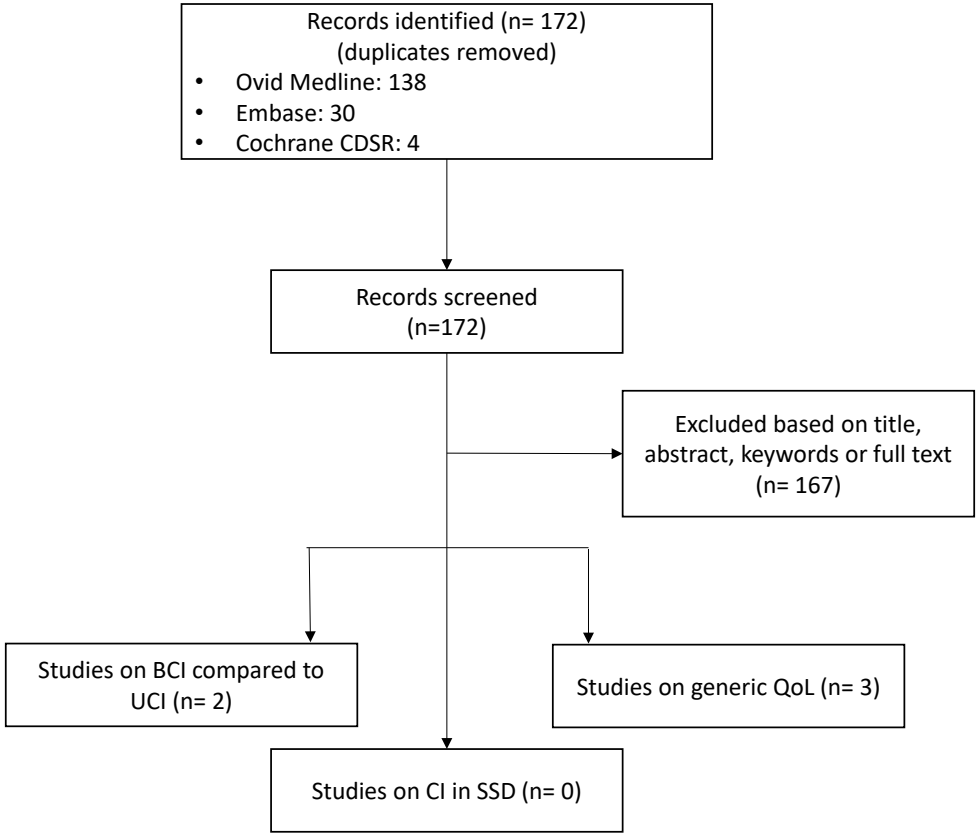
CI: cochlear implantation, SSD: Single sided deafness, tBCD: transcutaneous bone conduction device, HTA: Health technology assessment, CRD: Centre for research and dissemination database

Note that the NICE Technology appraisal guidance [TA566][69] of 2019 is not included in Table 15 as the guidance did not include a review of the economic (nor clinical) literature. The study of Healthcare Improvement Scotland[70] of 2019 to assess the budget impact of changing the eligibility criteria for CI in NHS Scotland is not included in our overview either as it concerns a budget impact analysis only.

In the second step of our search, we updated the reviews from Health Quality Ontario with more recent economic evaluations. For this we searched the Medline (OVID), Embase as well as Cochrane CDSR databases from 2018 onwards until January 2020 (see Appendix 4.2 for the search strategies).

Figure 7 shows the flow diagram for the identification and selection of economic studies in Medline (OVID), Embase and Cochrane CDSR for the period from 2018 onwards until Janunary 2020.

Figure 7 – Flow diagram for the identification and selection of recent studies in Medline (OVID), Embase and Cochrane CDSR



BCI: bilateral cochlear implant, UCI: unilateral cochlear implant, SSD: single sided deafness, QoL: Quality of life

5.2 Results of the literature search

5.2.1.1 Bilateral vs unilateral CI in adults

For the evaluation of bilateral versus unilateral CI in adults, we included in total five economic evaluations. Three economic evaluations identified in the Health Quality Ontario report were included (two economic evaluations in the review and the primary economic evaluation):

- Chen et al. 2014[71]; Kuthubutheen et al. 2015[72]
- Smulders et al. 2016[73]
- Health Quality Ontario 2018[68]

In our own search we identified two more recent economic evaluations:

- Theriou 2019[74]
- Laske 2019[75]

5.2.1.2 CI in SSD

For the evaluation of CI in SSD a single economic evaluation was identified, notably the primary evaluation in the Health Quality Ontario report. The Health Quality Ontario review did not identify any preceding economic evaluations on this topic. In our own search we did not identify any more recent economic evaluations either.

Note that one article of interest was identified describing a study protocol for a cost-utility analysis of CI in SSD and asymmetric hearing loss alongside a randomized controlled study, but this article did not include any results and was therefore not retained.[76]

5.2.1.3 Active tBCD in SSD / conductive and mixed hearing loss

Also only one economic evaluation was identified evaluating active tBCD in each of the indications SSD and conductive-mixed hearing loss, notably the primary economic evaluations conducted in the Health Quality Ontario report.

The Health Quality Ontario review identified one economic evaluation on bone conduction implants in SSD and conductive-mixed hearing loss, however, this study (of 2011) concerned passive BCDs and was therefore not considered of particular relevance for this report. Note that the Health Quality Ontario primary evaluations were based on active tBCD in adults, but on active pBCD in children, therefore we will focus on the results obtained in adults. The study compared active tBCD with no intervention. No other recent economic evaluations were identified in our own search.

5.2.1.4 Quality-of-life

Three studies were identified in our search to update the data from the Health Quality Ontario reviews with regard to generic quality-of-life instruments:

- A review of McRackan (2019) including quality-of-life for BCI compared to UCI[77]
- A primary data collection of Muigg (2019) on quality-of-life for CI in SSD in adults (using HUI-3)[78]
- A primary data collection of Hausler (2019) on quality-of-life for CI in SSD (using SF-36).[79]

Table 16 recapitulates the list of economic evaluations meeting the inclusion criteria and finally retained for this study.

Table 16 – List of economic evaluations identified and retained meeting the PICO criteria

Research question	Identified economic evaluations (Author, year)
Bilateral CI in adults	Chen et al. 2014[71]; Kuthubutheen et al. 2015[72] Smulders et al. 2016[73] Health Quality Ontario 2018[68] Theriou 2019[74] Laske 2019[75]
CI in SSD **Active tBCD in SSD / conductive and mixed hearing loss**	Health Quality Ontario 2020[6]

CI: cochlear implantation, SSD: Single sided deafness, tBCD: transcutaneous bone conduction device

5.2.2 General characteristics of included economic studies

Table 17 lists for each of the included studies the location, the study characteristics (analytic technique, study design, perspective and time horizon), the study population as well as the intervention and comparator that meet our inclusion criteria.

Perspective

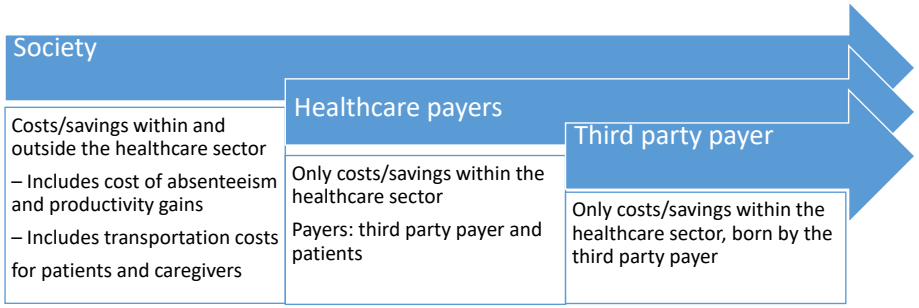
All studies identified were conducted from the perspective of the **third party healthcare payer**. This perspective takes into consideration direct costs (and savings) related to healthcare (such as costs of device, inpatient care, physician billings and outpatient care) paid by the public or private health payer, but excludes costs paid by the patient.

The HQ Ontario reports also comprised a scenario analysis from a **societal perspective**, taking into consideration costs and savings from a wider perspective, such as productivity losses or gains, costs to ministries other than the health ministry, as well as out-of-pocket costs paid by the patients.

The societal perspective ideally also takes into consideration the societal savings, such as those linked to possible improvements in education and employment performance, of particular relevance for the interventions under study, however including these in the calculations appeared difficult as there is a lack of evidence on the impact of CI or other hearing implants on these factors.

Note that according to the Belgian guidelines for economic evaluations, for costs the perspective of the **healthcare payers** should be taken, a perspective in between that of the third party healthcare payer and the society (see Figure 8). In the Belgian context this perspective includes payments out of the federal government as well as the communities' healthcare budget and besides that also patients' co-payments. Analysis from a broader, societal perspective is allowed, but not in the reference case.[80]

Figure 8 – Possible perspectives for calculating costs/savings in an economic evaluation



Time horizon

All studies on CI were conducted with a long term horizon, either 25 years or lifetime reflecting the long lifespan of a CI, taking into account the costs to upgrade the speech processor periodically. The studies on active tBCD were conducted on a 10 year time horizon.

Analytic technique

All studies were conducted as a cost-utility analysis, in which the results are expressed in terms of cost per quality-adjusted-life-year gained (cost per QALY), synonym for the incremental cost-effectiveness ratio (ICER). QALYs are calculated on the basis of utilities. Utilities are valuations of health-related quality-of-life, measured on a scale where full health is valued as 1 and death as 0. To calculate QALYs these utilities are multiplied by the duration of time in years that a subject spends in that particular health state.

One study[73] is a piggy-back evaluation, i.e. an economic evaluation embedded in a clinical trial. All inputs used in the piggy-back evaluation stem directly from the trial. The other studies are modelling studies, in which input data from different studies are combined. The modelling studies are either based on a decision analytic tree or a Markov model.

Table 17 – General characteristics of included economic evaluations

Name, year, location	• Analytic Technique • Study design • Perspective • Time horizon	Population	Intervention/Comparator
Bilateral CI in adults			
Chen et al. 2014[71]; Kuthubutheen et al. 2015[72], Ontario Canada	• CUA • Decision analysis • Public health payer perspective • 25-year time horizon	Adults (mean age=53) with severe to profound hearing loss, no benefit from hearing aids	BCI (sequential)/UCI
Smulders et al. 2016[73], Netherlands	• CUA • RCT (n=38) • Private health payer perspective • Max. lifetime horizon	Adults (age 18-70), postlingually deaf, severe to profound hearing loss, ability to hear (with hearing aids) until 10 years ago, marginal hearing aid benefit	BCI (simultaneous)/UCI

Health Quality Ontario 2018[68], Canada	• CUA • Markov cohort model • Public health payer perspective • Lifetime horizon	Adults 18 to 55 years with postlingual deafness	BCI (sequential)/UCI
Theriou 2019[74], UK and US	• CUA • Markov cohort model • Public healthcare service perspective • Lifetime horizon	Adults, severe to profound hearing loss	BCI/UCI Bimodal/UCI
Laske 2019[75], Switzerland	• CUA • Markov cohort model • Public health payer perspective • Lifetime horizon	Adults	BCI (sequential)/UCI
CI in SSD and asymmetric hearing loss			
Health Quality Ontario 2020[6], Canada	• CUA • Markov cohort model • Public health payer perspective • 25-year time horizon	Adults and children with SSD	CI/no intervention
Active tBCD in SSD / conductive and mixed hearing loss			
Health Quality Ontario 2020[6], Canada	• CUA • Markov cohort model • Public health payer perspective • 10-year time horizon	Adults with • SSD • conductive and mixed hearing loss	Active tBCD in adults /no intervention

CUA: Cost utility analysis, RCT: Randomized controlled trial, BCI: Bilateral cochlear implant, UCI: Unilateral cochlear implant, tBCD: transcutaneous bone conduction device, SSD: single sided deafness

5.3 Description and discussion of the economic studies

5.3.1 Cost-effectiveness results and thresholds applied

5.3.1.1 Bilateral CI vs unilateral CI

Most studies were positive on the cost-effectiveness of bilateral CI (BCI) compared to unilateral CI (UCI). Four out of 5 studies concluded BCI was cost-effective compared to UCI. Different utility instruments are used and various willingness-to-pay thresholds are referred to:

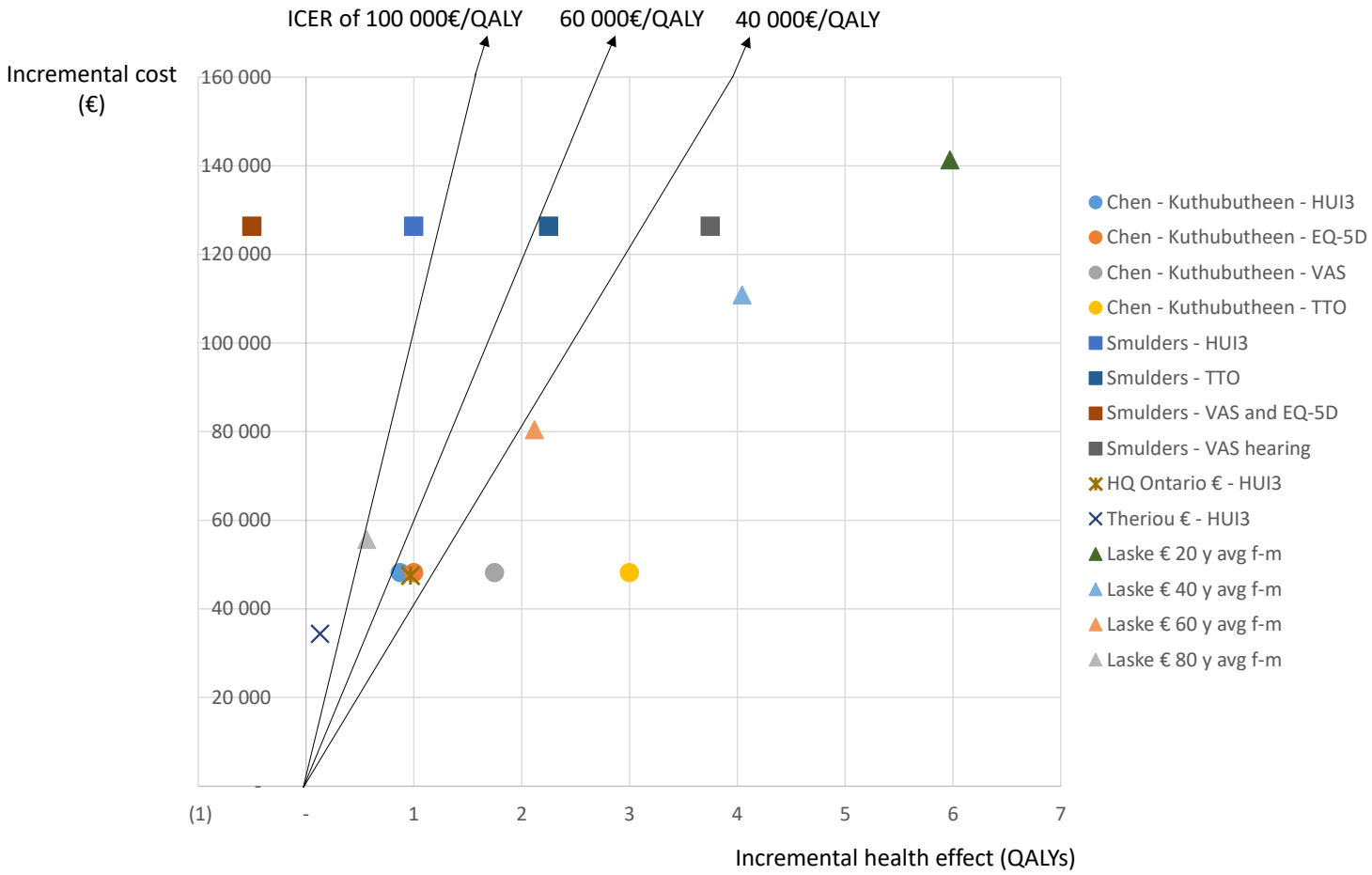
- Based on a study conducted in the Netherlands[73] concluded BCI to be cost-effective compared to UCI when using the utility instruments VAS hearing and TTO, with base case ICERs of around € 34 000/QALY and € 56 000/QALY respectively, but not with HUI-3 with an ICER of around € 126 000/QALY. When using the instruments VAS general health and EQ-5D, BCI appeared not cost-effective at all compared to UCI with very high ICERs. (See appendix for more detail on the utility instruments used.)
    - The Dutch society's willingness-to-pay was considered to range from € 24 500 to € 80 000/QALY.
- A study conducted by HQ Ontario (2018)[68] in Canadian setting concluded BCI to be cost-effective compared to UCI with a base case ICER of CAN$ 48 978/QALY. The study used HUI-3 utilities.
    - 'Commonly used willingness-to-pay thresholds' of $ 50 000/QALY and $ 100 000/QALY are mentioned.
- Based on a study in a Swiss setting, Laske (2019)[75] concluded BCI to be cost-effective compared to UCI and this for all age categories of patients, from 20 years up to 80 years for women and up to 78 years for men, with base case ICERs from CHF 25 000/QALY to around CHF 100 000/QALY.
    - A 'contemporary threshold' of CHF 100 000/QALY' is taken as reference.
- Based on a study conducted in Canada, Chen (2014)[71] and Kuthubutheen (2014)[72] concluded BCI in the base case to be 'borderline cost-effective' compared to UCI when using the HUI-3 utility instrument. The base case ICER was $ 55 020/QALY.
    - A 'commonly accepted willingness-to-pay threshold' of $ 50 000 in North America is mentioned.

One study, concluded BCI was not cost-effective compared to UCI:

- Based on an analysis in UK and US setting, Theriou (2019)[74] concluded that BCI was not the optimal choice at any of the willingness-to-pay threshold values considered. The base case ICERs using HUI-3 were £ 219 900/QALY and $ 239 926/QALY respectively.
    - The lowest willingness-to-pay thresholds considered are £ 20 000 adopted by NICE for the UK and $ 50 000/QALY for the US.

The results of the studies are graphically depicted in the cost-effectiveness plane in Figure 9.

Figure 9 – Cost-effectiveness plane with results of reviewed economic evaluations on BCI compared to UCI in adults



All results were converted to Euros. Note: Results on 25-year time horizon for Smulders (2016)

ICERs vary considerably across studies but also within the studies. Comparison between studies and scenario and sensitivity analyses within studies gave more insight into what factors are most influential on the ICER.

Factors influencing the incremental health effect (the denominator of the ICER):

- One of the most influential parameters are the **utilities** and the utility instrument used. The study of Kuthubutheen (2015)[72] showed that the ICER varied from $ 16 047/QALY using TTO to $ 55 020/QALY using HUI-3. The impact of the utility instrument was also illustrated in the study of Smulders (2016). We will look deeper into the utility gain of BCI compared to UCI in a further section.
- Unfortunately no studies were found that examined the impact of the length of period of hearing loss before implantation. It is known that an implantation shortly after sudden hearing loss gives better results than implantation years after a sudden or gradual hearing loss. This difference in result is expected to impact the utility gain, but no data are thus available on this.
- As also stated in the clinical part, the **duration** of hearing loss before implantation has possibly also an impact on the health effect and ICER. However, this was not studied in these retrieved articles.

Factors influencing both the incremental costs and the incremental health effect (both the numerator and the denominator of the ICER):

- As illustrated by the study of Laske (2019)[75] the result varies considerably depending on the **age at implantation**; the earlier the implantation takes place, the lower and the better the ICER. The longer a person lives with BCI, the longer they can benefit from it, resulting in more QALYs. The longer a person lives with BCI, the higher also the total incremental costs, as there are yearly follow-up costs and periodical renewal of the speech processor. However, the high initial cost of the implantation can be spread over a longer period which makes that the yearly average cost is lower for younger persons. For an adult implanted at 20 years, the study showed an ICER of CHF 25 101-25 730/QALY (females-males). When implanted at 80 years, the ICER rises to CHF 97 810-114 408/QALY (females-males). As females on average live longer they have a lower ICER.
- The ICER also depends on the **discount rates** applied as illustrated in the study of Chen (2014).[71] In the base case, costs and utilities were equally discounted at 3%. In sensitivity analysis the impact of differential discounting was assessed. When costs were discounted at 3% and utilities at 1%, the ICER improved from $ 55 020 to $ 33,032/QALY. When costs were discounted at 3% and utilities at 0%, the ICER further improved to $ 25 693/QALY. Note that according to the Belgian guidelines for economic evaluations[80], costs and utilities are discounted at 3% and 1.5% respectively.

Factors influencing the incremental costs (the numerator of the ICER):

- Costs vary from one country to another, they also vary depending on the time horizon (which can be linked to the age of implantation) and on the **perspective** taken. The analysis from HQ Ontario[68] showed that when a societal perspective was adopted, the results were less favourable for BCI than when a healthcare payer perspective was adopted. This may seem somewhat counterintuitive as one might expect BCI improves education and employment performance which in turn may contribute to increased productivity and societal gains. The less favourable result however can be explained by the following factors:
  - The study could not include societal benefits of BCI as there is a lack of empirical studies on the topic.
  - On the other hand, BCI implies an increased number of surgeries and health care visits, leading to lost productivity during that time for patients and caregivers. Costs of lost productivity are taken into account in the societal perspective but not in the healthcare payer perspective.
  - Most rehabilitation costs in Ontario are covered by the patients themselves. Therefore extra out-of-pocket costs are considered in the societal perspective that were not considered in the healthcare payer perspective.

Which ICER threshold to apply?

Belgium does not have an explicit official threshold value for decision-making and there is no commonly agreed-upon method to determine a country's cost-effectiveness threshold or threshold range. In the past the World Health Organization (WHO) has suggested that interventions with an ICER below one time the average income per capita/QALY can be considered very cost-effective and that interventions with an ICER between one to three times the average income per capita/QALY can still be considered cost-effective. However the WHO warns that none of these thresholds should be used alone as a decision rule for funding, they merely give an indication. 'While cost–effectiveness ratios are undoubtedly informative in assessing value for money – from either the supply or demand side – they also need to be considered alongside affordability, budget impact, fairness, feasibility and any other criteria considered important in the local context.'[81]

In US health economic literature commonly referenced threshold values are US$ 50 000 and US$ 100 000 per QALY; the former stemming from a benchmark cost analysis conducted for dialysis in the 1980s, the latter having no real justification. 77.5% of the authors of studies in US setting use one of these thresholds as a reference point for cost-effectiveness.[82] In the UK, NICE has since long used an explicit cost–effectiveness threshold of between £ 20 000 and £ 30 000 per QALY.[81] In the Netherlands, a threshold range of € 20 000 to € 80 000 is used. The maximum threshold is used for treatments for diseases that cause a very high proportional loss of remaining health. For less severe and mild diseases, the threshold is going down to the lower level threshold.[83]

5.3.1.2 CI in SSD

Only one economic evaluation on CI in SSD was identified in our search. This study[6] reports that CI may be cost-effective compared with no intervention, but that there is large uncertainty around the results and that further research on utility values is warranted with larger sample sizes and longer follow-up. ICERs reported are relatively low varying from CAN$ 17 783/QALY in children to CAN$ 18 148/QALY in adults. These results however are based on utility data measured with HUI-3 in a small patient sample (see further).

Of note is that in the same study bone conduction implants appeared not cost-effective in SSD. On the basis of these conclusions, Health Quality Ontario recommended to reimburse CI in SSD and bone conduction implants (defined in the report as all types of BCDs and MEIs) only when there is a contraindication for CI in SSD.

5.3.1.3 Active tBCD in SSD / conductive and mixed HL

Also for active tBCD in SSD or conductive and mixed hearing loss only one economic evaluation was identified. For the indication of conductive and mixed hearing loss, active tBCD was found to be potentially cost-effective compared to no intervention, with an ICER of CAN$ 74 155/QALY in adults.

For the indication of SSD, active tBCD was found unlikely to be cost-effective compared to no intervention, with an ICER of CAN$ 408 350/QALY in adults.

5.3.1.4 Overview of cost-effectiveness results and conclusions from the studies

Table 18 summarises the cost-effectiveness results and conclusions from the included studies for the different interventions under research.

Table 18 – Cost-Effectiveness results and conclusions of reviewed economic evaluations

Name, year, location	Results: Cost-Effectiveness (ICER)	Conclusion
Bilateral CI in adults		
Chen et al. 2014; Kuthubutheen et al. 2015, Ontario Canada	BCI vs UCI: • HUI-3: $55 020/QALY • EQ-5D: $48 142/QALY • VAS: $27 510/QALY • TTO: $16 047/QALY (US$)	• The choice of utility instrument in cost-utility analysis of BCI heavily influences whether the second implant is deemed cost-effective. The HUI3 is the utility of choice in CI studies and is the most conservative. • Cost-effectiveness of BCI compared to UCI was borderline but improved through base case variations to reflect long-term gains or cost-saving measures. ICER improved with differential discounting, further second-side price reduction and reduced frequency of processor upgrades. ICER worsened with reduced length of use and higher failure rates.
Smulders et al. 2016, Netherlands	- (Results only provided in graph)	• BCI reported as cost-effective vs. UCI using HUI-3, TTO and VAS hearing, but not cost-effective using EQ-5D or VAS (lower utilities with BCI than with UCI). The utility increments on the EQ-5D and VAS on general health questionnaires were so small (or even negative) that they led to absurdly high ICURs. • When using the HUI-3, TTO and 'VAS on hearing', a second CI becomes cost-effective after 5 to 10 years of use, even if utility scores were not significantly higher in the BCI than UCI group. • Results are not applicable to prelingually deafened adults.
HQ Ontario, Canada	Sequential BCI vs UCI: • CAN$48,978/QALY	• On average, sequential BCI is cost-effective compared to UCI for adults with sensorineural hearing loss. BCI was more expensive and more effective than UCI. Cost-effectiveness was highly dependent on the quality-of-life values used.
Theriou 2019, UK and US	BCI vs UCI: • £219 900/QALY Bimodal vs UCI: • £1 521/QALY (UK£)	• Despite producing more QALYs than either unilateral CI (CI alone) or bimodal stimulation (CI + conventional acoustic hearing aid), BCI was found not to be cost-effective because it was associated with excessive costs. • Bimodal stimulation was found to be more cost-effective than unilateral and bilateral CI across a wide range of willingness-to-pay thresholds. • Sensitivity analysis indicated the utility weights as the most sensitive parameter.
Laske 2019, Switzerland	Sequential BCI vs UCI: Implant age (female/male): • 20 yrs: f-m: CHF 25 101-25 730/QALY • 40 yrs: f-m: CHF 29 345-30 710/QALY • 60 yrs: f-m: CHF 40 371-44 323/QALY • 80 yrs: f-m: CHF 97 810-114 408/QALY	• If a threshold of 100 000 CHF per QALY is applied, sequential BCI in comparison to UCI is cost-effective up to an age of 80 for women and 78 for men.

CI in SSD		
Health Quality Ontario 2020, Canada	CI vs no intervention: CAN$17 783/QALY (children) CAN$18 148/QALY (adults)	• Among adults and children with SSD, CI may be cost-effective compared with no intervention. • Results and uncertainty are mainly driven by changes in health utilities associated with having a hearing implant. Hence, further research on utility values in this population is warranted with larger sample sizes and longer follow-up. • In sensitivity analyses, results were most sensitive to changes in health-related utilities (measured using generic quality-of-life tools), highlighting the limitations of currently published data (i.e., small sample sizes and short follow-up).
Active tBCD in SSD		
Health Quality Ontario 2020, Canada	Active tBCD vs no intervention: CAN$408 350/QALY (adults)	• Active tBCD is unlikely to be cost-effective in adults with SSD. • Note that for children similar conclusions are drawn but the analysis is based on active pBCD.
Active tBCD in conductive and mixed HL		
Health Quality Ontario 2020, Canada	Active tBCD vs no intervention: CAN$74 155/QALY (adults)	• Compared with no intervention, active tBCD may be cost-effective in adults with conductive or mixed hearing loss. • Note that for children similar conclusions are drawn, but the analysis is based on active pBCD.

BCI: Bilateral Cochlear Implant, UCI: Unilateral Cochlear Implant, tBCD: transcutaneous Bone Conduction Device, SSD: Single Sided Deafness, HUI-3: Health Utility Index 3, EQ-5D: EuroQoL-5D, VAS: Visual Analogue Scale, TTO: Time Trade Off, ICER: Incremental Cost-Effectiveness Ratio, CI: Cochlear implant, QALY: Quality Adjusted Life Years, pBCD: percutaneous Bone Conduction Device.

5.3.2 Utility results and instruments used

5.3.2.1 Bilateral CI vs unilateral CI

The studies used different sources for assessing the incremental health effect of BCI compared to UCI. Two studies based the health effect on primary collected utility data: Chen (2014)[71] and Smulders (2016)[73]. Three studies based the health effect on utility data collected in other studies: HQ Ontario (2018)[68] used utilities from Chen (2014)[71]); Theriou (2019)[74] used utilities from Summerfield (2002 & 2006)[84, 85]; Laske (2019)[75] used utilities from a narrative review of Crowson (2017)[86]. In what follows we take a deeper look at the original sources used for utilities.

Note that according to the Belgian guidelines for economic evaluations,[80] health state descriptions are preferably obtained from patients (instead of e.g. health professionals or proxies), whilst utilities assigned to these health state descriptions should come from the general public. They have to be measured by generic instruments, preferably EQ-5D. Disease-specific instruments should not be used in the reference case.

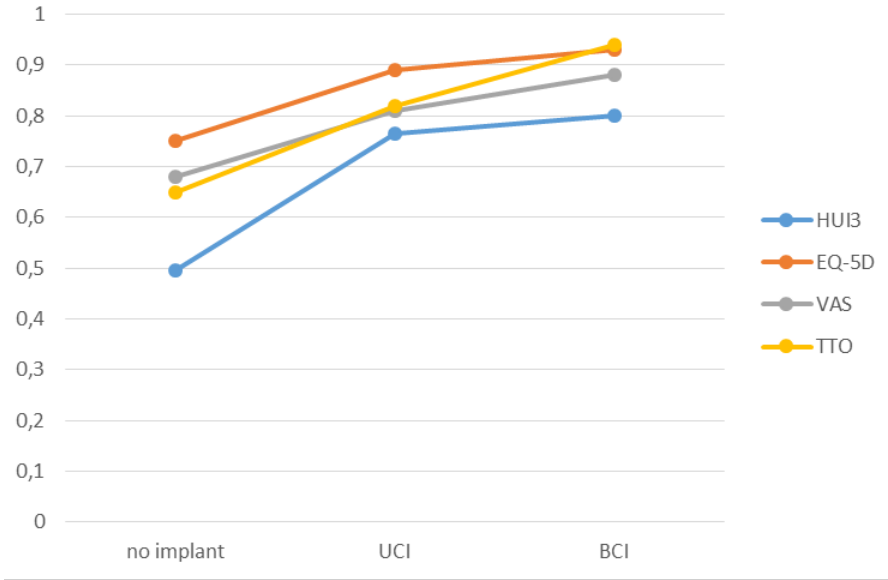
- Chen et al. (2014)[71] and Kuthubutheen et al. (2014)[72] measured utilities by surveying 142 subjects in total, subdivided into four groups: three adult patient groups comprising preimplantees (n = 30), patients with UCI (n = 30) and patients with BCI (n = 30) and one expert group composed of audiologists, researchers, surgeons and therapists (n = 52). Each of them were asked to be introspective in each scenario

(UCI/BCI) and to estimate utilities for each scenario using the HUI-3, EQ-5D, VAS and TTO instruments (see Appendix 4.3 for detail on the instruments).

Regardless of utility instrument used, it appears that the first CI gives the largest improvement; the additional gain going from UCI to BCI is smaller (see Figure 10 and Table 19). With HUI-3, an average utility increment of 0.035 was reported going from UCI to BCI. This gain represents 11.5% of the total increment going from no CI to BCI. Compared to other utility measures, HUI-3 provided the most conservative estimate of utility increment from UCI to BCI. With EQ-5D, an average utility increment of 0.04 was reported. With VAS 0.07 and with TTO 0.12. Nevertheless, the HUI-3 was considered the utility of choice in CI studies. As the questionnaire includes hearing and speech attributes, it was considered most suitable for studies on CI.

Note that the utility scores for BCI reported by the professional group were higher than those reported by the patient group. Conversely, the utility scores for 'UCI' and 'no intervention' reported by the professional group were lower than those reported by the patient group. This implies that the professional group was more optimistic about the improvement from UCI to BCI than the patient groups.

Figure 10 – Utility results from Chen (2014)[71] and Kuthubutheen (2015)[72]

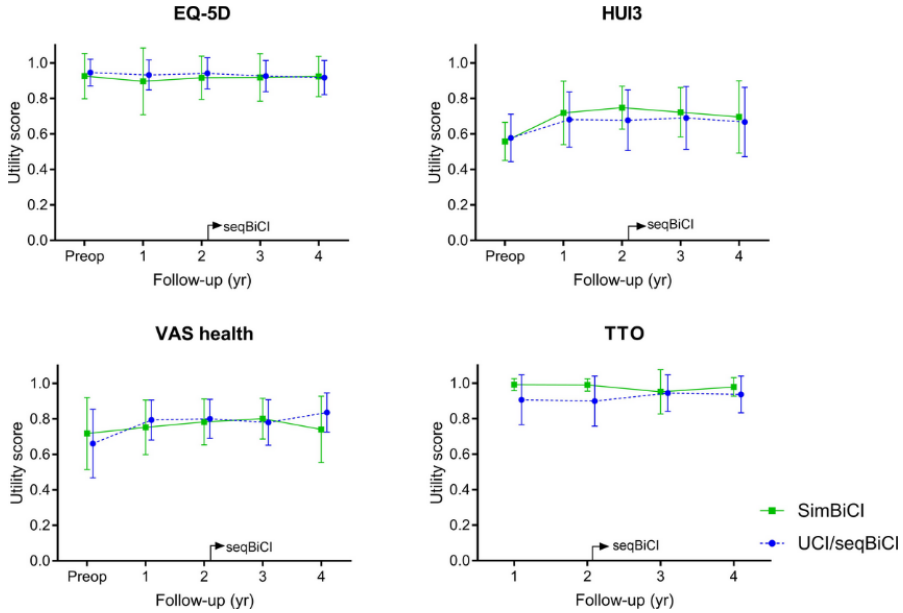


- Smulders et al. (2016)[73] measured utilities directly in the RCT population randomized to either BCI (n=19) or UCI (n=19), using different questionnaires (HUI-3, TTO, EQ-5D, VAS for general health and VAS for hearing). Participants were asked to complete the questionnaires before implantation and after a 1- and 2-year follow-up period.

  One year after implantation, utilities were significantly higher in BCI patients on the VAS for hearing questionnaire. On the other questionnaires, (HUI-3, EQ-5D, TTO, and VAS for general health), there were no significant differences between groups (see Figure 11). Depending on the questionnaire used, there was a utility difference of 0.02 to 0.04 between UCI and BCI.

Note that EQ-5D and VAS for general health even showed lower utilities with BCI than UCI.

Figure 11 – Utility results from Smulders (2016) and Kraaijenga (2019)



Source: Kraaijenga (2019)[87]

- Laske (2019)[75] used the weighted average of disease-specific instruments from a narrative review of Crowson (2016).[86] The following disease-specific instruments were included: the Nijmegen Cochlear Implant Qestionnaire (NCIQ), the Cochlear Implant Function Index (CIFI), the Speech, Spatial and Qualities Questionnaire (SSQ), the Patient Quality of Life Form (PQLF), the Index Relative Questionnaire form (IRQF), the Hearing Participation Scale (HPS) and the Complete Intelligibility Spatiality Quality (CISQ). The weighted average utility gain from UCI to BCI with these disease-specific instruments was 0.1. Note that the weighted average with generic instruments was slightly lower: 0.08.
- Theriou (2019)[74] used the utilities from a RCT of Summerfield et al. (2006).[85] Summerfield measured utilities in the UK using the HUI-3 questionnaire in 24 adults. This study reported a mean utility increment of 0.031 from BCI over UCI, and this was the same incremental value found in an earlier study that estimated utility values using a scenario-based approach (Summerfield et al. 2002)[84] with 202 adults. On the basis of this argumentation, Theriou used an increment of 0.031 from BCI over UCI. (It is unclear however how this utility increment only results in 0.13 incremental QALYs compared to UCI + HA and 0.24 incremental QALYs compared to UCI, as the time horizon of the study is lifetime, as the mean age of the implanted patient is 50 years and as utilities are discounted at 3%.)

Table 19 – Overview of utilities used in economic evaluations on bilateral CI in adults

Author, year, location	Source(s) used; number of patients	Utilities BCI	Utilities UCI	Utilities No implant	Utilities Bimodal treatment
Chen et al. 2014; Kuthubutheen et al. 2015, Ontario Canada	Primary utility data collection; 90 patients (30 with UCI, 30 with BCI, 30 with severe-profound HL) and 52 health professionals	• HUI-3: 0.800 • EQ-5D : 0.93 • VAS : 0.88 • TTO : 0.94 Utility increment BCI over UCI: 0.035 (HUI-3)	• HUI-3: 0.765 • EQ-5D : 0.89 • VAS : 0.81 • TTO : 0.82 Utility increment UCI over no implant: 0.270 (HUI-3)	• HUI-3: 0.495 • EQ-5D : 0.75 • VAS : 0.68 • TTO : 0.65	
Smulders et al. 2016, Netherlands	Primary utility data collection; 38 patients	Mean 1-yr/2-yr postop. • HUI-3: 0.71/0.72 • EQ-5D : 0.90 /0.92 • TTO : 0.99/0.99 • VAS : 0.75/0.78 • VAS hearing : 0.74/0.72 Utility increment BCI over UCI (2-yr postop.): 0.04 (HUI-3); 0.09 (TTO); 0.15 (VAS hearing)	Mean 1-yr/2-yr postop. • HUI-3: 0.68/0.68 • EQ-5D : 0.93/0.94 • TTO : 0.91/0.90 • VAS : 0.79/0.80 • VAS hearing : 0.63/0.57		
HQ Ontario Canada	Chen et al. (2014) and Kuthubutheen et al. (2015)	• HUI-3 : 0.800	• HUI-3 : 0.765	• HUI-3 : 0.495	
Theriou 2019, UK and US	Summerfield (2006); 24 adults (12 immediately implanted BCIs, 12 controls) Summerfield (2002); 202 adults	• HUI-3: 0.509 Utility increment from BCI over UCI : 0.031 (HUI-3)	• HUI-3: 0.478	• HUI-3: 0.433	• HUI-3: 0.510
Laske 2019, Switzerland	Crowson (2017)	Weighted average utility increment from BCI over UCI: 0.1 (measured by disease-specific QoL instruments: NCIQ, CIFI, SSQ, PQLF, IRQF, HPS, CISQ)			

NCIQ: Nijmegen Cochlear Implant Questionnaire, CIFI: Cochlear Implant Function Index , SSQ : Speech, Spatial and Qualities Questionnaire , PQLF : Patient Quality of Life Form, IRQF: Index Relative Questionnaire Form, HPS: Hearing Participation Scale, CISQ: Complete Intelligibility Spatiality Quality, HUI-3: Health Utility Index 3, EQ-5D: EuroQoL-5D, VAS: Visual Analogue Scale, TTO: Time Trade Off, BCI: Bilateral Cochlear Implant, UCI: Unilateral Cochlear Implant, QoL: Quality of Life.

In summary, Chen (2014)[71] and Kuthubutheen (2014)[72] found a utility increment of 0.035 (HUI-3); Smulders (2016)[73] found utility increments of 0.04 (HUI-3), 0.09 (TTO) and 0.15 (VAS hearing); HQ Ontario (2019) used the HUI-3 utility increment of Chen[71] and Kuthubutheen[72] and applied disutilities for extra complications with BCI; Theriou (2019)[74] used a utility increment of 0.031 (HUI-3) based on two studies from Summerfield[84, 85] and finally Laske (2019)[75] used a utility increment of 0.1 (based on several disease-specific instruments).

Data on HUI-3 were collected in the studies of Chen (2014), Smulders (2016) and an older study from Summerfield (2006) for BCI compared to UCI. These studies report rather consistent results, with a utility increment of 0.035; 0.04 and 0.031 respectively for BCI compared to UCI. However, the data remain too limited to draw firm and definitive conclusions and further research is recommended.

QALYs gained for bilateral CI vs unilateral CI

Looking at the total QALYs gained over a long term horizon (depending on the study either over 25 years or lifetime horizon) when using HUI-3 utility data, the studies of Chen (2014)[71], Smulders (2016)[73] and HQ Ontario (2018)[68] converge, showing roughtly around 1 incremental QALY for BCI over UCI. The study of Laske (2019)[75] is the most optimistic on the long term incremental health effect, calculating 4 incremental QALYs for BCI over UCI in an adult aged 40 years and 2 incremental QALYs in an adult aged 60 years. In contrast, the study of Theriou (2019)[74] only reports 0.13 incremental QALY for BCI over UCI+HA over lifetime horizon; with this result, the study of Theriou is the most conservative on the incremental health effect.

5.3.2.2 CI in SSD

CI in SSD: utilities

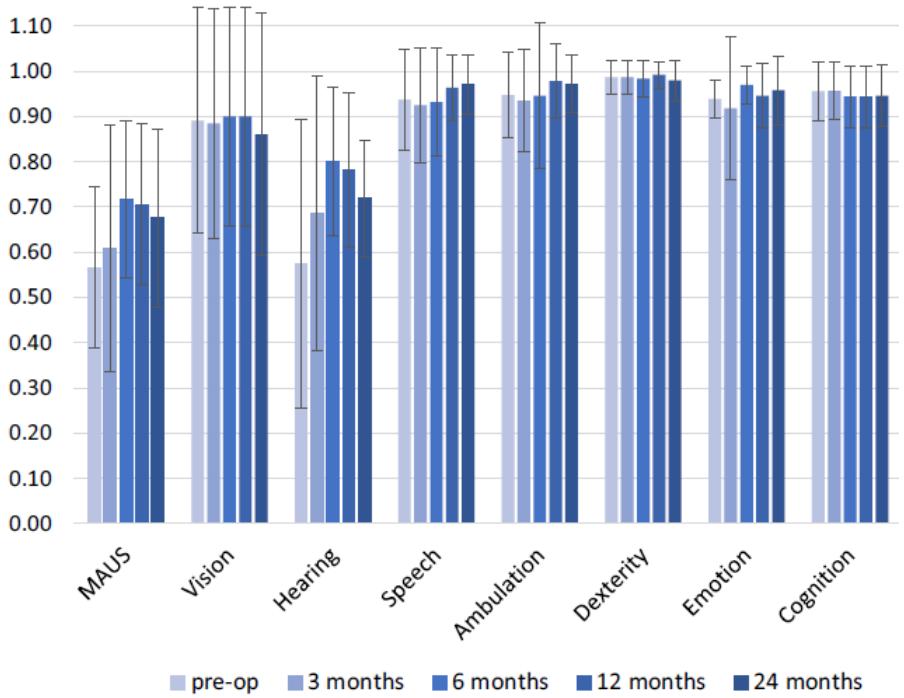
The economic evaluation of HQ Ontario (2020) based utilities on an older study of 2010 reporting utilities in people with CI, BCD and CROS for SSD.[6]

- The study from Arndt et al. (2010)[88] was conducted in 11 adults who responded to HUI-3 in a single centre in Germany. They reported a significant postoperative increase in the total HUI-3 score compared to the pre-implant unaided condition and the pre-implant condition with either contralateral routing of signals (CROS) or bone conduction device (BCD). Compared to the unaided condition, the study reported a utility increment of 0.24 from CI. The HQ Ontario study assumed these utility values from adults (for CI versus unaided) also to be applicable for children. Extrapolated on a lifetime period, this translated into an incremental effect of 2.76 QALYs. Note that compared to CROS, Arndt et al. reported a utility increment of 0.15 for CI. Compared to BCD, they reported a utility increment of 0.13 for CI.

Our search yielded 2 more recent studies measuring the impact of CI on generic QoL of patients with SSD.

- Muigg et al. (2019)[78] assessed the 2-year outcomes of CI in SSD on the NCIQ and the HUI-3 in 20 adults. With the HUI-3, a utility increment of 0.11 (from 0.57 pre-operative to 0.68 after 24 months) was reported (see Figure 12).
- Hausler et al. (2019)[79] assessed the outcomes of CI in SSD on the SF-36 in 20 patients. The study reports an increase on the vitality domain of SF-36 from 55.5 to 64.0, but no change in the other domains. The change in overall score of SF-36 was not reported.

Figure 12 – Utility results from Muigg (2019) on HUI-3 for CI in adults with SSD



MAUS: multi-attribute utility score. Source: Muigg (2019)[78]

A general overview of the utilities for the economic evaluations on CI in SSD is given in Table 20.

Table 20 – Overview economic evaluations on CI in SSD: utilities

Author, year	Source(s) used; number of patients	Utilities CI	Utilities Comparators
Health Quality Ontario 2020	Arndt et al. (2010) 11 patients	HUI-3: 0.80 Utility increment CI over unaided: 0.24	HUI-3 : • Unaided : 0.56 • CROS : 0.65 • Bone anchored hearing aid : 0.67
	Muigg et al. (2019) 20 adults	HUI-3: 0.68 Utility increment CI over unaided: 0.11	HUI-3: • Unaided: 0.57
	Hausler et al. (2020) 20 patients	SF-36: 64.0 Only in 'vitality' domain a utility increment CI over unaided: 8.5	SF-36: • Unaided: 55.5

HUI-3: Health Utility Index 3, CI: Cochlear Implant, CROS: Contralateral Routing Off Signals, SF-36: Short Form Survey

For CI in SSD, an older study[88] in 11 adults reported a utility increment of 0.24 for CI compared to unaided with HUI-3. A more recent study in 20 adults reported an increment of 0.11, also based on HUI-3. These data remain too limited to draw firm and definite conclusions and further research is recommended.

QALYs gained by CI in SSD

Total QALYs gained over a 25 year horizon in the HQ Ontario report (2020)[6] amounted to 2.76 for CI in SSD compared to no intervention, based on HUI-3 data.

5.3.2.3 Active tBCD in SSD / conductive and mixed HL

The economic evaluation of HQ Ontario (2020[6]) based utilities on HUI-3 data provided by a hospital in Ontario. The study sample comprised 17 adults with active tBCD in SSD who were surveyed up to 12 months after implantation (Table 21).

Table 21 – Overview economic evaluations on active tBCD in SSD: utilities

Author, Year	Source(s) used; number of patients	Utilities Active tBCD	Utilities Comparators
Health Quality Ontario 2020[6]	Ontarian hospital; 17 adults	HUI-3: 0.79 Utility increment active tBCD over unaided: 0.01 (12 months)	HUI-3 : • Unaided : 0.78

HUI-3: Health Utility Index 3, tBCD: transcutaneous Bone Conduction Device

For active tBCD in SSD, data from an Ontarian hospital in 17 adults reported a utility increment of 0.01 for active tBCD compared to unaided with HUI-3. However, an older study[88] in 11 adults reported a utility increment of 0.11 for pBCD compared to unaided in SSD with HUI-3; whilst results of active tBCD would be expected to be equal, if not better. We conclude that the data remain too limited to be robust and further research is recommended.

QALYs gained by active tBCD in SSD

Total QALYs gained over a 10 year horizon in the HQ Ontario report (2020)[6] amounted to 0.06 in adults and 0.05 in children compared to no intervention, based on HUI-3 data.

The economic evaluation of HQ Ontario (2020)[6] based utilities on HUI-3 data provided by an Ontarian hospital. The study sample comprised 33 adults with active tBCD mixed and conductive hearing loss who were surveyed up to 12 months after implantation (Table 22).

Table 22 – Overview economic evaluations on active tBCD in mixed and conductive hearing loss: utilities

Name, year, location	Source(s) used; number of patients	Utilities Active tBCD	Utilities Comparators
Health Quality Ontario 2020[6]	Ontarian hospital; 33 adults	HUI-3: 0.73 Utility increment active tBCD over unaided: 0.07 (12 months), after 12 months goes down to 0.04	HUI-3 : • Unaided : 0.69

HUI-3: Health Utility Index 3, tBCD: transcutaneous Bone Conduction Device

For active tBCD in mixed and conductive hearing loss, data from an Ontarian hospital in 33 adults reported a utility increment of 0.07 for active tBCD (12 months, after decrease to 0.04) compared to unaided with HUI-3. We conclude that the data remain too limited to be robust and further research is recommended.

QALYs gained by active tBCD in mixed and conductive hearing loss

Total QALYs gained by active tBCD in mixed and conductive hearing loss in the HQ Ontario report (2020)[6], calculated over a 10 year horizon, and amounted to 0.30 in adults compared to no intervention, based on HUI-3 data.

5.3.2.4 Overview of utility results and discussion of instruments used

In order to promote consistency across studies, the Belgian guidelines for economic evaluations[80] encourage the use of generic utility instruments, and more specifically of the EQ-5D, at least in the reference case. If the EQ-5D instrument is not considered suitable, then the use of another generic utility instrument or direct measurement of utilities can be considered. If it is thought that a generic instrument is insufficiently sensitive to relevant changes in health in a specific disease, additional disease-specific quality-of-life results can be described in separate analyses.

The clinical review showed that benefits of BCI compared to UCI in adults are found in better hearing in noisy environments and better sound localisation. It has been illustrated in the economic review that these improvements are not easily captured by generic quality-of-life instruments. A meta-analysis of Mcrackan (2019)[77] showed that with none of the generic quality-of-life instruments (EQ-5D, HUI-3, VAS health) significant improvement in quality-of-life was obtained between UCI and BCI.[89] Especially the EQ-5D appears not sensitive to capture the more subtle benefits of BCI; indeed EQ-5D has no dimension directly related to hearing.

HUI-3 on the other hand, has been described as a more suitable instrument to measure quality-of-life in economic evaluations of hearing related conditions, as it includes dimensions on hearing and speech. In France, HUI-3 is accepted by the Haute Autorité de Santé (HAS) for economic evaluations besides the EQ-5D. The National Institute for Health and Care Excellence (NICE) in the UK also has accepted the use of HUI-3 in the past for deciding on the criteria for CI,[74] although it generally only accepts EQ-5D as preferred measure and makes exceptions for other generic instruments only when they are mapped to EQ-5D using validated mapping functions.[90] Taking all this into consideration, HUI-3 appears to be the most viable instrument when it comes to conducting economic evaluations for the discussed interventions, although comparability of the resulting cost-effectiveness ratio is limited with regard to ratios calculated on the basis of EQ-5D.

Still also with HUI-3 there are very limited data on quality-of-life improvement from the interventions under research and more studies with larger samples are required to produce more robust data on which reliable economic evaluations can be based:

- For **BCI compared to UCI**, data on HUI-3 from three studies are available (including respectively 30–19-12 BCI patients plus controls). The studies though show rather consistent results, with utility increments of **0.035-0.07-0.031**.
- For **CI in SSD**, two studies are available and results vary. An older study in 11 adults available reporting a utility increment of **0.24** for CI compared to unaided with HUI-3. A more recent study reported an increment of **0.11**.
- For **active tBCD in SSD**, data from a single hospital in Ontario in 17 adults are available. The hospital reported a utility increment of **0.01** for active tBCD compared to unaided with HUI-3. An older study[88] however comparing pBCD to unaided in 11 adults with SSD reported a utility increment of 0.11 with HUI-3; whilst results of active tBCD would be expected to be equal, if not better.
- For **active tBCD in mixed and conductive hearing loss**, data from the same hospital in Ontario in 33 adults are available. The hospital reported a utility increment of **0.07** for active tBCD compared to unaided with HUI-3.

These results are also briefly recapitulated in Table 23.

Table 23 – Summary of utility results (on a scale from 0 – death to 1 – perfect health) based on HUI-3

	Utility
BCI compared to UCI	0.03 - 0.07
CI in SSD compared to unaided	0.11-0.24
Active tBCD in SSD compared to unaided	0.01
Active tBCD in mixed and conductive hearing loss	0.07

HUI-3: Health Utility Index 3, tBCD: transcutaneous Bone Conduction Device, BCI: Bilateral Cochlear Implant, UCI: Unilateral Cochlear Implant, CI: Cochlear Implant, SSD: Single Sided Deafness

5.3.3 Costs

The total long-term costs in the studies generally comprise pre-procedural, procedural (device, surgical and hospitalisation costs) and post-procedural costs (follow-up visits, extra batteries, sound processor renewal and in most studies also rehabilitation). In some of the studies costs for complications are also accounted for.

As costs are country-specific we only briefly report on the total long-term incremental costs from the studies. For the costs specific to the Belgian situation we refer to the cost-consequence analysis in a further part of this chapter, which is mostly based on data from the data analysis chapter.

Bilateral CI vs unilateral CI

As also illustrated on the cost-effectiveness plane above, there is considerable variation in long-term incremental costs of BCI compared to UCI reported in the studies. Post-procedural costs over the long term constitute a considerable, if not the largest, part of the total costs.

- Smulders (2016)[73] reported the highest long-term incremental costs of € 126 346 on 25 years. These costs comprise a doubling of the unilateral fees, which likely is an overestimation according to the authors:

- Direct costs of implantation (preoperative assessments, surgery, implant and rehabilitation): UCI: € 43 883 / BCI: € 87 765
- Cost of consecutive years (per year): UCI: € 3 435 / BCI: € 6 871

- Chen (2014)[71] reported an incremental cost of US$ 48 132 on 25 years (cost of BCI: US$ 111 764 versus cost of UCI: US$ 63 622)
- HQ Ontario (2018)[68] reported an incremental cost of CAN$ 47 509 on lifetime horizon for adults aged 18 to 55 years, detailed as follows:
  - Preprocedural costs:
    - UCI: CAN$ 446
    - Sequential BCI: CAN$ 892
    - Simultaneous BCI: CAN$ 446
  - Procedural costs:
    - Device cost, 1st: CAN$ 25 000; for the 2nd device, a 50% discount was assumed: CAN$ 12 500
    - Surgical costs UCI: CAN$ 4 644
    - Surgical costs BCI simultaneous: CAN$ 6 200
    - Surgical costs BCI sequential: CAN$ 9 288
  - Postprocedural Costs (first 2 years, not including rehabilitation)
    - UCI: CAN$ 371
    - Simultaneous BCI: CAN$ 371
    - Sequential BCI: CAN$ 742
  - And finally also complications, including sound processor replacement every 3 years (covered for 75% of the cost: CAN$ 5 444).
  - Not included are costs for rehabilitation in adults, they are assumed to be funded by the patient.
- Theriou (2019)[74] reported an incremental cost of £ 29 287 on lifetime horizon for adults with mean age 50 years.
- Laske (2019)[75] differentiated costs in function of age category, for adults aged 40 years, for instance, costs reported were about CHF 115 774 - 122 314 (male-female) ; for adults aged 60 years, costs reported were CHF 83 074 - 89 614 (male-female). Costs were calculated on lifetime horizon.

CI in SSD

- Incremental costs of CI in SSD compared to no intervention were estimated by HQ Ontario (2020)[6] at CAN$ 50 089 on 25 years, a slightly higher figure than that reported for BCI compared to UCI, mainly because of a higher device cost for the 1st than for the 2nd CI. Sound processor replacement in this model on the other hand was assumed to take place less frequently, after 5 to 10 years.

Active tBCD in SSD / mixed and conductive hearing loss

- Incremental costs of active tBCD in adults compared to no intervention were estimated by HQ Ontario (2020)[6] at CAN$ 22 478 on 10 years. This incremental cost equals the total cost of active tBCD and comprises the following components:
  - Preprocedural costs of CAN$ 369
  - Procedural costs of CAN$ 15 436, including the cost of the implant (including sound processor) of CAN$ 11 000
  - Postprocedural costs of CAN$ 287
  - Cost of complications (a range of possible complications weighted by their event rate).

  It is the procedural cost, and more specifically the device cost, that constitutes the largest cost.

5.4 Cost-consequence analysis in a Belgian setting

Given that the literature shows that the incremental utilities as measured by the EQ-5D are limited, it was found appropriate to present the economic analysis as a cost-consequences analysis (present costs and consequences in diaggregated form) rather than a cost-utility analysis. A cost–consequence analysis is a type of economic evaluation that provides costs and outcomes (consequences) separately and in full transparency, rather than calculating a summary ratio of an ICER or cost per QALY. It leaves the final judgement regarding the relative importance of outcomes vis-à-vis the costs to the decision-maker.

For complete detail on health outcomes we refer to the clinical chapter. For quality-of-life data, we also refer to the above economic review. In this section we will focus on the incremental costs of the studied interventions in a Belgian setting. These cost data are primarily based on the data analysis chapter.

5.4.1 Long-term incremental costs for (sequential or simultaneous) BCI compared to UCI or bimodal treatment

Table 24 shows the estimated long-term incremental costs for BCI compared to UCI in adults in Belgium. Incremental costs are differentiated as to whether the second ear is implanted sequentially or simultaneously. In case the implantation is done simultaneously, the second CI is expected to involve considerably lower costs.

The data show incremental costs of BCI compared to UCI with one ear unaided. Note that if we compare BCI to bimodal treatment (i.e. CI on one ear and a conventional hearing aid on the other ear), then long-term costs of a conventional hearing aid have to be further deducted.

Table 24 – Estimation of long-term incremental costs for BCI compared to UCI in adults

	Incremental cost of BCI compared to UCI in adults	Frequency
Implant (taking into account the price reduction of 2019)	€ 15 984	
Renewal of the sound processor	€ 5 138	every 5 years
Other costs in procedural phase: hospitalisation, surgical procedure, other procedures and drugs:		Calculated on TCT data (Table 35 in data analysis)
- sequential BCI	€ 3 207 (per implant)	
- simultaneous BCI	€ 3 953	
Preprocedural costs		Calculated on IMA data (Table 37 in data analysis)
- sequential BCI	€ 437	
- simultaneous BCI	€ 1 345	
Postprocedural costs up to 4 years after procedure. Max. 288 rehab. sessions are reimbursed over 4 years. This holds for BCI as well as UCI.		Calculated on IMA data (Table 37 in data analysis)
- sequential BCI (include costs after first and second implantation)	€ 7 994	

- simultaneous BCI	€ 7 622

Discount rate 3%	
Total discounted costs on 25 years	
- sequential BCI	€ 54 823
- simultaneous BCI	€ 52 956

BCI: Bilateral Cochlear Implant, UCI: Unilateral Cochlear Implant

5.4.2 *Long-term incremental costs for CI in SSD compared to unaided or treatment with CROS or BCD*

Long-term incremental costs for a CI in SSD are esteemed largely comparable to the costs for a sequential CI in bilateral hearing loss, but may require more rehabilitation sessions since it is the first CI to learn to hear with. We refer to Table 24.

Note that if we compare to CROS or BCD, then long-term costs of these hearing aids have to be further deducted.

5.4.3 *Incremental long-term costs for active tBCD in SSD / mixed and conductive hearing loss*

Table 25 shows the estimated long-term incremental costs for active tBCD compared to no intervention for Belgium. If we want to compare costs to CROS or BCD, then long-term costs of these hearing aids have to be further deducted. The cost of a passive tBCD is around € 5 500 (implant of € 1 128.34 + sound processor of around € 4 400). Other costs in procedural phase (hospitalisation, surgical procedure, other procedures and drugs) are on average € 1 160 (see chapter 6).

Table 25 – Estimation of long-term incremental costs for active tBCD compared to no intervention and passive tBCD in adults

	Incremental cost of active tBCD		
	Compared to unaided	**Compared to passive tBCD**	
Implant (assuming price to be equal to Vibrant Soundbridge (MEI))	€ 9 390	€ 3 890	
Renewal of the sound processor (MEI)	€ 2 384	€ 4 400	
Other costs in procedural phase: hospitalisation, surgical procedure, other procedures and drugs (costs for active tBCD assumed to be equal to passive tBCD)	€ 3 218	€ 1 162	Calculated on TCT data (Table 35 in data analysis)
Preprocedural costs (assumed to be equal to MEI)	€ 701	€ 701	Calculated on IMA data (Table 38 in data analysis)
Postprocedural costs (assumed to be equal to MEI)	€ 1 509	€ 1 509	Calculated on IMA data (Table 38 in data analysis)
Discount rate 3%			
Total discounted costs on 10 years	€ 14 373	€ 7 044	

tBCD: transcutaneous Bone Conduction Device, MEI: Middle Ear Implant

5.5 Conclusions

Bilateral CI vs unilateral CI

Five economic evaluations have been conducted in recent years to calculate the cost-utility of BCI compared to UCI in adults. Four of them conclude BCI is cost-effective or borderline cost-effective compared to UCI.

Results of the studies

- Cost-utility results vary considerably in function of quality-of-life questionnaire used and costs reported, as well as the time horizon (age of patients). The younger the patients, the better the cost-effectiveness. Simultaneous BCI is slightly more cost-effective than sequential BCI because of its lower costs.
- Regardless of utility instrument used, it is the first CI that gives the largest improvement. The gain of the second CI is estimated to represent 11.5% of the total increment going from no CI to BCI.
- When the generic EQ-5D instrument is used, as recommended by the Belgian and the EUnetHTA guidelines, the impact of BCI compared to UCI is so small that BCI turns out not cost-effective.
- Using HUI-3, also a generic instrument, BCI has been found cost-effective in some but not all studies. In contrast to EQ-5D, HUI-3 contains questions on hearing and speech. In the described studies it is considered a more suitable instrument than EQ-5D for economic evaluations on hearing related disorders.
- Using the HUI-3, the long-term (25 years) incremental health effect of BCI over UCI fluctuates around 1 QALY. Compared to other

generic instruments HUI-3 still appears to be on the conservative side.

Discussion and applicability to the Belgian context

- Long-term incremental costs of BCI compared to UCI in Belgian setting (including preprocedural, procedural and postprocedural costs) are estimated at € 54 823 for sequential BCI and € 52 956 for simultaneous BCI. These costs are from the healthcare payer perspective and no potential societal gains (e.g. from increased labour market participation) have been deducted.
- A nuanced interpretation of the reviewed studies is required and caution regarding the generalisability to the Belgian decision-making context is warranted. Using HUI-3, positive cost-effectiveness results have been shown abroad. Putting HUI-3 data alongside Belgian cost data also points in the direction of a rather favourable, though borderline, balance. Since cost-effectiveness ratios calculated with HUI-3 are not strictly comparable to ratios calculated with EQ-5D in other clinical domains, and since there is no formal ICER threshold in the Belgian decision-making context, further research is required on quality-of-life (e.g. HUI-3) to obtain more robust data.
- The recent lowering in price of CI in Belgium has led to a considerable cost reduction. Further lowering of price for bilateral implantations, e.g. as part of a price-volume agreement like in France, would still improve the cost-effectiveness of BCI compared to UCI.

CI in SSD vs no intervention

A single economic evaluation has been conducted in recent years to calculate the cost-utility of CI in SSD compared to no intervention. The study concludes CI is cost-effective in children as well as adults.

Results of the studies

- The study used a utility increment of 0.24 based on HUI-3. With this utility increment, the long-term incremental health effect of CI in SSD over no intervention approached 2.8 QALYs on a time horizon of 25 years. (Note that this is nearly three times the value reported for BCI compared to UCI). However, utility data are based on a single older study in 11 adults only. Further research on quality-of-life is required to obtain robust data.

Discussion and applicability to the Belgian context

- Long-term incremental costs of CI compared to unaided in Belgian setting (including preprocedural, procedural and postprocedural costs) are estimated at €54 823.
- One cannot draw firm conclusions on the cost-effectiveness of CI in SSD given the very limited data on quality-of-life measured by generic instruments.
- Based on this study no firm conclusions can be drawn but one can expect that the younger the patients, the better the cost-effectiviness, als also seen in BCI versus UCI.

Active tBCD in SSD / conductive and mixed hearing loss vs unaided or passive tBCD

We identified one economic evaluation, conducted in Canadian setting, calculating the cost-effectiveness of active tBCDs compared to 'no intervention' in SSD as well as in conductive and mixed hearing loss.

Results for active tBCD in SSD compared to no intervention

- For generic quality-of-life data on active tBCD in SSD, only data from a single hospital in Ontario in 17 adults are available. The hospital reported a small quality-of-life increment of 0.01 (on a scale from 0 – death to 1 – perfect health) for active tBCD compared to unaided with HUI-3. An older study however comparing Baha to unaided in 11 adults with SSD reported an increment of 0.11 with HUI-3, whilst results of active tBCD would be expected to be equal, if not better. We conclude that the data remain too limited to draw firm and definite conclusions and further research is required.
- Based on this data from Ontario, total QALYs gained over a 10 year horizon amounted to 0.06 in adults compared to no intervention.
- With a resulting ICER of CAN$ 408 350/QALY in adults, the authors conclude that active tBCD is unlikely to be cost-effective in adults with SSD. Note that for children similar conclusions are drawn but the analysis is based on pBCD.

Results for active tBCD in conductive and mixed hearing loss to no intervention

- For generic quality-of-life data on active tBCD in mixed and conductive hearing loss, only data from the same hospital in Ontario in 33 adults are available. The hospital reported a quality-of-life increment of 0.07 for active tBCD compared to unaided with HUI-3. Also here we conclude that the data remain too limited to draw firm and definite conclusions and further research is recommended.
- Resulting total QALYs gained by active tBCD in mixed and conductive hearing loss, calculated over a 10 year horizon, amounted to 0.30 in adults compared to no intervention.
- Calculating the cost per QALY rendered a result of CAN$ 74 155/QALY in adults. The authors conclude that, compared with no intervention, active tBCD may be cost-effective in adults with conductive or mixed hearing loss. For children similar conclusions are drawn, but the analysis is based on pBCD.

Discussion and applicability to the Belgian context

- The choice of 'no intervention' as comparator in the Canadian study may have led to rather conservative results, as the extra cost compared to 'no intervention' is considerably higher than compared to an alternative intervention. In the Belgian context, for many patients, active tBCD constitutes an alternative to another BCD. No data have been reported on the net cost compared to passive tBCDs or pBCDs and there is not sufficient data available to precisely balance the gains (less complications or better results) against the costs.
- In the Belgian setting, incremental costs of active tBCD compared to passive tBCD in initial phase (comprising implant, sound processor and hospitalisation, assuming costs for hospitalisation being equal) are estimated at €5 500 per ear. This cost is calculated from the healthcare payer perspective so includes both costs paid by public healthcare payer and the patient. Considering this incremental cost, even with a small increase in quality-of-life a favourable cost-effectiveness ratio could be achieved. A price reduction for active tBCD would obviously improve its cost-effectiveness.
- Since cost-effectiveness ratios calculated with HUI-3 are not strictly comparable to ratios calculated with EQ-5D in other clinical domains, and since there is no formal ICER threshold in the Belgian decision-making context, further research is required on quality-of-life (e.g. HUI-3) to obtain more robust data.

6 DATA ANALYSIS

6.1 Introduction

In this chapter, we aim to give an overview of the conventional hearing aids (CHAs) and hearing implants including bone conduction devices (BCDs), cochlear implants (CIs), and middle ear implants (MEIs) available on the Belgian market. The data analysis will focus on:

- The RIZIV-INAMI budget for hearing aids and implants.
- The number of hearing devices delivered during the years 2014 to 2018.
- The number of patients (and their characteristics) who had an implant during the years 2016 to 2018.
- The global reimbursed amount of the procedural phase.
- The overall reimbursed amount of the pre- and post-procedural phases.

6.2 Data sources

Three different data sources were consulted for this study: the doc N (Document N) from the National Institute for Health and Disability Insurance (NIHDI) (Rijksinstituut voor ziekte- en invaliditeitsverzekering – Institut national d'assurance maladie-invalidité (RIZIV-INAMI)), the Minimal Hospital Data (MZG-RHM:Minimale Ziekenhuis Gegevens' – 'Résumé Hospitalier Minimum') and the administrative data from the InterMutualistic Agency (IMA-AIM: Intermutualistisch Agentschap – Agence Intermutualiste).

6.2.1 *Document N data*

Doc N (Document N) includes data concerning the reimbursement of all services for all RIZIV-INAMI billing codes. KCE regularly receives updates from the RIZIV-INAMI (last update: first semester 2019).

For the present study, this data has been used to study the evolution of expenditures on hearing implants and conventional hearing aids based on the RIZIV-INAMI nomenclature codes (see in Appendix 5.1), between 2008 and 2018.

6.2.2 *Minimal Hospital data:*

The Minimal Hospital Data (MZG-RHM) is a standardized set of data on all inpatient hospital stays (hospitalisation of minimum one night), day-care hospital stays (admission and discharge during the same day) and emergency room contacts, originating from all Belgian general hospitals. These hospitals are legally bound to submit these data to the Federal Public Service for Health, Food Chain Safety and Environment (FPS Public Health). Access of the KCE to the MZG-RHM within the TCT 'Technische Cel – Cellule Technique' is regulated by article 256 of the Progamlaw (I) of 24 December 2002.[a] The TCT has the mission to collect, link, validate and anonymize data relating to hospitals. Data are available for the years 2008 to 2018, but no data are available for the year 2015. Of note, people who received a non-reimbursed implant are not included in the database.

This data has been used to describe hearing implants patient's characteristics, place of implantation and procedural costs. Data selection has been done in order to only have patients who received conventional hearing aids (CHA) and/or implants, based on the INAMI/RIZIV nomen codes (see in Appendix 5.1). Demographic data (age, gender, and region), hospital data (implantation centre, date of implant, duration of the stay, etc.) and cost data were retrieved for the years 2016-2018.

[a] http://www.ejustice.just.fgov.be/eli/wet/2002/12/24/2002021488/justel#Art.265

6.2.3 *Administrative data from the Intermutualistic Agency*

The Intermutualistic Agency (IMA-AIM) is a non-profit organisation that manages and analyses information on all reimbursements related to the compulsory health insurance (sickness funds). These data, transmitted by the 7 Belgian sickness funds, cover all reimbursed services (consultations, pharmaceuticals, diagnostic and therapeutic procedures) and some patient socio-demographic characteristics as well as social security related data to the extent they influence reimbursement.

A random sample (called Permanent sample – EPS) from this database is available. It is a random selection stratified for age and gender containing approximately 300 000 individuals followed since 2002 and yearly updated to compensate for mortality and aging and new members are added according to the same sample size rules. The sample proportion is 1/40 among subjects younger than 65 and 1/20 among subjects aged 65 years and older. KCE has a permanent access (by law[b]) via a secure connection to use the data within the boundaries of their legal missions.

For the present study, both databases were analysed:

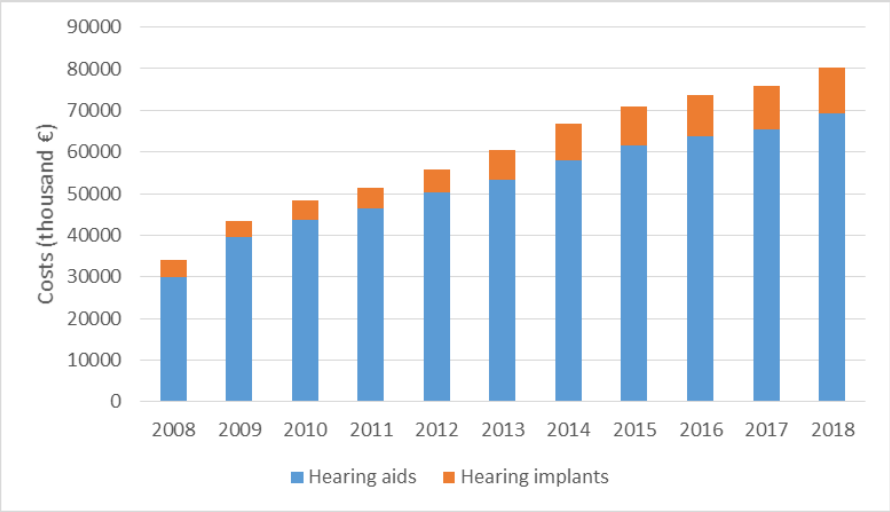
- The entire IMA-IAM database: used to analyse one year pre and five years post hospitalisation costs for cochlear and BCD implants. Fot this, ENT consultation and prescriptions, re-education by speech therapy or in a centres for ambulatory rehabilitation were identified based on the INAMI/RIZIV nomenclature. More details is found in Appendix 5.4.
- EPS in order to only will focus on CHA. A selection of data has been done in order to only have patients who have hearing aids and/or hearing implants, based on the RIZIV-INAMI nomen codes (see in Appendix 5.1). Demographic data (age, gender, region), and cost data were retrieved for the years 2016-2018.

[b] Royal decree amending the Royal Decree of 9 May 2007 implementing article 278 of the program law (I) of 24 December 2002 — 2013-03-21

6.3 RIZIV-INAMI budget for hearing aids and hearing implants

The annual RIZIV-INAMI budget for hearing implants and hearing aids is growing each year (Figure 13). In ten years, this budget has doubled, from less than 40 million € in 2008, to more than 80 million € in 2018. The traditional hearing aids (including the non-implatable part of a BCD) have the biggest place in this budget (86.5%), the other 13.5% of budget is for hearing implants which has been slowly growing throughout the years.

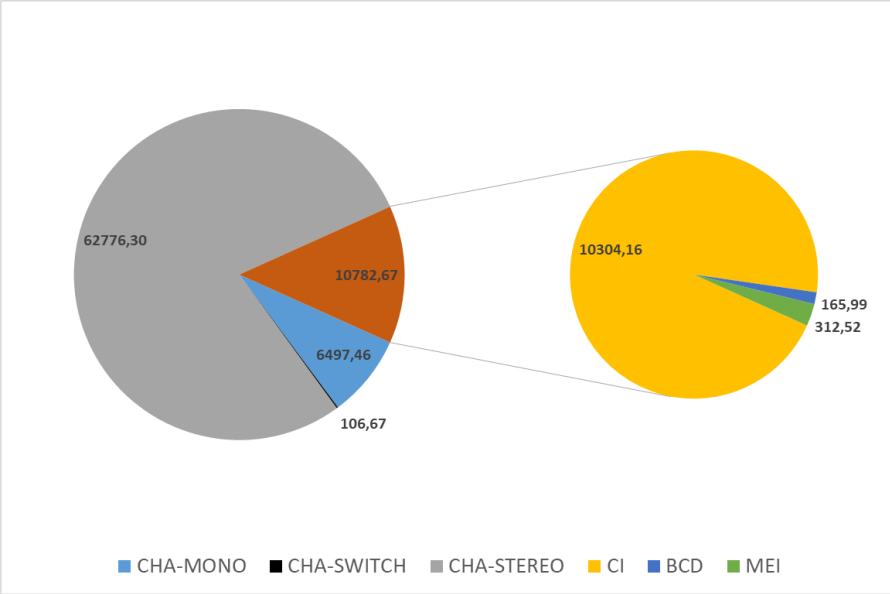
Figure 13 – RIZIV-INAMI budget for hearing aids and hearing implants for the years 2008 up to 2018 (thousand €)



Source: Doc N

From the 13.5% of the budget for hearing implants, 95.6% is taken by the CIs whereas BCD and MEI represent only 4.4% (BCD: 1.5%, MEI: 2.9%; Figure 14). Note that a BCD has two components: an implantable part and a non-implantable sound processor that is connected to the implanted part. Only the implanted part is included in the BCD budget. The non-implantable part falls under the budget of the conventional hearing aids.

Figure 14 – RIZIV-INAMI budget conventional hearing aids and hearing implants for the year 2018 (thousand €)



Source: Doc N; BCD: Bone conduction device, CI: Cochlear Implant, MEI: Middle Ear Implant, CHA: Conventional Hearing Aid, CHA-mono: unilateral CHA (first ear), CHA-switch: unilateral CHA for the contralateral ear, CHA-stereo: bilateral CHA (both ears).

6.4 Amount of reimbursed hearing devices during the years 2014 up to 2018 in Belgium

The total number of reimbursed hearing devices has grown during the years 2014-2018. Table 26 shows the total number of hearing implants (primary implants and replacements of the implantable parts) and CHAs by year. The number of hearing implants by year stays relatively stable, with around 160 for BCD, 320 for CI and 30 for MEI. The MEI is only reimbursed since September 2015, explaining why there are none in 2014. The number of delivered conventional hearing aids is increasing each year with around 3 000 devices per year since 2014.

Table 26 – Amount of reimbursed conventional hearing aids and hearing implants per year for the years 2014-2018

	CHA	Hearing Implants			
Year		BCD	CI	MEI	Total
2014	86 625	154	276	-	430
2015	92 042	155	300	3	460
2016	95 727	202	312	28	542
2017	97 367	162	349	32	544
2018	103 020	149	330	37	518

Source: Doc N; CHA: Conventional Hearing Aid, BCD: Bone conduction device, CI: Cochlear Implant, MEI: Middle Ear Implant

6.4.1 Conventional hearing aids

Details of the evolution of the number of reimbursed conventional hearing aids during the period 2014-2018 are presented in Table 27. There are monophonic CHAs (for one ear only, which also include contralateral CHAs), and stereophonic CHAs (for both ears). The latter are provided about 10 times more. Distinction is made according to age (≥18 yr and < 18 yr) and intensity of hearing loss (>40 dB and <40 db).

Table 27 – Number of conventional hearing aids per year for the years 2014-2018

Hearing Loss		2014	2015	2016	2017	2018
>40 dB	MONO <18 years	246	247	252	262	328
	MONO ≥18 years	9 418	9 350	8 960	8 882	8 712
	Contralateral <18 years	2	2	2	3	2
	Contralateral ≥18 years	176	167	176	179	145
	STEREO <18 years	1 290	1 172	1 080	1 100	1 220
	STEREO ≥18 years	74 386	79 686	82 676	83 718	88 462
<40 dB	MONO <18 years	7	17	24	35	45
	MONO ≥18 years	142	177	234	288	321
	Contralateral <18 years	0	0	0	1	1
	Contralateral ≥18 years	6	4	7	9	12
	STEREO <18 years	66	84	112	154	202
	STEREO ≥18 years	886	1 136	2 204	2 736	3 570
Total		86 625	92 042	95 727	97 367	103 020

Source: Doc N

6.4.2 Bone conduction devices

6.4.2.1 Implantable part of the bone conduction device

The amount of reimbursed implanted BCDs for the period 2014-2018 is listed in Table 28. The number of replacements of the bone anchored abutment represent about 10% of the total BCD implants by year.

Table 28 – Number of BCD implants (placement or replacement of the abutment) per year for the years 2014-2018

	2014	2015	2016	2017	2018
BCD	139	143	178	152	135
Replacement abutment	15	12	24	10	14

Source: Doc N; BCD: Bone conduction device

6.4.2.2 Non implantable part of the bone conduction device

The non-implantable part of the BCD is a sound processor specifically developed to be attached to the implanted part. The non-implantable part is already used alone (keeping in place with a softband for example) before an implantation particularly in children (in whom the skull bone is still too weak to have an implant). These non-implantable parts are identifiable among conventional hearing aids through a specific nomenclature code. The amount of reimbursed non implantable BCDs for the period 2014-2018 is listed inTable 29.

Table 29 – Number of reimbursed non-implantable parts of a BCD.

	2014	2015	2016	2017	2018
Non implantable part of a BCD for >40dB HL	195	221	248	219	207
Non implantable part of a BCD for <40dB HL	3	7	3	6	5
Total	198	228	251	226	212

Source: Doc N; BCD: Bone conduction device

Note that on February 1st 2019, there was a change in the nomenclature and specific codes were created, making a distinction for hearing loss above or below 40dB and for age categories (<18y, 18-65y and ≥65y), for first hearing aid for BCD with bone conduction, renewal hearing aid for BCD with bone conduction and hearing aid for BCD without bone conduction. At the same time, older codes were deleted (see Appendix 5.1).

6.4.3 Cochlear implants

The amount of reimbursed cochlear implants for the period 2014-2018 is listed in Table 30. Distinction is made according to age and the type of hearing loss i.e. bilateral hearing loss or asymmetrical hearing loss.

Each CI implant includes an implantable and a non-implantable part (sound processor). Replacement of the sound processor is mainly done in ambulatory care and reimbursement for replacement is foreseen each 3 years for children < 8 years old, and each 5 years for the children between 8 and 12 years.

Table 30 – Amount of cochlear implants per year for the years 2014-2018

		2014	2015	2016	2017	2018
Bilateral hearing loss	First Ear <8 years	58	60	66	65	57
	Contralateral Ear <8 years	40	46	56	74	44
	First Ear	160	171	159	178	191
	Contralateral Ear 8-12 years	11	7	11	9	9
Asymmetrical hearing loss	First Ear <8 years	0	6	7	12	10
	First Ear 8-12 years	0	1	6	6	10
Replacement of implantable part	First Ear	7	8	6	5	9
	Contralateral Ear	0	1	1	0	0
Replacement of non-implantable part	First Ear <8 years	95	83	53	38	78
	Contralateral Ear <8 years	42	39	31	28	39
	First Ear ≥8 years	328	371	371	377	430
	Contralateral Ear ≥8 years	31	58	68	59	63

Source: Doc N

6.4.4 Middle Ear Implants

The amount of reimbursed middle ear implants (MEI) for the period 2014-2018 is listed in Table 31. Since 2016 between 24 and 32 MEIs each year are reimbursed. Up until now, only one model i.e. the semi-implantable MEI (Vibrant Soundbridge) is on the market and reimbursed in Belgium. No replacements of the implantable part were noted.

Table 31 – Amount of MEI implants per year for the years 2014-2018

	2014	2015	2016	2017	2018
MEI – Full kit (new complete device)	-	3	26	24	32
MEI - Replacement implantable part	-	0	0	0	0
MEI - Replacement non-implantable part	-	0	2	8	5

Source: Doc N; MEI: Middle Ear Implants

6.5 Amount of patients with hearing aids or implants

6.5.1 Conventional hearing aids

Table 75 in Appendix 5.2 shows the number of patients with a conventional hearing aid. The amount of patients who have a reimbursed CHA is 51 400 in 2016, 52 800 in 2017 and 56 900 in 2018. As seen in Figure 32 in Appendix 5.2, 78% of CHA are delivered to patients older than 65 and 90% to patients older than 45 years.

6.5.2 Hearing implants

Table 32 shows the amount of reimbursed hearing implants (first implantation and replacement of the implantable part), the amount of patients, age and gender of patients for the years 2016 to 2018. If one patient received an implant in two different years, (s)he is counted one time in each year. The number of patients is lower than the number of implants, which can be explained by the fact that one patient may receive more than one implant (a bilateral implant or a replacement).

The mean age at which the patients receive a specific implant varies between the implants. Patients receive a BCD around the mean age of 47, while the mean age to receive a CI is around 34 years (with a large proportion in children (up til 12 years) and in adults (around 60-70 years)) and for a MEI around 58 years old.

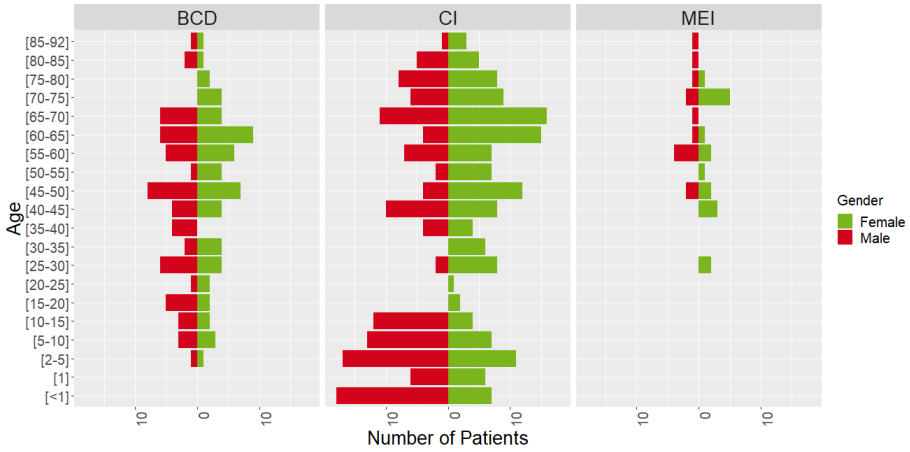
Table 32 – Evolution of the amount of hearing implants and patients (with accompanying mean age and gender) for 2016-2018

Implant		2016	2017	2018
BCD	Number of implants	189	159	134
	Number of patients	173	144	124
	Mean Age ± SD Median [P25-P75] Min-Max	47.5 ± 22.1 53 [36;63] 2-90	47.9 ± 23.1 52 [30;66] 4-88	44.9 ± 21.2 48 [28;62] 3-87
	Gender (% females)	49.4	52.8	51.6
CI	Number of implants	298	344	319
	Number of patients	270	306	283
	Mean Age ± SD Median [P25-P75] Min-Max	33.2 ± 29.1 30.5 [3;61] 0-89	33.0 ± 30.0 26.5 [4;62] 0-90	37.9 ± 29.0 42 [6;65] 0-91
	Gender (% females)	51.1	55.9	53.0
MEI	Number of implants	27	25	30
	Number of patients	27	25	30
	Mean Age ± SD Median [P25-P75] Min-Max	57.9 ± 12.8 59 [47;67] 29-86	58.0 ± 15.2 60 [52;69] 13-76	59.4 ± 15.6 59 [48;72] 27-87
	Gender (% females)	61.5	45.8	56.7

Source: MZG-RHM, BCD: Bone Conduction Device, CI: Cochlear Implant, MEI: Middle Ear Implant.

Figure 15 shows population pyramids for patients with hearing implants in 2018. For BCD, the skull bone of children under 7 years old is often to weak for receive an implantation. For CI, it shows that before 15 years, 37% of patients received a CI, and after 45 years, 47% of patients received a CI. For MEI, implantation is done later in life (range between 27y-87y), because it is especially for patients with mixed hearing loss (combination of conductive and sensorineural hearing loss) where MEI is a good option.

Figure 15 – Population pyramid for number of patients, by implant, age group and gender for the year 2018



Source: MZG-RHM. BCD: Bone Conduction Device, CI: Cochlear Implant, MEI: Middle Ear Implant

6.5.2.1 Amount of patients with a reimbursed BCD

During 2016 to 2018, 408 patients had a first BCD implant (Table 33) of which 378 patients had one BCD implant (unilateral) and 30 patients had more than one BCD implant. There were 10 BCD implantable part replacements. For the non-implantable, 370 devices were reimbursed to these 408 implanted patients during the period for the period 2016-2018.

Table 33 – Amount of patients with bone conduction devices, according to age category for the period 2016-2018

	Total number of patients with a BCD	One BCD implant	More than 1 BCD implant	BCD Replacement	Number of non-implantable BCD*
Unilateral <18y	63	52	11	5	79
Unilateral 18-64y	246	234	12	5	216
Unilateral ≥65y	99	92	7	0	75
Total	408	378	30	10	370

*Source: MZG-RHM, *IMA-IAM; BCD: Bone Conduction Device.*

6.5.2.2 Amount of patients with a reimbursed CI

There are differences in reimbursement rules according the age of the patients, such as for patients with bilateral hearing loss older than 12 y, the contralateral implant is not reimbursed. Accordingly, in Table 34 we show per age class (<8y, 8-12y and ≥12y) the number of patients who received a CI for the first ear (unilateral implantation), and among those, the amount of patients who also received a contralateral CI (bilateral implantation). For this analysis, patients in the database with only a contralateral implant (and for which first implant was placed before 2016) were left out.

For bilateral hearing loss, 692 patients received 824 implants of which 3 patients younger than 8 years received two times a first implant, and 122 received bilateral implantation. Five patients between 8 and 12 years received a bilateral implantation, and for patients older than 12 year, 2 received a bilateral implantation. For asymmetric hearing loss, 47 patients received 50 implants (2 patients younger than 8 years and one patient between 8 and 12 years received 2 implants).

Table 34 – Amount of patients with uni- and bilateral (simultaneous or sequential) implantation in bilateral hearing loss or unilateral implantation in asymmetrical hearing loss for the period 2016-2018

	Total number of patients	Bilateral hearing loss		Asymmetrical hearing loss
		Unilateral implantation	Bilateral implantation	Unilateral implantation
Patients <8years	206	57	122	27
Patients 8-12years	40	21	5	14
Patients ≥12y	496	488	2	6
Total	742	563	129	47

Source: MZG-RHM

There was only one replacement of the implantable part for a patient younger than 8 years. Very few replacements of the non-implantable part of a CI (<3) were observed in this population during the period 2016-2018, because replacement of the CI non-implantable part is reimbursed after 3 years for patients <8 years, and after 5 years for the other patients.

6.5.2.3 Amount of patients with reimbursed MEI

There were 82 patients who received a reimbursed MEI during the period 2016-2018. No replacements of the implantable part were reported.

6.6 Reimbursed costs of the different implantation phases

This analyse only includes patients covered by the compulsory health insurance. Note that no correction has been made to remove outliers such as patients staying long due to complications or bad health conditions.

6.6.1 Procedural phase

The total reimbursed cost consists of five cost items:

- The hearing implant: The total costs for a hearing implant consists of the reimbursed cost which is the amount paid by the national health insurance (RIZIV-INAMI).There is a fixed maximum pricing for hearing implants. The evolution of these prices are detailed in Appendix 5.1.
- The surgical procedure: It is the honorarium of the surgeon. Specific codes for each implant are used, prices are detaied in Appendix 5.1.
- The non-surgical procedures: this covers all other procedures during the hospitalisation (anesthesia, medical devices used during the procedure, other surgical procedures...) .
- The hospital stay cost: this cost is directly related to the length of stay (the in-patient days). For the calculation, the 100% per diem correction[c] has been used correcting for additional hospital funding, specific to each hospital, to not underestimate the actual hospitalisation costs.
- The cost of drugs: it includes reimbursed costs and co-payements (“remgeld”/“ticket modérateur”) for the consumed drugs during the hospitalisation.

[c] Cleemput I, Neyt M, Van De Sande S, Thiry N. Belgian Guidelines for economic evaluations and budget impact analyses: second edition. KCE; 2012. KCE Report 183C HTA Available from: https://kce.fgov.be/sites/default/files/atoms/files/KCE_183_economic_evaluations_second_edition_Report_update.pdf

Table 35 shows the total reimbursed cost details for the year 2018. The difference in cost between the different types of implants is mainly related to the cost of the implant itself. A cochlear implant is more expensive (i.e. € 20 345 for one implant and € 35 027 for two (simultaneously placed implants), compared to a MEI (~ € 9 370) or to BCD (~ € 1 128). Looking at the other cost items, we see that these are in general also lower for a BCD compared to MEI or CI.

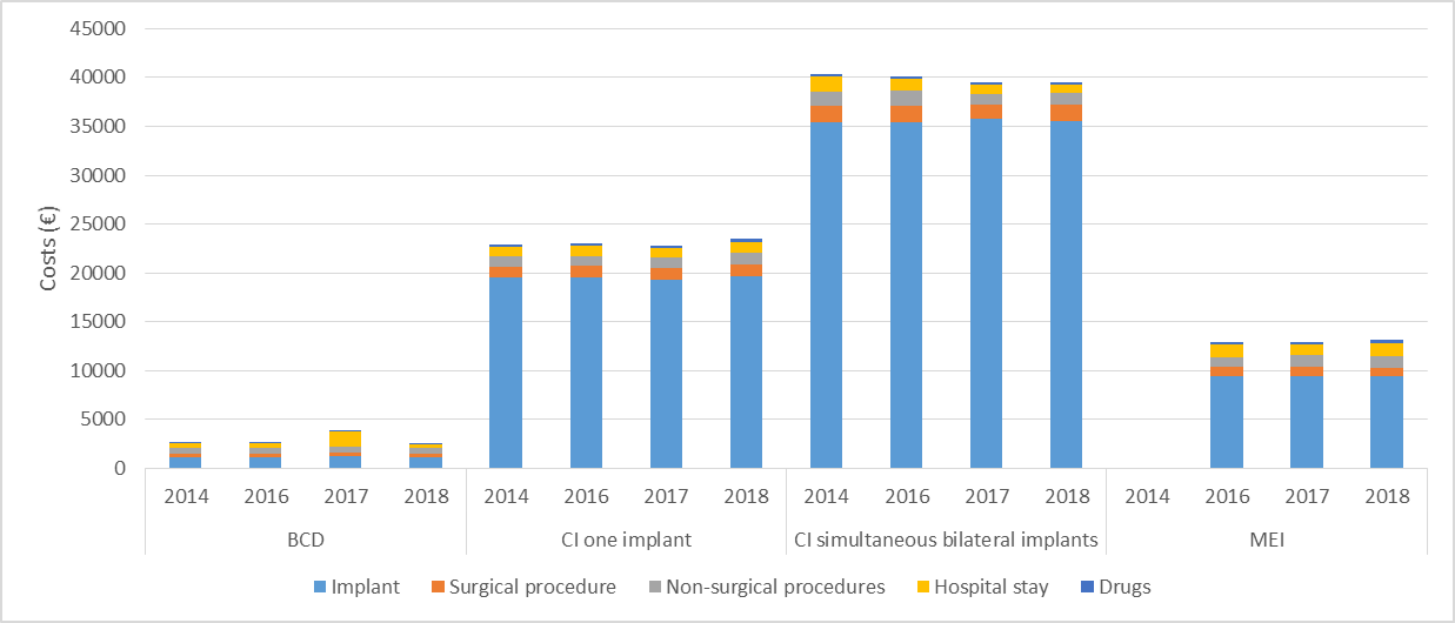
Table 35 – Median reimbursed costs per patient for the different hearing implants for the year 2018 (in euro).

		BCD (n=120)	CI one implant (n=270)	CI simultaneous bilateral implants (n=17)	MEI (n=30)
Implant	Median	1 128	20 345	35 027	9 371
	[P25-P75]	[1 128;1 139]	[19 961;20 345]	[35 027;35 363]	[9 371;9 371]
Surgical procedure	Median	343	1 191	1 787	953
	[P25-P75]	[312;343]	[1 191;1 191]	[1 787;1 787]	[953;953]
Non-surgical procedures	Median	372	1 049	1 214	1 007
	[P25-P75]	[255;434]	[964;1 155]	[928;1 504]	[820;1 269]
Hospital stay	Median	365	718	652	1 019
	[P25-P75]	[174;583]	[536;1 347]	[347;1 125]	[576;1 684]
Drugs	Median	82	249	300	239
	[P25-P75]	[49;141]	[211;291]	[190;386]	[140;305]
Total		2 290	23 552	38 980	12 589

Source: MZG-RHM ; BCD: Bone Conduction Device, CI : Cochlear Implant, MEI : Middle Ear Implant

Figure 16 shows the average reimbursed costs for each implant. The distinction is made between implanting one CI or simultaneous implantation of bilateral CI. The represented data is for the first procedure only i.e. the first implantation, not the replacement implants.

Figure 16 – Median reimbursed costs per patient for the different hearing implants for the years 2014-2018



Source: MZG-RHM ; BCD: Bone Conduction Device, CI : Cochlear Implant, MEI : Middle Ear Implant

Hospital length of stay for hearing implants for the year 2018

The costs of the hospital stay is directly linked to the stay duration. The Table 36 present the type of hospitalisation (day care or inpatient stay) and the length of stay for inpatients according to the kind of implant for the year 2018.

The number of daycare hospitalisations for a BCD is higher than for a CI, either for one or simultaneous bilateral implants (51% vs 15%) or MEI where there are only 2 daycare hospitalisations. And the median length of stay is longer for MEI than for CI or BCD.

Table 36 – Hospital length of stay for hearing implants for the year 2018

LENGTH OF STAY	BCD	CI one implant	CI simultaneous bilateral implants	MEI
Daycare hospitalisation (n, %)	61 (51%)	35 (13%)	7 (41%)	2 (7%)
Number of inpatient stays (n, %)	59 (49%)	235 (87%)	10 (59%)	28 (93%)
Number of days for inpatients stays (Average ± standard deviation in days)	1.36 ± 1.31	2.30 ± 6.12	1.80 ± 1.03	2.29 ± 1.30
Median [P25-P75] (days)	1 [1;1]	1 [1;3]	1 [1;3]	2 [1;3]
Min-Max (days)	1-10	1-92	1-3	1-6

Source: MZG-RHM; BCD: Bone Conduction Device, CI : Cochlear Implant, MEI : Middle Ear Implant

6.6.2 Pre- and postprocedural phase

The pre-procedural phase includes the reimbursed costs one year before intervention, and the post-procedural costs include those up to 5 years after the intervention. These reimbursed costs consist of five cost items:

- ENT costs: all medical care dispensed by the ENT specialist. It includes consultations, examinations and treatments realized by ENT specialist (i.e. speech audiometry, pure-tone audiometry, tympanoscopy)
- ENT prescriptions related costs: all medical care prescribed by ENT specialists. It includes imaging (as MRI or CT-scanner), blood analysis, physiotherapy, etc.
- Speech therapy costs: all cares dispensed by the speech therapists.
- Rehabilitation centres costs: all cares dispensed in centers for ambulatory rehabilitation.
- Replacement of the non-implantable part of the implant.

6.6.2.1 Cochlear implants

The reimbursed costs for the pre- and postprocedureal phase for cochlear implantation (calculated per patient) are presented in Table 37. The reimbursed costs with co-payements are detailed in Appendix 5.4. Patients are grouped according to age (<8years and ≥8years), the type of hearing loss (asymmetrical or bilateral) and the type of implantation (unilateral or bilateral). For bilateral implantation, a distinction is made for sequential and simulataneous implantation only for patients younger than 8 years. This distinction of items was not possible for patients over 8 years because there are less than 4 patients, and only global pre- and post-procedural costs are presented.

Table 37 – Pre- and post-procedural reimbursed costs of a cochlear implant (per patient) according to age and type of hearing loss (in euro).

	Number of patients	ENT costs	ENT prescriptions	Speech therapy	Rehabilitation centres	Replc. sound processor	Total
Asymmetrical hearing loss – Age <8years							
- One year pre-implantation	26	449	706	142	4 340	0	5 637
- Up to 5 years post-implantation	26	577	547	504	8 325	0	9 953
Asymmetrical hearing loss – Age ≥8years							
- One year pre-implantation	22	343	569	105	6 263	0	7 280
- Up to 5 years post-implantation	22	467	337	139	8 717	0	9 660
Bilateral hearing loss – Age <8years, UNILATERAL implantation							
- One year pre-implantation	101	448	793	57	4 324	0	5 622
- Up to 5 years post-implantation	101	666	511	250	17 310	1 819	20 556
Bilateral hearing loss – Age <8years, SEQUENTIAL BILATERAL implantation							
- One year pre-implantation	127	630	707	38	3 323	0	4 698
- Between implants	127	317	132	83	4 476	0	5 008
- Up to 5 years post-implantation	127	740	81	556	14 645	2 505	18 527
Bilateral hearing loss – Age <8years, SIMULTANEOUS BILATERAL implantation							
- One year pre-implantation	50	526	589	78	3 354	0	4 547
- Up to 5 years post-implantation	50	436	34	387	20 649	2 063	23 569
Bilateral hearing loss – Age ≥8years, UNILATERAL implantation							
- One year pre-implantation	835	391	425	10	524	0	1 350
- Up to 5 years post-implantation	835	584	273	218	4 991	0	6 066
Bilateral hearing loss – Age ≥8years, BILATERAL implantation (including sequential and simultaneous)							
- One year pre-implantation	10	296	180	437	5 043	0	5 956
- Between implants	7	294	0	0	3 721	0	4 015
- Up to 5 years post-implantation	10	242	0	0	9 786	0	10 028

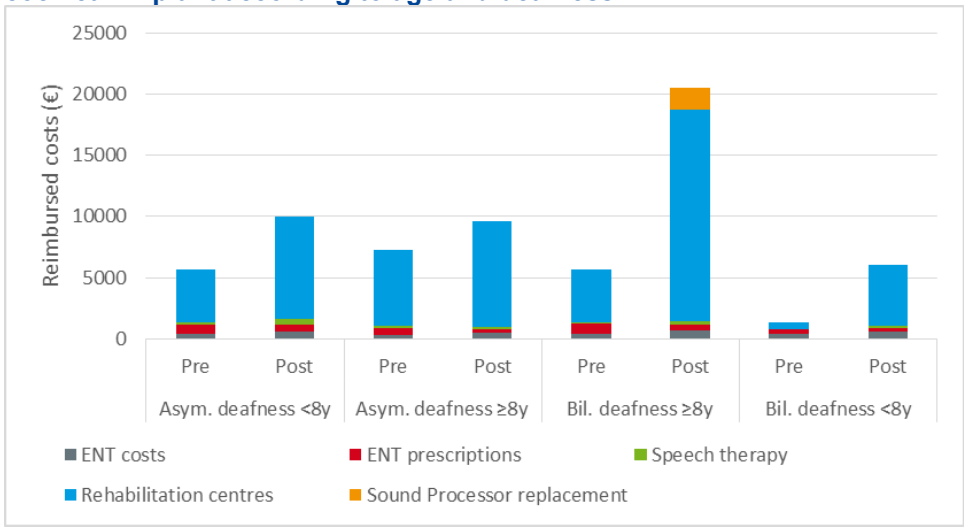
Source: IMA – IAM

For asymmetrical hearing loss, pre-procedural reimbursed costs are € 5 637 and € 7 280 for patients <8 years and ≥8 years, and post-procedural reimbursed costs are € 9 953 and € 9 659 respectively. For bilateral deafness, unilateral implantation, pre-procedural reimbursed costs are € 5 622 and € 1 350 for patients <8 years and patients ≥8 years, and post-procedural reimbursed costs are € 20 556 and € 6 066 (Figure 17).

For bilateral implantation in bilateral hearing loss, pre-procedural reimbursed costs are € 4 655 and € 5 956 for patients <8 years and ≥ 8 years respectively (Figure 18). Post-procedural reimbursed costs in patients younger than 8 years are € 23 569 for simultaneous implantation. And for sequential implantation, post procedural costs is calculated as the addition of the amount between the implantations and the amount after the second implantation, and corresponds to € 23 535 (€ 5 008 and € 18 527). Post-procedural reimbursed costs for patients ≥ 8 years are 14 043€ (€ 4 015 and € 10 028).

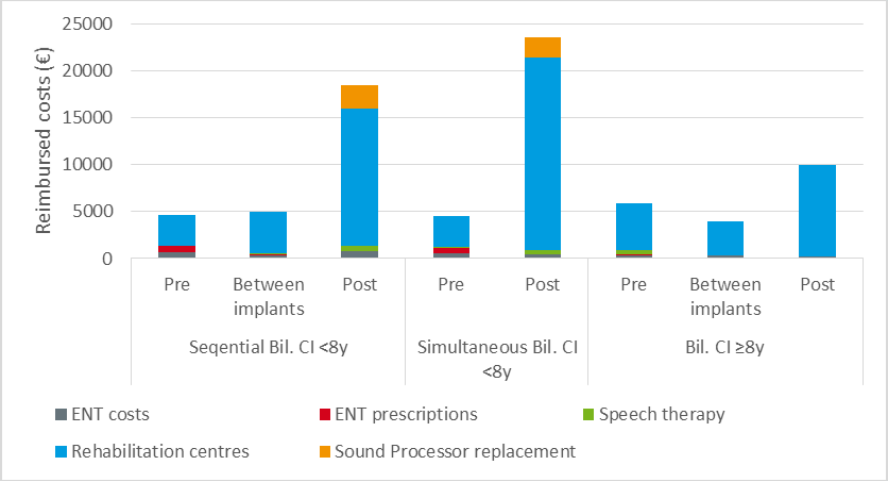
Pre-procedural reimbursed costs for sequential CI implantation for patients ≥8 years are € 9 444, and post-procedural reimbursed costs are € 6 668. For simultaneous implantation, pre-procedural reimbursed costs are € 9 073 and post-procedural reimbursed costs are € 7 586. Details are not shown because of lack number of patients (≤3) include in the analysis.

Figure 17 – Pre- and post-procedural reimbursed costs for unilateral cochlear implant according to age and deafness



Source: IMA – IAM. ENT: Ear-Nose-Throat.

Figure 18 – Mean reimbursed costs components of one year pre and global post hospitalisation for bilateral cochlear implant according to age and timing of replacement.



Source: IMA – IAM. CI: Cochlear Implant, ENT: Ear Nose Throat.

6.6.2.2 BCD implants

All these costs are calculated per patients. All reimbursed costs are presented in Table 38, and reimbursed costs with co-payements are detailed in Appendix 5.4. BCD implants had been placed in 687 patients, of which 40 patients received a sequential BCD, for both ears. Total pre-procedural costs are € 701, and total post-procedural costs are € 1 509.

Table 38 – Pre- and post-procedural costs of a bone conduction devices (in euro).

	Number of patients	ENT costs	ENT prescriptions	Speech therapy	Rehabilitation centres	Total
- One year pre-implantation	687	281	232	28	160	701
- Between implants	40	12	28	0	0	40
- Up to 5 years post-implantation	687	345	828	64	232	1 469

Source: IMA – IAM. ENT: Ear Nose Throat

6.7 Distribution of the delivered hearing aids and implants in Belgium and the place of implantation

6.7.1 Accessibility

In order to get a general view of the distribution of the conventional hearing aids and hearing implants across the regions and in Belgium, Table 76 in Appendix 5.3 shows the amount of patients who received a reimbursed hearing device during the years 2016-2018. Note that the patients who only had an implant replacement (implantable or non-implantable part) are not included in this table.

In Appendix 5.3, two figures can be found which illustrate the amount of conventional hearing aids and hearing implants per 1 000 inhabitants by province for the year 2018 in Belgium (Figure 33 and Figure 34).

6.7.2 Place of implantation

As seen in Table 39, there are more hospitals that implant BCD compared to CI or MEI. The amount of implants (depending on type) placed in each hospital is widely varying. For each type of implant, less than 50% of the hospitals shared more than the average amount of implants: in 2018, only 9 out of 31 hospitals implanted more than 4 BCDs, only 6 out of 21 hospitals implanted more than 15 CI, and only 3 out of 10 hospitals implanted more than 3 MEIs.

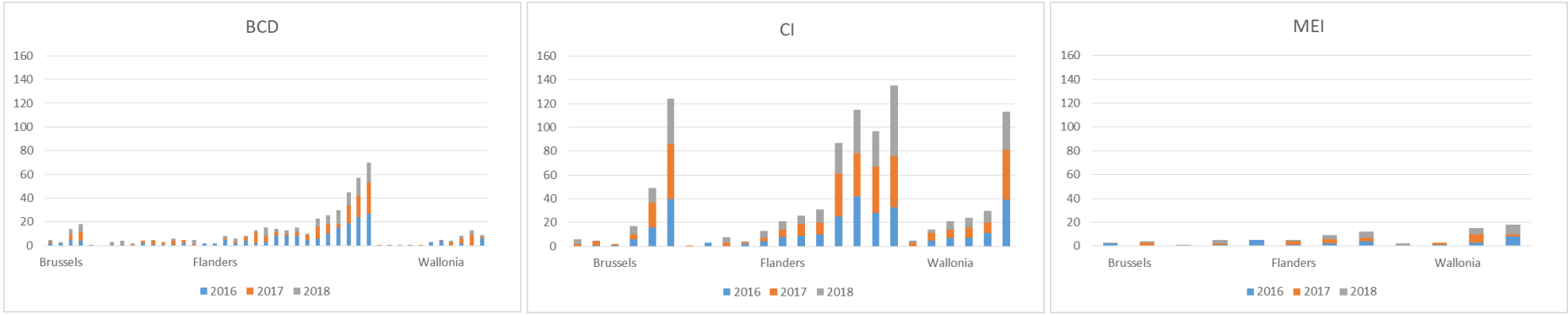
Table 39 – Average number of implants by hospital by year for years 2016-2018

		BCD	CI	MEI
2016	Amount of hospitals	34	20	9
	Average amount of implants per hospital ± SD	5.6 ± 6.5	14.9 ± 14.1	3.0 ± 2.3
	Median [min;max]	3 [1;27]	8.5 [1;42]	2 [1;8]
	Amount of hospitals with more than the average amount of implants	8	7	3
2017	Amount of hospitals	31	23	8
	Average amount of implants per hospital ± SD	5.1 ± 5.7	14.8 ± 16.2	3.1 ± 1.8
	Median [min;max]	3 [1;26]	7 [1;46]	3 [1;7]
	Amount of hospitals with more than the average amount of implants	8	7	2
2018	Amount of hospitals	31	21	10
	Average amount of implants per hospital ± SD	4.3 ± 4.3	14.9 ± 15.7	3.0 ± 2.4
	Median [min;max]	3 [1;17]	7 [1;59]	2.5 [1;8]
	Amount of hospitals with more than the average amount of implants	9	6	3

Source: MZG-RHM; BCD: Bone conduction device, CI: Cochlear Implant, MEI: Middle-Ear Implant

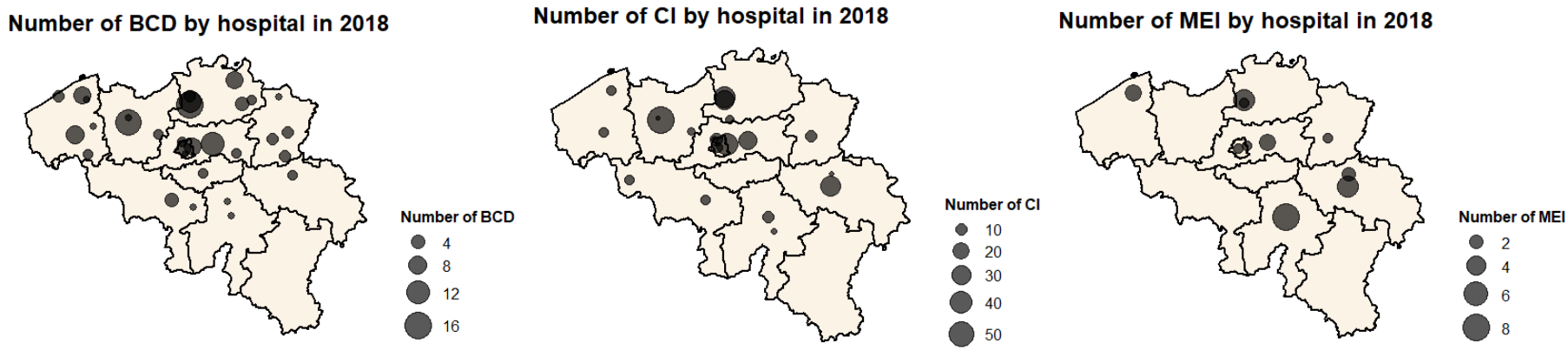
The distribution of the amount of hearing implants implanted in the hospitals by region is presented in Figure 19, representing all hearing implants (first implants as well as replacements). For BCD, big centers (i.e. hospitals that place more than the average number of implants) are located in Flanders and in Brussels. For CI there is at least one big center in each region (with the majority in Flanders). Since the low amount of implanted MEIs, the data is more evenly distributed across the regions.

Figure 19 – Amount of BCD, CI and MEI implants for each hospital and categorized by region and year (2014-2018)



In Figure 20 the number of BCD, CI and MEI by hospital across Belgium for 2018 is visualized.

Figure 20 – Amount of BCD, CI and MEI implants for each hospital by province for the year 2018



7 INTERNATIONAL COMPARISON

In this chapter we examine how hearing implants (cochlear implants, middle ear implants and bone conduction devices) are reimbursed in other countries. We investigate for which indications these implants are reimbursed, the level of reimbursement and the type of devices reimbursed

7.1 Introduction

Special attention is given to the following questions:

- How do reimbursement schemes deal with the overlaps in indications. Who stipulates guidelines on thresholds and eligibility criteria?
    - Are the indications defined at national level by the reimbursement body or do the implanting centers get flexibility in how they select patients? Are there national guidelines? Are there volume restrictions?
    - Is the decision for selection mainly based on functional outcomes or rather on audiometric results? What are the speech perception testing practices for adult candidacy assessment: sentences or words or a combination, testing in noise or in quiet or a combination? …
- How is hearing implant care organised? How many centers are allowed to perform the implants? What conditions are imposed to the centers or physicians to be allowed to implant?

International comparison of traditional (air conduction) hearing aids has been subject of a previous KCE report [91] and is not covered in the current report.

7.2 Methods

The information in this chapter was retrieved through search in legal documents, grey literature (mainly websites from reimbursement bodies, governments, patient organisations), documentation from manufacturers and contacts with a number of ENT experts in the country (Dr. Luis Lassaletta, Spain; Dr. Isabelle Mosnier, France; Dr. Thomas Lenarz, Germany) and with Mr. Hennie Epping, president of the independent platform for cochlear implants in the Netherlands.

7.3 Selection of countries

For this report we selected the following countries: the Netherlands, France, Germany, Switzerland, Spain, the United Kingdom (NHS England) and Canada (Ontario and Quebec). For the countries with a social insurance scheme, we focus on the legal, mandatory scheme, not on voluntary additional private insurance schemes. For the countries with a public health insurance, we focus on the services provided by the public health service, not on the private insurance schemes.

Table 40 – List of analysed countries

Country	Considered health insurance	Social insurance	Public health insurance
The Netherlands	Verplichte basisverzekering voor zorg: 'basispakket'	X	
France	Couverture Maladie Universelle (CMU)	X	
Germany	Gesetzliche Krankenversicherung (GKV)	X	
Switzerland	Sozialversicherung	X	
Spain	Sistema Nacional de Salud (SNS)		X
The UK (England)	NHS England		X
Canada (Ontario and Quebec)	Ontario/Quebec health insurance plan (OHIP/QHIP)		X

7.4 Netherlands

7.4.1 Cochlear Implants

7.4.1.1 Reimbursed indications for CI

In the Netherlands certain flexibility is given to the implanting centers to decide in which patients a CI will be implanted. Zorginstituut Nederland (ZN, former CVZ) has put a restriction though on bilateral implantation. Bilateral implantation is only reimbursed in the following cases:

- up to the age of 5;[92]
- under certain conditions up to the age of 18 years[93]: children with either acquired or congenital bilateral deafness or severe hearing loss, including children with progressive hearing loss, in which CI is expected to give better results compared to a bimodal treatment;
- for deaf blind adults.[94]

No other national restrictions on indications are set and flexibility is given to the centers to specify their criteria for patient selection. A criterion on speech understanding is mentioned in the Veldnorm (CVC phoneme score <50%), but centers are allowed to deviate from this criterion on individual basis. As such the criterion has gradually shifted towards about <70% in quiet. As can be read on the website of OPCI ('Onafhankelijk Platform Cochleaire Implantatie')[95], criteria actually applied by the centers may differ slightly. As an example, we list the indication criteria applied by the Nijmegen center (Radboud UMC), which has the largest volume of CI implants in the Netherlands:

- Adults: Criteria: dB hearing loss, percentage speech understanding with hearing aid, other criteria such as personal characteristics.
    - For speech understanding scores the general rule is a score <70% (on the basis of NVA ('Nederlandse vereniging audiologie') word lists)
    - Other criteria that play a role are a.o. the communication need, how fast the hearing loss deteriorates, other impairments such as decreased visus, social situations, psychic factors etc.
    - There is no limit on age, but factors that do play a role are comorbidities and cognitive capabilities.
    - In case of sudden deafness and menengitis CI is implanted in emergency.
- Children:
    - In young children or children with multiple impairments in who speech understanding cannot be measured, an audiologic criterion of a loss >80 dB at 2000 and 4000 Hz is applied.
    - If measurable, when the score of speech understanding at 70 dB <75%, a child is audiologically eligible for CI.
    - In addition to the audiologic criterion other factors are considered, a.o. communication and learning capabilities of the child, as well as the possibilities of parents and environment, to decide whether CI is indicated or not, and if yes, what factors should be considered for support and rehabilitation.

Of note is that a retrospective study from Leiden UMC [96] also includes speech-in-noise tests when defining potential candidates for CI:

- Preoperative scores of either ≤ 80% (phonemes correct) or ≤ 60% (words correct) in an optimal-aided situation AND
- Preoperative speech perception score < 50% (phonemes correct) or < 20% (words correct), when background noise is added at a +5 dB signal to noise ratio.

According to the decision aid "Keuzehulp cochleair implantaat voor volwassenen" of 'Stichting Hoormij', 'Dovenschap', 'Divers Doof' and 'Oogvereniging Oor en Oog' (published/reviewed in 2018) (available on the websites cikeuzehulp.nl; cikeuzehulpkinderen.nl) , single sided deafness or asymmetric hearing loss (in which one ear does not meet the thresholds for CI) are no established indications for a cochlear implant. Research on these indications is ongoing. In case of auditory neuropathy, however, an implant on one side can be reimbursed in children (up til 18y).

7.4.1.2 Summary of reimbursement of CI

Table 41 – Overview of reimbursement of cochlear implantation in the Netherlands

	Unilateral implant	Bilateral implant	SSD	AHL	AN	Guideline by	Speech criteria	Audiometric criteria*
Adults	Reimbursed	Not reimbursed except if blind	No established indication (research ongoing)	No established indication (research ongoing)	-	Veldnorm	* CVC phoneme score ≤50% (best ear), best aided condition, in quiet at 65 dB SPL ** CVC phoneme score ≤ 70% at 70 dB SPL	-
Children	Reimbursed	Reimbursed if <5y or <18y with additional requirements	No established indication (research ongoing)	No established indication (research ongoing)	Reimbursed on one side if indicated by the team	Veldnorm	* CVC phoneme score ≤50% (best ear), best aided condition, in quiet at 65 dB SPL ** CVC phoneme score ≤ 75% at 70dB SPL	>80 dB at 2000 and 4000 Hz

*SSD: Single sided deafness (best ear ≤30dB and worst ear ≥70 dB); AHL: Asymmetric hearing loss (with at least one ear that is better than cut-off for best ear in case of bilateral deafness); AN: Auditory neuropathy; * Based on Veldnorm; ** Based on indications in Radboud UMC*

7.4.1.3 Organisation of care

There are 8 centres that implant CIs in the Netherlands. The lowest volume centre performed 32 implants in 2017. The highest volume centre (Nijmegen) performed 139 implants (see Table 42).

Table 42 – Overview of CI centres in the Netherlands and number of implants (2017)

CI-team	Number of implants			Bilaterally implanted patients			Number of re-implants		
	children	adults	total	children	adults	total	children	adults	total
Amsterdam AMC	3	29	32	0	1	1	1	1	2
Amsterdam VUMC	30	12	42	13	0	13	1	0	1
Groningen	15	37	52	5	0	5	0	2	2
Leiden	19	65	84	8	3	11	0	3	3
Maastricht	13	40	53	5	3	8	3	0	3
Nijmegen	47	92	139	16	0	16	2	0	2
Rotterdam	24	42	66	12	1	13	0	2	2
Utrecht	21	40	61	6	1	7	2	2	4
The Netherlands total	**172**	**357**	**529**	**65**	**9**	**74**	**9**	**10**	**19**

Source: [97]

7.4.1.4 Veldnorm

To guarantee and promote the quality of care for cochlear implantation in the Netherlands, CI-ON ('CI-Overleg Nederland', in which the different Dutch CI centres are represented), the LGB ('Landelijke Beleidscommissie Gezinsbegeleiding'; National Policy Commission Family Support) and OPCI ('Onafhankelijk Platform Cochleaire Implantatie') have created a field standard ('Veldnorm')[98]. The Veldnorm stipulates the conditions imposed to the care process and a number of quality indicators. It includes how many patients a CI team must operate per year, how many hours follow-up care a CI patient should get per year, etcetera. The Veldnorm was created in 2008 and rewritten in 2013. It is planned to be reviewed in 2020 (personal communication Hennie Epping, president OPCI). The Veldnorm is intended to be used by new cochlear implant teams, the inspection services for Healthcare, the health insurers and possible other instances.

Registration

All patients have to be registered in a detailed database. There is registration of medical complications, the care trajectory and outcome results. Hard and soft failures are registered. The data registration is intended to be used for national evaluation and discussion at the level of CI-ON and is used during a visitation.

Education

With view on the complexity of care around cochlear implants and new developments, both internal and external education is realised. Internal education takes place during periodical meetings of the CI team. External education is realised by attending national and international workshops, symposia and congresses on cochlear implantation. At least once per year the members of the CI team attend a symposium or congress (international or in the Netherlands) on CI.

Research

CI teams are expected to actively participate to research, both autonomously and in collaboration with the scientific workgroup of CI-ON. This research activity leads to scientific publications and presentations on scientific meetings and congresses.

Visitation

All CI teams periodically get visitation. New CI teams get visitation before the actual start of the activities (before the first patient is treated) and 2 and 5 years after the start. Already active teams get visitation once every 5 years.

The visitation should lead to a recognition ('erkenning') by the board of the Dutch Association for ENT and Head and Neck surgery ('Nederlandse Vereniging voor Keel-Neus-Oorheelkunde en Heelkunde van het Hoofd-Halsgebied'). The visitation commission is composed of at least an ENT physician, a clinical physicist-audiologist, a linguist/speech therapist/speech-language pathologist and a psychologist/ortho-pedagogist/social worker.

Embeddedness

The CI team is part of a center where the following disciplines are present: radiology, pediatrics including intensive care for children, anaesthetics including anaesthetics for children, clinical genetics, child neurology and geriatrics.

The CI team furthermore has good work relationships with other institutions outside the center that provide care, guidance, or education to CI-users.

The CI team is embedded in a structure with a ENT department and an audiologic centre, where full spectrum specialised care (diagnosis, therapy and rehabilitation) are provided, to moderately up to seriously hard-of-hearing perons. The audiologic centre must comply to quality norms imposed by the federation of Dutch audiologic centres (FENAC).

Multidisciplinary consultations

The CI team periodically organises (at least once per month) multidisciplinary consultation so that for each new patient a discussion takes place on the definite advice and, in case of special circumstances, the progress of the implanted patients.

Minimum number of patients

Each ENT physician operates minimum 15 patients per year. Each CI team yearly treats minimum 30 new patients with a CI. For CI teams that also treat children, amongst these 30 there are at least 8 children below 12 years.

A starting team must treat minimum 15 patients in the first year, 20 in the second year and 30 in the fifth year. In the first years, the starting team only treats adults. Performing implants in children can only be done by CI teams that have several years of experience in treating adults.

The underlying structure of the ENT department and the audiologic center of a new CI team must have elaborate experience with diagnostics and rehabilitation of hard-of-hearing neonates (minimum 40), children (minimum 40) and adults.

Minimum hours of rehabilitation

In the first year after activation of the CI, the CI team must have direct contact with the patient during minimally 35 hours in children as well as in adults. In case of any setback, or any other limitation, the patient must be encouraged to come back for adjustments or rehabilitation support. The CI team must be well accessible during office hours and should provide a solution within 2 working days in case of technical calamities. The CI team answers within 1 working day to questions posed by e-mail by CI patients.

7.4.1.5 Referral to CI centers

According to the guideline on perceptive hearing loss in adults, referral to a CI center should be considered in case of progressive and or severe perceptive hearing loss and when the speech understanding score with hearing aids is insufficient. This can be evaluated based on tests of the audiologic centre or an audiologist. In order to evaluate communication with adapted hearing aids and to estimate the communication need, a consultation with an audiologic centre should be considered. [99]

7.4.1.6 Pricing

CIs are considered medical-specialist care which means that for the implantation and the device, hospitals are directly financed by the health insurers on the basis of DBC codes (‘diagnose behandelcombinatie’). The DBC codes for cochlear implants are part of segment B, which means that health insurers can freely contract with the hospitals on volume and tariffs of this health care service. The prices of CI are not publically available for legal and competition reasons. However, so called ‘passenger price lists’ (‘passantenprijslijst’) are consultable for each hospital. UMC Utrecht for instance lists a price of € 50 589 (CIs have product code 89999036 and declaration number 15C400.) This tariff covers the full process, from pre-operative consultations to implantation of the CI and follow-up consultations as well as the rehabilitation which has to be done by the implanting hospital.

7.4.1.7 Wait lists

Due to the fact that health insurers contract with hospitals on volumes of cochlear implantation, wait lists have arisen. The wait lists are only for adults as children get priority at all time. In 2019, the waiting time for adults varied from 4 months to 21 months, depending on the hospital.[100]

7.4.1.8 Reimbursement

Implantation of a CI and the CI are fully reimbursed under the base insurance package, except for the ‘own risk’ level. At the expense of the patient are: insurance for the processor against damage and loss, the batteries and extra accus.[101]

7.4.1.9 Upgrade term

CI can be upgraded with reimbursement after 5 years. When a child has sequentially received a second CI, the replacement of the processors of both CIs is planned at the same time (for the first CI this can be a bit later than 5 years, e.. 6 years, for the second CI it can be a bit shorter, e.g; 4 years. The goal is that children use processors of the same type.[101]

7.4.2 Middle Ear Implants

7.4.2.1 Indications for MEI

No nationwide data could be retrieved on MEI, but it is known that in one of the largest centers for hearing problems, UMC St Radboud Nijmegen, so far more than 60 patients received a semi-implantable middle ear implant. These were all patients with chronic otitis.[102]

A cost-effectiveness analysis was performed in this centre (in 2006) for 21 of these patients with severe chronic external otitis. The mean health utility gain was 0.046 (0.012-0.079) (P = .01) measured at the mental component of the SF-36. With a mean profitable time of 19.4 years and an overall cost of the implantation procedure (selection phase, surgery, hospital stay, follow-up care, and materials) of € 14 354, minimal cost-effectiveness of middle-ear implantation was € 16 085/QALY. Based on this cost per QALY, middle-ear implantation proved to be a cost-effective and justified health care intervention in the Netherlands.[103]

7.4.2.2 Reimbursement

Just like CI, MEI implantation is financed by health insurers on the basis of DBC codes ('diagnose behandelcombinatie'). This means that the health insurers pay for the procedure and implant directly to the hospital. This implies that they are fully reimbursed for the patient (except for the 'own risk' level).

7.4.3 Bone Conduction Devices

7.4.3.1 Indications for BCD

A national guideline has been developed on Bone Conduction Devices upon initiative of the Dutch Association of ENT and Head and Neck ('Nederlandse Vereniging van Keel-Neus-Oorheelkunde en Heelkunde van het Hoofd-Halsgebied', NVKNO). The guideline was developed by a commission with representatives from ENT physicians and clinical physicist-audiologists and was submitted for comments to patient associations. The guideline is available in the Guidelines database for second line healthcare (richtlijnendatabase.nl). It was last reviewed in December 2018.

The guideline details the indications for BCD in different types of hearing losses:

- bilateral conductive hearing loss,
- mixed hearing loss,
- unilateral conductive hearing loss,
- unilateral perceptive hearing loss.[104]

7.4.3.2 Quality of care

The guideline also covers the following topics related to quality of care:

- Clinical and audiologic diagnostics in patients with an indication for a BCD
- Requirements imposed to a test with BCD
- Minimal criteria for a headband or softband
- The effect of different operation techniques in view of complications in patients with an indication for a percutaneous BCD
- Patient education
- Minimal quality requirements for audiometry and audiologic care

- Minimal quality requirements to be met by the ENT physician and the hospital
- Organisation of patient flow and after care for patients with BCD.[104]

7.4.3.3 Organisation of care

According to the guideline, the workgroup states that patient care benefits 'sufficient concentration' of BCD care. Hospitals with only a few BCD patients per year and/or without multidisciplinary embeddedness provide less good perspectives. This holds all the more for BCD care in children and in mentally retarded. Children with microtia are by preference treated at a center with specific expertise in microtia.

Other potential advantages of centralisation are that

- it can lead to certain scale effects and more cost-effectiveness in purchasing and maintaining stock of materials and in organisation of consultation hours, hospitalisations and surgery centre.
- it can have advantages for evaluation of care and scientific research.

A further point of attention is the safeguarding of independency of the ENT physician and the hospitals from the manufacturers (for pricing, compatibility between different products, launching innovative products, etc.). Hositals may be inclined to purchase only products from the cheapest manufacturer, and to group their purchases with other hospitals, and to maximise the number of BCD procedures (out of fear for loss-making). The workgroup however recalls the importance of the right of the patients for freedom of choice and full information about all possible options, alternatives, compatibility, complications, risks and follow-up.

7.4.3.4 Wait lists

Also for BCD there are wait lists, as insurers contract with the hospitals on volume (and tariffs) for the applicable DBC.

7.4.3.5 Reimbursement

Just like CI and MEI, BCDs (except for BAHA with softband (applied in young children)) are financed on the basis of DBC codes, including both the implant and the placement or replacement of the outer non-implanted part. This means that they are fully reimbursed to the patient, except for the 'own risk' level. A general guarantee is included in the purchase, but for damage, loss or theft the patient has to pay for an own insurance. Costs for accessories are also often at charge of the patient.[104]

7.4.3.6 Bonebridge

Bonebridge is not yet reimbursed.

7.4.3.7 Renewal term

On average after 5 years a patient can be eligible for replacement of the hearing aid. The replacement hearing aid is fully reimbursed by the health insurers to the hospital.[104]

7.5 France

7.5.1 Cochlear Implants

7.5.1.1 Reimbursed indications for CI

The indications covered by national health insurance are described by a decree [105] and a document on proper use of medical technologies ('fiche de bon usage des technologies médicales') from the Haute Authorité de Santé (HAS) which was last reviewed in 2011.[106] The general rule for candidacy states "Bilateral severe to profound sensorineural (perceptive) hearing loss, after failure or ineffectiveness of conventional hearing aids." The indications are further specified as follows.

Unilateral implantation in infants

The implantation must be done as early as possible, after a complete evaluation of hearing loss, a language assessment and a prosthesis test have been done.

- If the child has started oral communication, it can benefit from an implant regardless of its age. In particular young congenitally deaf adults can be implanted.
- However, in case of non evoluting profound or total congenital deafness, if the child above the age of 5 has not developed interest in oral communication, an implant is not recommended except for particular cases.
- In case of profound deafness, CI is indicated when the hearing aid does not allow language development.
- In case of severe deafness, CI is indicated when the speech discrimination in audiometric tests is lower than or equal to 50%, the test being adapted to the age of the child. The tests must be conducted at 60 dB, in free field, with well adapted prostheses and without lipreading.
- In case of fluctuations, CI is indicated when the above mentioned criteria are met multiple times per month and/or when the fluctuations impact the language of the child.

Unilateral implantation in deaf adults

There is no age limit for the implantation, except in case of neuro-cognitive disorders. In the elder patient, a geriatric centre must perform an individual psychocognitive evaluation. CI is indicated in the following cases:

- In general there is no indication for first implantation in adults with prelingual deafness.
- Speech discrimination in audiometric tests is lower than or equal to 50%. The test is conducted with the cochlear list of Fournier (or equivalent). The tests are conducted at 60 dB, in free field, with well adapted prostheses and without lipreading.
- In case of fluctuations, when the frequency and the duration of the fluctuations have a major impact on communication.

Bilateral implantation in children

Bilateral implantation is indicated in children in case of deafness following meningitis, a trauma or Usher syndrome.

Bilateral implantation in deaf adults

Bilateral implantation is indicated in the following circumstances:

- Deafness with risk on the short term of bilateral cochlear ossification, whatever the cause, in particular bacterial meningitis, bilateral temporal bone fracture;
- Loss of benefit from the audioprosthesis on the other side of the cochlear implant, with impact on social life and work, or a loss of autonomy in elder patients.

Is considered as bilateral any implantation of the second ear being implanted within a period of 6 months, in children as well as adults.

7.5.1.2 Summary of reimbursement by indication

The indications for cochlear implants in France are only based on the speech discrimination test with adapted prostheses, not on etiology. Therefore, cochlear implants are also taken charge of in case of auditory neuropathy in infants and adults. The hearing loss however has to be bilateral, therefore, SSD and ASHL (with one ear better than cut-off of 50% speech discrimination) is not reimbursed.

Table 43 – Overview of reimbursement of cochlear implantation in France

	Bilateral severe-profound hearing loss		SSD	AHL	AN	Guideline by	Speech criteria	Audiometric criteria
	Unilateral implant	Bilateral implant						
Adults	Reimbursed	Reimbursed (price-volume agreement)	Not reimbursed	Not reimbursed	Reimbursed	Haute Autorité de Santé (HAS)	• Fourier sentences at 60dB in quiet with best aided condition < 50% • With fluctuating HL, when duration & frequency of HL has major impact on communication	Severe to profound bilateral sensorineural hearing loss
Children	Reimbursed	Reimbursed	Not reimbursed	Not reimbursed	Reimbursed	Haute Autorité de Santé (HAS)	• Profound: no language development • Severe: Fourier sentences at 60dB in quiet with best aided condition < 50% • With fluctuating HL, when several times a month	Severe to profound bilateral sensorineural hearing loss

SSD: Single Sided Deafness, AHL: Asymmetric Hearing Loss (with at least one ear that is better than cut-off for best ear in case of bilateral deafness, AN: Auditory Neuropathy.

7.5.1.3 Organisation of care

CIs can only be implanted in accredited centers. For the follow-up and rehabilitation, centers are financed through MIG (dotations finançant les missions d'intérêt general). Data on MIG financing shows that in 2018 24 centers received such financing for this mission.[107] (Note that the implants are financed through the "liste en sus".)

Conditions imposed to centers are stated in the same Decree of 2009.[105] Conditions mainly concern minimum activity, networking, registration, multidisciplinarity and follow-up of patients as described hereafter.

Minimum activity

The following conditions are imposed concerning minimal activity of the centers:

- Centers for adults have a forecasted yearly number of implantations above 20.
- Centers for children have a forecasted yearly number of implantations above 10.
- Centers for adults and children have a forecasted yearly number of implantations above 20, amongst which minimum 10 in children.

The forecasts are based on the activity in the three latest years.

According to the website of CISIC, a French patient organisation, 31 centers perform CI implantation (treating either adults, children or both).[108]

Network

The centres must work in network with the rehabilitation centres and the other intervenants in the care chain for the orthophonic rehabilitation in order to ensure long term follow-up of implanted adults. In association with patient organisations the center organises meetings with patients so that they can exchange experiences.

Registration

Each center must make a report on its activities on regular basis. It holds a registry of implanted patients. According to the requirements of the HAS (cf. « avis de la CEPP en date du 16 mai 2007 »), the registry includes the result of the perceptive level, complications if any and the future of the patients.

Multidisciplinarity

The principal intervenors are:

- ENT physician, audiologist for realising audiometric tests and goals;
- Orthophonist evaluating communication and development of lipreading;
- Audioprothesist determining possibilities of hearing aids and their limits in terms of benefit;
- Psychologist considering the personal motivation, as well as of the family and environment;
- Radiologist precising the state of the cochlea, the peripheral and central auditory pathways;
- ENT surgeon validating with the team the indication.

Certain situations require to call upon other disciplines:

- Genetic evaluation with specialised consultation to investigate the diagnostic of genetic deafness;
- Neuropsycholigic an cognitive evaluation in elderly patients.

Follow-up of patients

Implanting centers must ensure the following follow-up after surgery to do the adjustments of the implant, medical surveillance and orthophonic evaluations:

- For adults for at leat 1 year;
- For children for at least 5 years.

Long-term follow-up comprises yearly evaluations in terms of communication (orthophonist, physician audiologist) and the possibility of contralateral hearing aid (audioprothesist).

7.5.1.4 Pricing

Negotiations with the Health Ministry have led to a gradual decrease in implant price until 2020, from € 16 000 in June 2017 to:

- € 15 250 (including taxes) on July 1st, 2017
- € 14 750 (including taxes) on July 1st, 2018
- € 14 200 (including taxes) on July 1st, 2019
- € 13 650 (including taxes) on July 1st, 2020

The price for the sound processor (upgrade and implantation) remains unchanged: € 6 000 (including taxes).[109]

7.5.1.5 Price-volume agreements

The “Sécurité Sociale” funds an unlimited amount of CIs. However, for adult bilateral CI a price-volume agreement has been agreed with the manufacturers. Adult bilateral CIs are funded up to 100 units per year. If this number is exceeded, a 25% discount will be applied to all bilaterals. (Note however that from an inter implant interval of 6 months and more, the second CI is no longer counted as a bilateral).

7.5.1.6 Upgrade term

CI can be upgraded with reimbursement after 5 years in case of defect or if a decrease in performance is measured with the current sound processor.[110]

7.5.2 Middle Ear Implants

7.5.2.1 Reimbursed indications

Since 2017 a new section for MEI has been added to the LPPR (Liste des Prestations et Produits Remboursés). The first MEI on the list is the Vibrant Soundbridge (MED-EL). MEI is reimbursed in case of conductive or mixed hearing loss, but not for neurosensorial hearing loss.[111] Reimbursed indications are specified as follows.

Conductive or mixed hearing loss, unilateral or bilateral, in children and adults, after failure or impossibility of

- Middle ear surgery
- Traditional hearing aids by airway or by bone
- Osseointegrated auditory device (bone conduction device).

7.5.3 Bone Conduction Devices

7.5.3.1 Reimbursed indications

BCDs listed on the LPPR are reimbursed for the following indications:

- Conductive or mixed hearing loss
  - for which middle ear surgery cannot be realised and
  - for which traditional hearing aids by airway or bone is ineffective or impossible (unilateral implant)

Unilateral neurosensorial hearing loss which is severe or worse. [112, 113]

7.5.3.2 Bonebridge

The Bonebridge is currently not listed for reimbursement by the Sécurité Sociale. The costs of the implant and the processor are at full charge of the patient. In 2015, the cost of the implant was € 6 200 and of the processor € 3 200. In some cases, however, the hospital could pay for the Bonebridge from its budget for innovative technologies.

7.5.3.3 Organisation

BCDs can be implanted both in public and private hospitals in France.

7.5.3.4 Pricing

The BCD implant, magnet and abutment have a price fixed by government, as detailed in the table below.

Table 44 – Pricing of bone conduction device implant, magnet and abutment in France

	Reimbursement (€)(including 5.5 % tax)
Implant	428.33
Abutment	498.52
Implant with abutment	917.85
Attract magnet	527.50
SP magnets (x2)	104.45

Source:[114 115]

The price of the sound processor is also fixed by government: Pricing limited to public sale since November 15 2019 to € 3 400 (including tax) and sale price € 2 550 (excluding tax)).[116]

7.5.3.5 Reimbursement level

The BCD implant, magnet and abutment are 100 % covered by the "Sécurité Sociale". Since november 2019 also the sound processor is fully reimbursed (previously only for € 900, which left a considerable out-of-pocket expenditure for the patient). The sound processor can be renewed every 2 years.[116]

7.6 Germany

In Germany, approximately 90% of the German population is covered by one of the social health funds, only about 10% of the population is covered by private health insurance. In what follows we discuss the reimbursement by the social health funds.

7.6.1 Cochlear Implants

7.6.1.1 Reimbursed indications for CI

In Germany, reimbursement of CI is not restricted to certain indications by insurance law, but a white book ('Weissbuch') written by the 'Deutschen Gesellschaft für HNO-Heilkunde, Kopf- und Hals-Chirurgie' (DGHNO) (2018) stipulates the criteria as follows.[117]

The indication has to be decided by the surgeon, based on the findings and the results of interdisciplinary case discussion:

- Patients who are expected to reach better hearing and speech understanding with CI than with other hearing aids.
- The auditory nerve and pathway must be functional, on the basis of pre-examinations.
- In case of bilateral indication, there should be a bilateral CI implant.
- On average in all postlingual patients with unilateral CI, there should be an expected improvement of monosyllabic speech test result of ≥ 20%-points at the end of the follow-up therapy.
- According to current knowledge, from audiologic point of view, a result of ≤60% on a monosyllabic speech test result, performed with hearing aids and at 65 dB, is an indication for CI.
- Postlingual patients (after speech acquisition), either deaf or with residual hearing, are as a rule eligible for CI.
- In prelingual deaf adults, selected individual cases can be eligible for CI, when there are signs of loudspoken language acquisition.
- Children who are prelingual deaf or perilingual deaf or with residual hearing should get an implant as soon as possible (in the first life year).
- In case of suspicion of suppurative labyrinthitis, a CI should be implanted as soon as possible.

The guideline in the white book is now under revision and is expected to be republished in 2020.

7.6.1.2 Summary of reimbursement

The table summarises the criteria as defined in the white book. Speech and audiometric criteria may however vary somewhat in practice. Criteria mentioned in another German publication reported mean audiometric criteria of >75 dB HL (250–4000 Hz) and speech understanding criteria of <45% on the Freiburg monosyllabic test at 65 dB under best-aided condition as well as the measurement of speech understanding in noise (e.g. HSM sentence test, OLSA, HINT, AzBio).[118]

Table 45 – Overview of reimbursement of cochlear implantation in Germany

	Bilateral hearing loss		SSD	AHL	AN	Guideline by	Speech criteria	Audiometric criteria
	Unilateral implant	Bilateral implant						
Adults	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Not mentioned in the guideline	DGHNO	≤60% Speech understanding in Freiburger Monosyllables	pure PTA HL not sufficient for decision
Children	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Not mentioned in the guideline	DGHNO	≤60% Speech understanding in Freiburger Monosyllables	pure PTA HL not sufficient for decision

SSD: Single Sided Deafness, AHL: Asymetrical Hearing Loss, AN: Auditory Neuropathy. Source: [117].

7.6.1.3 Organisation of care

The white book of the DGHNO also includes recommendations on structure, organisation, medical equipment, qualification and quality assurance for the CI care process in Germany. The white book serves as basis for certification of CI centers as well as for the establishment of a national CI registry.

One of the rules included in the white book is a minimum volume of examinations, to guarantee the continuity of process quality:

- > 1000 examinations in routine audiometry
- > 100 specialised audiology examinations (e.g. evaluation of CI indication) [117]

Nearly 100 hospitals perform CI implantation in Germany. [119]

7.6.1.4 Registration

According to the white book, all CI centers in Germany must keep record of their patients in a registry. The DGHNO has detailed the data blocks and fields that must be included: 1. Basic and patient data, 2. pre-operative audiometric results, 3. pre-operative hearing anamnesis, 4. implant data, 5. operation data, 6. complications, 7. use of CI and progress of rehabilitation, 8. post-operative audiometry, 9. quality-of-life according to the Nijmegen Cochlear Implant Questionnaire (NCIQ).

7.6.1.5 Pricing

Prices of the DRG codes for CI i.e. D01A- bilateral CI is € 52 297.98 and for D01B – unilateral CI is € 28 076.16. In case of simultaneous surgery, the DRG tariff for the second CI is reduced by 20%.

7.6.1.6 Reimbursement level and volume

CI implantation, as well as pre- and post-operative care are fully reimbursed. Reimbursement covers surgery, the implant, the hospital stay and rehabilitations. The volume of CI implants is uncapped, but not unlimited either in the sense that the total budget of most hospitals is frozen.

7.6.1.7 Upgrade term

The speech processor can be upgraded with reimbursement upon prescription of a physician, the soonest after 5 to 6 years. A minimum 10% improvement in hearing must be demonstrated on 2 measures.[120]

7.6.2 Bone Conduction Devices and Middle Ear Implants

7.6.2.1 Indications

A guideline ('Leitlinie') on implantable hearing aids (other than cochlear implants) has been written by the 'Arbeitsgemeinschaft Deutschsprachiger Audiologen, Neurootologen und Otologen' of the DGHNO ('Deutschen Gesellschaft für HNO-Heilkunde, Kopf- und Hals-Chirurgie'), in collaboration with 'Deutsche Gesellschaft für Audiologie' and 'Deutsche Gesellschaft für Phoniatrie und Pädaudiologie'. The guideline has been published in December 2017.[121] The guideline covers preoperative diagnostics, indications, contra-indications, operative and postoperative phase, in children as well as adults.

The guideline covers all active implantable hearing aids, including partially and fully implantable active MEIs as well as bone conduction hearing aids (active and passive bone conduction hearing aids, passive transcutaneous and percutaneous bone conduction hearing aids).

The indication criteria for implantable hearing aids are fulfilled in patients in whom a conventional hearing aid, either due to medical or audiological reasons cannot be used, and if by using an implantable hearing aid long-term rehabilitation can be expected.

Prior to any implantation a documented conventional hearing aid trial is mandatory, including professional setup and optimization and follow-up taking into consideration the individual hearing pattern.

The hearing aid chosen should be the optimal choice given the medical and audiological factors to provide the best possible rehabilitation. The expected aided SRS ("Speech Recognition Score") is most important. If bilateral hearing rehabilitation is indicated both sides should be aided. Bimodal hearing aids are possible. The indication should be made team based, after thorough counselling of the patient by the surgeon and in consideration of the available interdisciplinary information.

Limitations and indication criteria set by the producer are to be considered. In comparison to conventional hearing aids one or more of the following criteria should be met:

Conductive hearing loss

Wearing conventional hearing aids causes recurrent external ear canal inflammation (e. g. chronic otitis externa, inflammatory meatal fibrosis), sensitivity (e. g. pruritus) and other medical symptoms (such as external auditory canal eczema, pain in the ear canal) which prevent a lasting use of the conventional hearing aid.

Furthermore, if the conventional hearing aid does not sufficiently compensate the existing hearing loss, an implantable hearing could be indicated.

Conductive hearing loss and combined hearing loss

Better SRS through an implantable hearing aid could be achieved:

- Especially in cases of conductive hearing loss and combined hearing loss, in which conventional air conduction hearing aids do not sufficiently aid hearing. This includes malformations, acquired hearing loss as a result of middle ear surgery and temporal bone surgery as well as sclerosing middle ear conditions.
- In cases of acquired conductive hearing loss, all conventional surgical means should be exhausted.

Single sided deafness

Single sided deafness can be regarded as a special case: an indication could be set in patients who do not fulfill the indication for a CI (missing or destroyed vestibulocochlear nerve) and in whom satisfying hearing rehabilitation with CROS/BiCROS ((bilateral) contra lateral routing of signal) hearing aids cannot be achieved. The indication in these cases exists exclusively for bone conduction hearing aids.

Overlap in indications of the currently available implantable hearing aids

There is an overlap of indications and spectrum of use of the currently available implantable hearing aids. The patient should be thoroughly counselled about the existing implants, in order to be able to make an informed decision.

Children with dysplasia

Early stimulation of the affected ear should be aimed for children with dysplasia. Like in other forms of hearing loss a selective and direct stimulation of the affected ear should be aimed for, as far as the morphology permits.

A temporary transcutaneous bone conduction system (e. g. held by a headband) from birth should be considered, until the patient has fulfilled the criteria for an implantable hearing aid (see also: German guideline on peripheral hearing disorders in children). In individual cases an implantable hearing aid can be considered without a trial of a conventional hearing aid. The audiologic evaluation of the cochlear function is mandatory. Depending on the chosen implantable hearing aid, a preoperative simulation can be done.[121, 122]

7.6.2.2 Reimbursement

BCDs, both the implants and the processors, are fully reimbursed. Patients have to pay for the batteries.

MEIs are also fully reimbursed.

7.6.2.3 Bonebridge

Bonebridge is fully reimbursed through public health insurance. The average price is around €10 000, including implant and sound processor. Hospitals need to negotiate prices for the processor.

7.6.2.4 Pricing

There are list prices for the implants and the sound processors. (E.g. List price of implant D12A € 4 500; list price of the sound processor goes up to € 6 604.14 (for Baha 5 SP)).

The DRG code for MEI (D23Z) has a price of € 14 000.

7.7 Switzerland

7.7.1 Cochlear Implants

7.7.1.1 Indications for CI

Guidelines on CI have been drafted in Switzerland by the work group on CI of the Swiss ORL-association (CICH).[123] Conditions for coverage by social insurance of unilateral or bilateral CI, as well as CI in SSD are summarized hereunder.

Bilateral CI

Bilateral CI is indicated in the following cases:

- In children in case of pre- or perilingual deafness: congenital deafness or deafness acquired in early childhood
- In children or adults in case of postlingual deafness, under the following conditions:
  - Speech understanding is insufficient even with best possible hearing aids
  - With bilateral CI there is larger possibility to be able to maintain or get to work, to be independent and to take up activities of responsibility.

CI in SSD

CI is indicated in patients with SSD under the following conditions:

- Speech understanding <50% for monosyllabic in free field, at 65 dB SPL in noise and with hearing aids and with covered ear on the other side.
- Objective and subjective unsatisfactory hearing rehabilitation with CROS or BCD
- Duration of SSD < 10 years.

Table 46 – Overview of reimbursement of cochlear implantation in Switzerland

	Bilateral severe-profound hearing loss		SSD	AHL	AN	Guideline by	Speech criteria	Audiometric criteria
	Unilateral implant	Bilateral implant						
Adults	Reimbursed	Reimbursed when positive influence on work and independence	Speech understanding <50% for monosyllabic in free field, at 65 dB SPL in noise and with hearing aids and with covered ear on the other side.	Reimbursed	Not mentioned in the guideline	CICH : Arbeitsgruppe der Schweizer Zentren für Cochlea Implantate	Speech understanding is insufficient even with best possible hearing aids	Severe to profound bilateral sensorineural hearing loss
Children	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Not mentioned in the guideline	CICH : Arbeitsgruppe der Schweizer Zentren für Cochlea Implantate	Speech understanding is insufficient even with best possible hearing aids	Severe to profound bilateral sensorineural hearing loss

SSD: Single sided deafness, AHL: Asymmetric hearing loss (with at least one ear that is better than cut-off for best ear in case of bilateral deafness), AN: Auditory Neuropathy.

7.7.1.2 Organisation of care

In Switzerland 5 centers perform CI implantation: Basel, Bern, Genf/Lausanne, Luzern and Zürich.[124]

7.7.1.3 Registration of CI

Switzerland holds a registry on CI which is unique in its kind. The registry is complete for all CIs since the first implantations in 1977. Since then 3 589 implantations have been done in the five centers. Besides demographic data (gender and age of the patient) and etiology, also subjective and objective evaluation scores (Speech recognition performance (V08; C12; Freiburger), categories of auditory performance (CAP), speech intelligibility rating (SIR), LittlEars Auditory Questionnaire) are kept in the registry. Some results are shown in Appendix 6.1.

7.7.2 Middle Ear Implants

The Vibrant Soundbridge (MED-EL) is partially reimbursed with the same scheme as the Bonebridge:

7.7.3 Bone Conduction Devices

7.7.3.1 Bonebridge

Bonebridge is partially reimbursed in Switzerland:

- The implant and implantation costs are covered by the respective patient insurance, less a 10% retention and a franchise.
- The sound processor is fully reimbursed (up to CHF 4 829) together with a fitting charge (CHF 1 000) and battery costs (CHF 60) per year. All sound processor types for implantable devices are fully reimbursed.

7.8 Spain

7.8.1 Cochlear Implants

7.8.1.1 Indications for CI

The Scientific Committees of Otology, Otoneurology and Audiology from the Spanish Society of Otolaryngology and Head and Neck Surgery (SEORL-CCC) recently published a guideline on CI.[125] In general, CIs are suitable for patients who present with profound bilateral sensorineural hearing loss who have little benefit from hearing aids. The indications are further precised for age (children versus adults), hearing loss characteristics and aetiology.

Children

- Severe bilateral sensorineural hearing loss (71-90 dB HL) to profound (>90 dB HL) in conversational frequency range (from 500 to 4000 Hz) in children from 6 months of age. Apart from the audiometry criterion, consideration must be made to what extent the child has developed language and listening abilities, relative to age and cognitive development.
- **AND** With no or minimum benefit from a hearing aid after a trial period of 3-6 months (unless contraindicated).
- Pre-lingual, peri-lingual or post-lingual hearing loss.
- Imaging (MRI or CT+MRI) confirms the viability of insertion of electrodes into the cochlea and the presence of the cochlear nerve, in the absence of central alterations compromising the auditory pathway. Bilateral profound sensorineural hearing loss in the context of meningitis must be considered an emergency situation for implantation of a single or bilateral CI due to the risk of ossifying labyrinthitis.
- Positive psychological, paediatric and neurological assessment.

Adults (>18 years)

- The same as for children; **AND**
- With no or minimum benefit with hearing aid on both a tonal and functional level (under 40% in voice test to 65 dB SPL) after a trial period of 3-6 months.
- The same as for children: post-lingual or pre-lingual hearing loss.
- Patient's conviction that the auditory improvement of an implant would personally and socially enhance them. Prior evaluations on a personal, work-related and psychological level are recommended.

Table 47 – Overview of reimbursement of cochlear implantation according to the Spanish guidelines

Ear 1	Ear 2		Hearing aids	Adults	Children
PHL	**PHL**	Severe-profound bilateral hearing loss	CI in ear 1 or ear 2	Established indication	Established indication
PHL	**PHL**	Severe-profound bilateral hearing loss	CI in ear 1 + ear 2	Special indication (severe visual impairment; meningitis with obliteration in both labyrinths)	Established indication
PHL	**M-SHL**	Asymmetrical hearing loss	CI in ear 1 Hearing aid in ear 2 (=bimodal stimulation)	Emerging indication	Emerging indication
PHL	**Normal hearing or MHL**	Unilateral deafness	CI in ear 1 (besides other options of CROS or BCD)	Special indication (incapacitating tinnitus)	Special indication
M-PHL	**M-PHL**		CI + hearing aid in ear 1 Hearing aid in ear 2	Established indication	Emerging indication

PHL: profound sensorineural hearing loss, MHL: mild sensorineural hearing loss, M-PHL: mild to profound sensorineural hearing loss, M-SHL: moderate to severe sensorineural hearing loss. Established indication: has been demonstrated to be effective with an acceptable cost benefit. Emerging indication: of recent introduction, the initial results are positive and are engaged in cost-benefit study phase. Special indication: applicable to specific cases. Source: [125]

Bilateral implantation

Bilateral implantation in children

All the children with severe-profound pre- or post-lingual bilateral sensorineural hearing loss should receive, health permitting, a simultaneous bilateral implantation. In the case of sequential implantation in children the second implant must be undertaken if possible, within an interval of under one year. Children bilaterally implanted simultaneously or sequentially, before they are 4 years of age will obtain great benefit, with the performance of the bilateral implants gradually lessening between the ages of 4 and 7 years. In children over 7 years of age with pre-lingual deafness the sequential bilateral implant will be indicated in accordance with pronounced audiometric criteria, with a good development of the oral language, with early implantation of the first (recommended before 2 years of age) and with an interval between the 2 implants of no more than 5 years, provided that there is no major cognitive impairment or a severe degree of autism. However, the result of the second implant will always be variable, with the acoustic stimulation received prior to implantation being essential.

Bilateral implantation in adults

Bilateral implantation in adults is only indicated in people with sensorineural hearing loss associated with a severe visual impairment or a disease involving phenomena of bilateral labyrinth obliteration. In post-lingual deafness the sequential bilateral implant is indicated in adults with severe-profound sensorineural hearing loss who have used the first cochlear implant for at least one year and in accordance with the set criteria.

Unilateral deafness

Unilateral deafness in adults

In case of unilateral deafness with associated incapacitating tinnitus, CI can be indicated on the following conditions:

1. Adults over 18 years of age.
2. In the ear subject to CI:
   - Severe-profound sensorineural hearing loss
   - Speech performance tests with silent two syllables at 65 dB SPL in optimum conditions without lip reading assistance <50%
   - Score of >58 on the Tinnitus Handicap Inventory
   - Tinnitus causing disability related with or caused by hearing loss and not by other causes
   - Duration of tinnitus >1 year
3. In the contralateral ear of the CI:

Normal hearing or mild hearing loss.

4. Failure of conventional treatments of this symptom, including tinnitus retraining therapy, for at least 6 months.

Excluded are:

- Patients with tinnitus of central origin (for example tumour or stroke),
- pulsatile tinnitus connected to bloodflow,
- paroxistic tinnitus
- somatosensory tinnitus
- tinnitus related with headaches
- post-traumatic tinnitus.

Lastly, those patients with unrealistic expectations regarding the possible benefits, risks and limitations of the procedure and the prosthetic device will be excluded.

Unilateral deafness in children:

1. Children aged between 0 and 12 years
2. Unilateral hearing loss which involves the following characteristics:

- Ear to be treated with CI: severe-profound hearing loss, with a duration of hearing loss under 12 years
- Contralateral ear: normal hearing or mild hearing loss.

Excluded are:

- Ossification or other cochlear malformation which impedes the complete insertion of the implant's active electrodes
- Signs of retro-cochlear or central hearing loss
- Unrealistic expectations by parents regarding the possible benefits, risks and limitations of the procedure.

Mild to Profound Hearing Loss: Electro-Acoustic or Hybrid Stimulation

Inclusion criteria of these candidates are as follows:

1. Six years of age or older
2. Severe to profound sensorineural post-lingual hearing loss in frequencies of >1.500 Hz and mild to moderate sensorineural post-lingual hearing loss in frequencies of >500 Hz, without audiometric restrictions for the contralateral ear
3. Hearing loss duration <30 years
4. Recognition of two syllable words with help (correctly adjusted prosthesis) in the implantation ear between 10% and 50%, in silence and up to 65 dB SPL.

Aetiology

Contraindications of the cochlear implant are:

- congenital malformations with bilateral agenesis of the cochlea,
- absence of auditory canal function,
- the presence of diseases leading to central type hearing loss,
- severe psychiatric diseases,
- diseases that would contraindicate surgery using general anaesthesia,
- the absence of motivation towards implantation or
- noncompliance of audiological criteria.

Some patients with these contraindications (cochlear malformations and malformations of the cochlear nerve, total cochlear ossifications of meningitis origin) could be candidates for treatment with auditory brainstem implants. The indication of these devices which stimulate the auditory pathway at cochlear nuclei level in the brainstem require an exhaustive study prior to taking a final decision.

Auditory neuropathy

According to the Sydney Cochlear Implant Centre, in the majority of auditory neuropathies good outcomes were obtained following implantation. Suggestedly these are neuropathies due to a presynaptic alteration of the internal hair cell function. Neuropathies of postsynaptic origin, on the contrary, have a poor prognosis after CI. During patient selection clinical history, genetic assessment, MRI and intracochlear and cortical electric potentials may help to determine which patients with auditory neuropathy will obtain better outcomes with the CI.

7.8.1.2 Summary of indications for CI

Table 48 – Overview of reimbursement of CI in Spain

	Bilateral severe-profound hearing loss		SSD	ASHL	AN	Guideline by	Speech criteria	Audiometric criteria
	Unilateral implant	Bilateral implant						
Adults	Reimbursed	Only exceptionally (severe visual impairment; meningitis with obliteration in both labyrinths)	Only exceptionally (incapacitating tinnitus)	Emerging indication	Indication when of presynaptic origin	Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello	<40% in voice test to 65 dB SPL	Severe-profound HL: >70 dB HL; Hybrid stimulation: severe-profound HL > 1 500 Hz and mild-moderate HL > 500 Hz
Children	Reimbursed	Reimbursed	Only exceptionally	Emerging indication	Indication when of presynaptic origin	Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello		>70 dB HL

SSD: Single sided deafness, AHL: Asymmetric hearing loss, AN: Auditory Neuropathy. Source: [125]

7.8.1.3 Organisation

The CI technique does not merely consist of a surgical intervention. Implantation requires the organisation of a programme which ensures the following: correct candidate selection; effective execution of surgery and its programming; appropriate, sufficient rehabilitation; close coordination between the specialists involved in the programme and appropriate implanted patient follow-up and device maintenance.

Conditions are set as to involved professionals, a coordinator function, extra conditions for a programme in children and equipment.

7.8.1.4 Minimum volume

A minimum volume of on average 30 patients is recommended. It is on the other hand not recommended to implant a large number of patients within a short space of time when it would be difficult to subsequently offer them personalised attention. Furthermore, it should also be considered that a CI is for life, and as time passes and the number of implanted patients increase, the resources dedicated to their follow-up must also increase to the same proportion.

As abundant material and human resources are required for such a complex process as the selection, surgery, programming and follow-up of CI, rationalisation of resources must be made in function with needs. The corresponding healthcare administration could initially be responsible for ensuring the establishment of programmes which are sufficiently staffed and

adapted to the demands of the population so as to ensure homogenous and appropriate patient treatment. It could be of interest to create a national network of CI centres, with periodic audits, formed by centres which are experienced and highly qualified in the subject, so that they become benchmark units for candidates or users of a CI.

7.8.2 Middle Ear Implants

7.8.2.1 Indications for MEI

A clinical guide on active MEI was also recently published by the “Sociedad Espanola de Otorrinolaringologia y Cirugia de Cabeza y Cuello”.

To the extent possible, it is considered that conventional air conduction hearing aids, and reconstructive surgery of the ossicular chain, should be the first-line choice, and only when the results are not sufficiently good or if there is a contraindication will an implantable solution be chosen.

Currently the indications encompass patients with sensorineural, conductive or mixed hearing loss, moderate to severe in degree, with middle ear spaces that are normal or altered due to disease or previous surgery, patients who cannot wear hearing aids for medical reasons or who have not achieved sufficient benefits from other hearing systems, and patients who can achieve a gain in speech discrimination by mechanical stimulation.

Hearing loss that is retrocochlear in origin must be ruled out.

It must be confirmed that the patient is not satisfied with a hearing prosthesis that they have used at least in the ear that is to be implanted, that their hearing has remained stable over the past year, and that they have realistic expectations.

The indication will vary according to the site where the transducer is anchored in the middle ear (oval window, round window, mobile stapes, incus, directly to a passive middle ear prosthesis).

MEI are used in the following indications/pathologies:

- Malformations
- Otosclerosis
- Chronic ears
- Open cavities

7.8.2.2 Organisation

Speech rehabilitation is considered not essential with these devices, although in some cases it might be necessary to improve their performance. This can occur with older adults or those who have had long periods of hearing deprivation in the treated ear.

There is no set number of follow-up visits, although at least two check-ups are recommended during the first year following the implantation, and then annually. In these check-ups it is important to consider the audiological part with hearing checks as well as the ontological part, because many of these patients have chronic ear disease that can require periodic cleaning, and treatment of reactivation of their initial disease. Likewise, it is recommended that all aspects are covered, such as changes to the patients’ quality of life, their daily activity or their subjective perception of sound using questionnaires such as the Glasgow Benefit Inventory, Nijmegen Cochlear Implant Questionnaire, Health Utility Index (HUI 2&3) and the Hearing Implant Sound Quality Index.

7.8.3 Bone Conduction Devices

7.8.3.1 Bonebridge

Bonebridge is fully reimbursed through public health insurance.

7.9 NHS England

7.9.1 Cochlear Implants

7.9.1.1 Reimbursed indications

NICE published an updated guidance on cochlear implants in March 2019.[69]

Unilateral CI is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined as follows:

- Pure-tone audiometric threshold >= 80 dB at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.
- Adequate benefit from acoustic hearing aids is defined for this guidance as:
    - for adults, a phoneme score of >= 50% on the Arthur Boothroyd word test presented at 70 dBA
    - for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

CI should be considered for children and adults only after an assessment by a multidisciplinary team.

As part of the assessment children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate)

Simultaneous **bilateral** CI is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined by the criteria for unilateral CI:

- Children
- Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

7.9.1.2 Summary of indications for CI

Table 49 – Overview of coverage of CI in NHS England

	Bilateral severe-profound hearing loss		SSD	ASHL	AN	Guideline by	Speech criteria	Audiometric criteria
	Unilateral implant	Bilateral implant						
Adults	Covered	Only covered people who are blind or have other disabilities that increase their reliance on auditory stimuli	Not covered	Not covered	Not covered	NICE	Phoneme score <50% on Arthur Boothroyd word test at 70 dBA	>= 80 dB at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids
Children	Covered	Covered	Not covered	Not covered	Not covered	NICE	Speech, language and listening skills not appropriate to age, developmental stage and cognitive ability	>= 80 dB at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids

SSD: Single sided deafness, AHL: Asymmetric hearing loss, AN: Auditory Neuropathy. Source: [69]

7.9.1.3 Organisation of CI

NHS England made a standard contract for providers of cochlear implantation. [126] The contract contains several service specifications, a.o. on patient outcomes and resources.

Patient outcomes

The following key patient outcomes have to be achieved by the providers:

- >90% adults and >90% children using their cochlear implant consistently and reliably
- >80% of all patients to have thresholds of 40 dB HL or better inimplanted ears
- Improvement in developmentally age appropriate speech perception scores &/ or Quality of Life
- Service to present evidence of improvement in auditory and/or speech outcomes monitored in children
- >90% of patients reporting themselves to be satisfied or very satisfied with the service & their implant 12 months after surgery
- All audiological equipment must be calibrated to British Standards at least annually, and a system of daily checking in place.

Resources

The multidisciplinary team should comprise a core team for both children and adults and includes:

- Implant programme coordinator
- ENT consultant
- Audiological physician
- Audiological scientist / physicist
- Teacher of the deaf
- Specialist speech and language therapist
- Clinical psychologist
- Hearing therapist.

7.9.2 Bone Conduction Devices

The NHS England's clinical commissioning policy on bone-conduction implants states that, despite a lack of high-quality evidence, they are the only treatment option to restore hearing in a small number of patients. Furthermore the policy states that it is not appropriate to conduct RCTs for the clinical conditions that warrant the use of these implants.

BCDs and MEIs are only available to patients:

(1) For whom conventional air conduction hearing aids are not suitable, or do not provide adequate benefit; AND

(2) With a level of hearing loss that falls within BCD and MEI manufacturer's guidelines.

Implanted BCDs are commissioned for use in adults and children according to manufacturers' CE markings who have:

- (1a) Unilateral or bilateral conductive or mixed hearing loss within the manufacturers fitting criteria; AND Stable bone conduction thresholds (=<15 dB deterioration in >2 frequencies in a 2 year period); **OR**
- (1b) Unilateral sensorineural hearing impairment (including SSD) where the better ear has bone-conduction hearing thresholds within the manufacturers fitting criteria including SSD; **AND**
- (2) Trialled an air conduction hearing aid or wireless CROS/BiCROS hearing aid for a minimum of 4 weeks, or who are anatomically or physiologically unable to undertake a trial of an air conduction hearing aids; **AND**
- (3) Trialled a BCD on a softband or headband for a minimum of 14 days and show benefit in speech tests.

BCHDs are not commissioned for:

- Patients with a bone disease that is unable to support an implant.
- Patients who have a sensitivity or allergy to the materials used.
- Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely.

BCDs should be used with particular caution in patients who have had radiotherapy to the area of bone to be implanted and also in those patients who have a bone disease that affects the strength and integration integrity of an implant. In these patient groups the decision pathway and care should be undertaken by an auditory implant centre MDT.

The use of a device outside of the manufacturers specifications is not routinely commissioned unless part of a recognised and approved trial supported by suitable funding.

Centres implanting BCDs should aim not to implant devices at the upper range of their fitting range, as this is unlikely to offer long-term benefit to the patient.

Where a candidate is suitable for more than one BCD device, the most cost-effective option must be selected by the MDT with full patient involvement. [127]

7.9.2.1 Bonebridge

Bonebridge is fully reimbursed through NHS. Bonebridge is on the list of 'high-cost tariff-excluded devices' (HCTED), also known as the 'Zero-Cost-Model'. This applies only for Clinics within NHS England, but not to clinics in Wales or Scotland. Only clinics within the NHS England get a full reimbursement.

7.9.3 Middle Ear Implants

As stated above, the NHS England's clinical commissioning policy on bone-conduction implants states that, despite a lack of high-quality evidence, they are the only treatment option to restore hearing in a small number of patients. Furthermore the policy states that it is not appropriate to conduct RCTs for the clinical conditions that warrant the use of these implants.

Similar to BCDs, MEIs are only available to patients:

(1) For whom conventional air conduction hearing aid are not suitable, or do not provide adequate benefit; **AND**

(2) With a level of hearing loss that falls within BCD and MEI manufacturer's guidelines.

MEIs are commissioned for use in adults and children > 5 years of age (or as per manufacturers' CE markings) who have:

(1) Unilateral or bilateral conductive, mixed or sensorineural hearing loss within the manufacturers fitting criteria; **AND**

(2) Middle ear anatomy suitable to accommodate a MEI as determined by radiological and audiometrical testing; **AND**

(3) Stable bone conduction thresholds (=<15 dB deterioration in >2 frequencies in a 2 year period); **AND**

(4) Trialled an air conduction hearing aid or wireless CROS / BiCROS hearing aid for a minimum of 4 weeks, or who are anatomically or physiologically unable to undertake a trial of an air conduction hearing aid.

MEIs are not commissioned for:

- Patients with a recent history of uncontrolled middle ear infections.
- Patients who have a sensitivity or allergy to the materials used.
- Patients with physical, emotional or psychological disorders that, despite suitable treatment and support, would interfere with surgery or the ability to allow suitable rehabilitation such that significant benefit would be unlikely.

The use of a device outside of the manufacturers specifications is not routinely commissioned unless part of a recognised and approved trial supported by suitable funding.

Where a candidate is suitable for more than one MEI device, the most cost effective option must be selected by the MDT with full patient involvement.

BCDs will be routinely commissioned by NHS England when assessment by a multidisciplinary team leads to a clear recommendation of a BCD or MEI.

BCDs may be fitted bilaterally providing the above standards are met.[127]

7.10 Canada – Ontario

7.10.1 Cochlear Implants

7.10.1.1 BCI in adults

BCI in adults is not publicly funded in Ontario. However, bilateral implantations have been funded by research grants for a small number of adults in whom significant improvement in education and/or employment opportunities were expected, according to the following absolute and relative indications.

Absolute indications:

- Acute hearing loss after meningitis
- Deafness and severe visual impairment (e.g. Usher's Syndrome or congenital conditions)
- Sudden bilateral hearing loss from acquired causes

Relative indications (patients must meet all of the following criteria):

- Age 55 years or less
- Good physical and mental health, with realistic expectations
- No anatomical contraindications
- Preferably employed, in school, or active in the community
- Demonstrated commitment to cochlear implant program goals and rehabilitation
- Audiological status of the second ear being considered for implantation
    - Hearing loss at least severe (pure tone average ≥ 70 dB); word discrimination scores ≤40%
    - Aided Hearing In Noise Test score in quiet ≤ 60%; AzBio score ≤ 40%; consonant-nucleus-consonant score ≤ 50%
    - If not using hearing aids, period of nonstimulation is less than 10 years

The Ontario Cochlear Implant Program furthermore specified that contralateral cochlear implants should be limited to 10% of the total funding target for unilateral cochlear implantation in adults. Based on 270 funded cases of unilateral cochlear implantation in adults for the 2017/18 year, 27 additional CI devices would be needed for sequential bilateral implantation in patients who met the candidacy criteria above.[68]

7.10.1.2 CI in SSD

Adults

Following the Ontario Cochlear Implant Program's candidacy guidelines, there are three clinical indications for cochlear implantation in adults with SSD:

- (1) SSD due to acute or chronic causes (e.g., auto-immune disease, idiopathic viral neuropathy, acoustic neuroma or other intracranial tumors) where the other ear is at risk of future deterioration,
- (2) SSD from subacute or chronic inner ear disease, where other forms of sound amplification have been unsuccessful (i.e., CROS aids, bone-conduction hearing aids), and
- (3) a duration of deafness less than 10 years.

To have good hearing outcomes, patients must be willing to participate in a program of auditory rehabilitation (speech and sound exercises).

Children

In children with SSD, the duration of deafness (i.e.<4 years) and etiology of hearing loss (e.g. meningitis) are major factors to consider for cochlear implantation.[68]

Some patients with SSD are not candidates for a CI, such as those

- with cochlear nerve aplasia and
- whose inner ear is contraindicated for implantation (e.g., prior surgical removal of an acoustic neuroma).

These patients may be considered for bone-conduction implants to restore hearing. [68]

7.10.2 Bone conduction devices and middle ear implants

7.10.2.1 Bone conduction implants in conductive or mixed hearing loss

For patients with conductive or mixed hearing loss, candidates for bone-conduction implants (BCD or MEI) are those who would benefit from sound amplification but cannot use conventional air-conduction hearing aids. Candidacy is based on the person's hearing profile, age, needs, perceived risks, and preference. According to Health Canada's indications, the minimum age for children to receive a bone-conduction implant is 5 years old.[68]

7.10.2.2 Bone conduction devices in SSD

Some patients with SSD are not candidates for a cochlear implant, as described above, such as those with cochlear nerve aplasia and those whose inner ear is contraindicated for implantation. These patients may be considered for bone-conduction implants to restore hearing.

However, only people with a reasonably successful CROS trial and realistic expectation of improved hearing, and for whom a CI is not an option, would be considered eligible for a bone-conduction implant, as studies have shown that a considerable proportion of patients (approaching 50%) did not use their bone-conduction implant after a trial period.

7.10.2.3 Carina

According to the HTA of HQ Ontario, Carina is not used or promoted for clinical practice in Canada. It has been used only in research. In September 2018, its Health Canada licence was discontinued.

7.10.2.4 Bonebridge

According to the HTA of HQ Ontario, Bonebridge is the most used bone conduction implant in adults.

7.11 Canada – Quebec

7.11.1 Cochlear Implants

7.11.1.1 Reimbursed indications for CI

In Quebec the selection of CI patients is done by a selection committee (linked to the 'Centre québécois d'expertise en implant cochléaire'). This selection committee is composed of professionals of different disciplines (ENT, audiology, speech language pathology, psychology, social work, special education, and technical support). Its role is to make the candidate selection and to support the centers with education and practical training, to stimulate interactions between concerned parties and to organise events for knowledge-sharing. [128]

The selection criteria have evolved in function of technological developments and observed results in patients with CI. The selection committee makes a decision on the basis of all relevant factors.

- Status of the cochlea : cochlea must be without obstruction or severe malformation so that the electrodes can be put
- Functional audition : deafness must be permanent, usually at least severe at the best ear. The capability of the patient to recognise words and phrases (without lipreading) is limited, with optimal hearing aid.
- Age and communication:
  - Children:
    - No age limit for children with acquired or evoluting deafness
    - No age limit for children with congenital deafness with certain auditive experience and a functional oral language
    - Age limit of 7 years for children with congential deafness without auditive experience and/or without functional oral language. A child of older than 7 years who mainly uses sign language and who has only very limited help from auditive devices risks to obtain very limited results with an implant.

- Adults:
  - No age limit for adults with functional oral language
  - Adults who mainly use sign language and who have very limited help from auditive devices risks to obtain very limited results with an implant.

- Psychological state
  - Children and adults:
    - Persons must be in good mental state, without severe impairment that would inhibit the person to use the implant in an effective way. The persons also have to demonstrate a good motivation to engage themselves in each step of the process: surgery, programmation and intensive readaptation.

- Support from family and environment
  - A good motivation of the family and environment are also a requirement. For children, collaboration from parents is needed throughout the whole process.

7.11.1.2 Organisation of care

Since 2019 a second center (in Montreal) is allowed to perform CI. Before this decision, only one hospital, in Quebec city, was allowed to perform this procedure. Opponents of the decision to split the procedure over 2 hospitals argumented that the yearly volume was not high enough to split over 2 hospitals. The hospital of Quebec city treated around 250 CI cases a year.[129]

7.12 Cross-country comparison and key points for CI

7.12.1 Approaches in the reimbursement of CI

In our sample we broadly observe three approaches in the reimbursement or coverage of CI (see Table 50):

- **ENT specialists, as part of a multidisciplinary team, have flexibility to select the patients. All implanted patients get reimbursement**. The specialists are assumed to follow national or international guidelines for selection. Countries with this reimbursement approach are: Germany, the Netherlands, Spain. In the Netherlands no national indications are stipulated but there is a restriction on reimbursement of bilateral implantation in adults by 'Zorginstituut Nederland' (ZIN).

  In these countries, guidelines have been drafted by the professional societies of ENT specialists:

  - In Germany there is a guideline with indications for CI from the 'Deutschen Gesellschaft für HNO-Heilkunde, Kopf- und Hals-Chirurgie'.
  - In Spain there is a guideline with indications for CI from the Spanish Society of Otolaryngology and Head and Neck Surgery.

  In these countries, however, other measures are taken to control the budget:

  - In the Netherlands, health insurers contract with hospitals on the volumes of CIs. This has created wait lists for adults, as children get preferential treatment. This also means that Dutch ENT specialists are not entirely free to select their patients according to the guidelines, they have to make a selection at the level of their center in order not to exceed the agreed volume with the insurers.
  - In Germany, there is no cap specifically on the volume of CIs but there are caps on the total budgets of hospitals, so the budgets for CI at the center level are not totally unlimited.

- **Reimbursement is restricted by coverage rules**: In NHS England, CI may only be implanted in patients meeting the criteria as defined by NICE. In France the reimbursed indications have been determined by 'Haute Authorité de Santé'. In Belgium, reimbursement rules are set at the level of RIZIV-INAMI. In France and Belgium, ENT specialists (as part of a multidisciplinary team) are free to do the patient selection, but not all implanted patients get reimbursement (only the patients who meet the reimbursement criteria). The specialists are also assumed to follow national or international guidelines.
- **Selection of patients is done by a (multidisciplinary) central committee**. We refer to the example of Quebec, where there is a committee with experts that decide on the selection of patients for the two centers.
- Table 51 gives an overview of the institutions that created guidelines or reimbursement restrictions for each country.

Table 50 – Reimbursement approach for CI in the analysed set of countries

Country	Restrictions through reimbursement rules	National guidelines	Central committee decision	Restrictions on volume
B	X (RIZIV-INAMI)			
NL	X (no bilateral implant for adults – ZIN)	X (Veldnorm)		X (health insurers contract with hospitals on volumes)
FR	X (HAS) Based on speech understanding score			
DE		X (Weissbuch) Based on speech understanding score		
CH		X (CICH)		
ES		X		
NHS England	X (NICE) Based on speech understanding and audiometric criteria			
CA (Quebec)			X	
CA (Ontario)	X (Ministry of Health)			

HAS: 'Haute Authorité de Santé'; ZIN: 'Zorginstituut Nederland'; NICE: National Institute for Clinical Excellence

Table 51 – Overview of who sets reimbursement rules/guidelines in the analysed set of countries

Country	Guidelines by	Reimbursement rules by
B		RIZIV-INAMI
NL	Veldnorm	Zorginstituut Nederland (ZIN)
FR		Haute Autorité de Santé (HAS)
DE	Deutschen Gesellschaft für HNO-Heilkunde, Kopf- und Hals-Chirurgie (DGHNO)	
CH	Arbeitsgruppe Cochlea-Implantate der Schweizerischen ORL-Gesellschaft (CICH)	
ES	Spanish Society of Otolaryngology and Head and Neck Surgery	
GB		NHS England: National Institute for Clinical Excellence (NICE)
CAN		Ministry of Health Ontario

7.12.2 Reimbursed/Guideline indications for CI

In general CI indication criteria are based on either speech understanding or audiometric hearing loss or both. The international survey of Vickers et al. (2016)[130] on candidacy criteria for CI shows that 85% of countries in their sample have speech-based criteria for adults and approximately 60% have speech-based paediatric criteria, with assessments varying greatly depending upon the developmental age of the child. The speech tests consist of word tests, sentence tests or a mixture of both:

- Words and sentences – quiet (23.5% of countries)
- Words – quiet (23.5% of countries)
- Words – quiet and noise (17% of countries)
- Words and sentences – quiet and noise (12% of countries)
- Sentences – quiet and noise (12% of countries)
- Sentences – quiet (12% of countries)

Furthermore, 80% of countries in the sample of Vickers et al. (2016) have audiometric criteria in place for paediatric implantation, but only 70% of the respondents had audiometric guidelines for adult implantation. In what follows we take a deeper look into the precise speech understanding and audiometric criteria in our sample of countries.

7.12.2.1 Speech understanding and audiometric criteria for bilateral severe-profound hearing loss

Table 52 and Table 53 give an overview of the audiometric and speech criteria used in the different countries for determining eligibility for a CI, distinguishing between children and adults.

Table 52 – Overview of audiometric criteria used for CI in the analysed set of countries

		Audiometric criteria
B	Adults	≥ 70 dB PTA at ≥ 3 frequencies: .5, 1, 2 and 4 kHz in both ears BERA peak V ≥ 75 dB nHL
	Children	Same as for adults
NL	Adults	- (no audiometric criteria)
	Children	> 80 dB at 2000 and 4000 Hz
FR	Adults	≥ 70 dB (severe to profound bilateral sensorineural hearing loss)
	Children	Same as for adults
DE	Adults	Pure PTA HL not sufficient for decision
	Children	Same as for adults
GB (NHS England)	Adults	≥ 80 dB PTA at 2 or more frequencies (.5, 1, 2, 3, 4 kHz) in both ears without acoustic hearing aids
	Children	-
ES	Adults	≥ 70 dB HL (severe-profound hearing loss) Hybrid stimulation: severe-profound HL > 1.5 kHz and mild-moderate HL > 0.5 kHz
	Children	≥ 70 dB HL (severe-profound hearing loss)
CA (Quebec)	Adults-Children	Unspecified

A: Adults, C: Children

Table 53 – Overview of speech understanding criteria used for cochlear implantation in the analysed set of countries

		Speech understanding criteria	Tested with hearing aids (best aided condition) or without hearing aids	In quiet or with background noise	Criterion holds for both ears (best ear) or for each ear separately
B	A	CVC phoneme score at 70 dB SPL ≤ 50 %	Without hearing aids	Quiet	Both ears
	C	≥ 6yr: CVC phoneme score at 70 dB SPL ≤ 50 %	Without hearing aids	Quiet	Both ears
NL	A	• Veldnorm: CVC phoneme score at 65 dB SPL ≤ 50% • Nijmegen: CVC phoneme score at 70 dB SPL ≤ 70%	Best aided condition	Quiet	Both ears
	C	• Veldnorm: If measurable, CVC phoneme score at 65 dB SPL ≤ 50% • Nijmegen: If measurable, CVC phoneme score at 70 dB SPL ≤ 75%	Best aided condition	Quiet	Both ears
FR	A	• Fourier sentences at 60 dB < 50% • With fluctuating HL, when duration & frequency of HL has major impact on communication	Best aided condition	Quiet	Both ears
	C	• Profound: no language development • Severe: Fourier sentences at 60dB < 50% • With fluctuating HL, when several times a month	Best aided condition	Quiet	Both ears
DE	A	≤60% Speech understanding in Freiburger Monosyllables at 65dB, measured in each ear separately	Best aided condition	Quiet	Each ear separately
	C	≤60% Speech understanding in Freiburger Monosyllables at 65dB, measured in each ear separately	Best aided condition	Quiet	Each ear separately
CH	A	Insufficient speech understanding	Best aided condition		
	C	Insufficient speech understanding	Best aided condition		

NHS England	A	Phoneme score <50% on Arthur Boothroyd word test at 70 dBA	Not specified	Quiet	Not specified
	C	Speech, language and listening skills not appropriate to age, developmental stage and cognitive ability			
ES	A	<40% in voice test at 65 dB SPL	Best aided condition	Quiet	Both ears
	C	unspecified	-	-	-
CA (Quebec)	A – C	unspecified	-	-	-

A: Adults, C: Children

7.12.2.2 General criteria

Besides speech understanding and audiometric thresholds, some countries state the criteria more in general, see Table 54.

Table 54 – Overview of other criteria used for cochlear implantation in the analysed set of countries

	More general criteria
FR	Bilateral severe to profound sensorineural (perceptive) hearing loss, after failure or ineffectiveness of conventional hearing aids.
DE	• For patients for whom CI is expected to give better hearing and speech understanding than with hearing aids • On average across all postlingual patients treated in the center, an improvement of ≥ 20%-points in monosyllable understanding should be expected.
ES	In general, CIs are suitable for patients who present with profound bilateral sensorineural hearing loss who have little benefit from hearing aids.

7.12.2.3 Other criteria

Patient selection does not occur on the sole basis of speech understanding or audiometric hearing. Many countries have added other important factors in the reimbursement criteria. Examples from two countries are shown in the table below.

Table 55 – Overview of other criteria used for cochlear implantation in a subset of analysed countries

	Other general criteria (non exhaustive)
NL	Other criteria that play a role are a.o. communication and learning capabilities of the child, as well as the possibilities of parents and environment for support and rehabilitation, the communication need, how fast the hearing loss deteriorates, other impairments such as decreased visus, social situations, psychic factors etc. There is no limit age, but factors that do play a role are comorbidities and cognitive capabilities.
Quebec (Canada)	Persons must be in good mental state, without severe impairment that would inhibit the person to use the implant in an effective way. The persons also have to demonstrate a good motivation to engage themselves in each step of the process: surgery, programmation and intensive readaptation.

Criteria used for CI

Bilateral severe-profound hearing loss

The indication criteria for CI in adults in the analysed countries are predominantly based on speech understanding scores. The thresholds for speech understanding are as follows:

- In Germany: with hearing aids: monosyllabic speech test result at 65 dB ≤60%.
  - CI can also be indicated for high frequency hearing loss with residual hearing in the low frequencies.
- In France: with hearing aids: Fourier sentences at 60dB in quiet < 50%. For profound hearing loss in children: no language development.
- In the Netherlands: with hearing aids: CVC phoneme score at 65 and 75dB ≤ 70%. With speech shaped noise (SSN) < 50%.

Patient selection does not occur on the sole basis of speech understanding or audiometric hearing; other important factors are, for instance, cause and duration of hearing loss, progressiveness of hearing loss, age at implantation, central auditory factors, cognition, motivation, position of the electrode, lifestyle, socio-economic factors, etc. Some of these factors are mentioned in the reimbursement criteria.

7.12.2.4 Reimbursement of unilateral and/or bilateral CI

Table 56 gives an overview of whether, and under which conditions, bilateral implantation is reimbursed in the analysed set of countries.

Table 56 – Overview of reimbursement of unilateral and/or bilateral CI in the analysed set of countries

		Bilateral severe-profound hearing loss	
		Unilateral implant	Bilateral implant
B	A	Reimbursed	Not reimbursed
	C	Reimbursed	Reimbursed until 12 years; In case of threatening ossification or auditory neuropathy reimbursed until 18 years
NL	A	Reimbursed	Not reimbursed except if blind
	C	Reimbursed	Reimbursed
FR	A	Reimbursed	Reimbursed (price-volume agreement)
	C	Reimbursed	Reimbursed
DE	A	Reimbursed	Reimbursed
	C	Reimbursed	Reimbursed
CH	A	Reimbursed	Reimbursed in case of positive impact on labour market participation or independence
	C	Reimbursed	Reimbursed
ES	A	Reimbursed	Only exceptionally (severe visual impairment; meningitis with obliteration in both labyrinths)
	C	Reimbursed	Reimbursed
GB (NHS England)	A	Reimbursed	Reimbursed in adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.
	C	Reimbursed	Reimbursed

A: Adults, C: Children

Reimbursement for a bilateral CI

- In Germany, indication criteria hold for each ear separately. Bilateral implantation is indicated when both ears meet the criteria.
- In Switzerland, bilateral implantation can be indicated when results of hearing aids are unsatisfactory and, in adults, when it is expected to have a positive influence on labour market participation or independence.
- In France, bilateral implantation in children is indicated in case of deafness following meningitis, a trauma or Usher syndrome. Bilateral implantation in deaf adults is indicated in the following circumstances: risk on the short term of bilateral cochlear ossification, whatever the cause, in particular bacterial meningitis or bilateral temporal bone fracture; impact on social life and work, or a loss of autonomy in elder persons.
- In the Netherlands, bilateral implantation is only reimbursed until the age of 5, until the age of 18 under certain conditions and in deaf blind adults.
- In Spain, bilateral implantation in children is indicated in children with severe-profound pre- or post-lingual bilateral sensorineural hearing loss. Preferably before 4 years of age (great benefit), between 4 and 7 years (decreasing benefit). In children over 7 years of age with pre-lingual deafness the sequential bilateral implant will be indicated in accordance with pronounced audiometric criteria, with a good development of the oral language, with early implantation of the first (recommended before 2 years of age) and with an interval between the 2 implants of no more than 5 years,
- In Spain, bilateral implantation in adults is only indicated in people with sensorineural hearing loss associated with a severe visual impairment or a disease involving phenomena of bilateral labyrinth obliteration.

7.12.2.5 Reimbursement of CI for SSD, AHL and auditory neuropathy

Table 57 presents the reimbursement condition of CI in single-sided deafness (SSD), asymmetric hearing loss (AHL) and auditory neuropathy.

Table 57 – Overview of reimbursed/guideline indications for cochlear implantation in the analysed set of countries

		Single sided deafness	Assymetrical hearing loss	Auditory neuropathy
B	A	Not reimbursed	Reimbursed for ≥ 85 dB PTA at worst ear and 60 dB PTA at best ear	Not reimbursed or case by case analysis
	C	Not reimbursed	Same as for adults	Reimbursed on both sides up to 18y
NL	A	No established indication (research ongoing)	No established indication (research ongoing)	Reimbursed on one side if indicated by the team
	C	No established indication (research ongoing)	No established indication (research ongoing)	Reimbursed on one side if indicated by the team
FR	A	Not reimbursed	Not reimbursed	Reimbursed
	C	Not reimbursed	Not reimbursed	Reimbursed
DE	A	Reimbursed	Reimbursed	Guidelines do not make an exception for this aetiology.
	C	Reimbursed	Reimbursed	Guidelines do not make an exception for this aetiology.
CH	A	Reimbursed when speech understanding <50% for monosyllabic in free field, at 65 dB SPL in noise and with hearing aids and with covered ear on the other side.	Reimbursed	Guidelines do not make an exception for this aetiology.
	C	Reimbursed	Reimbursed	Guidelines do not make an exception for this aetiology.
ES	A	Only exceptionally (incapacitating tinnitus)	Emerging indication	Indication when of presynaptic origin
	C	Only exceptionally	Emerging indication	Indication when of presynaptic origin

A: Adults, C: Children

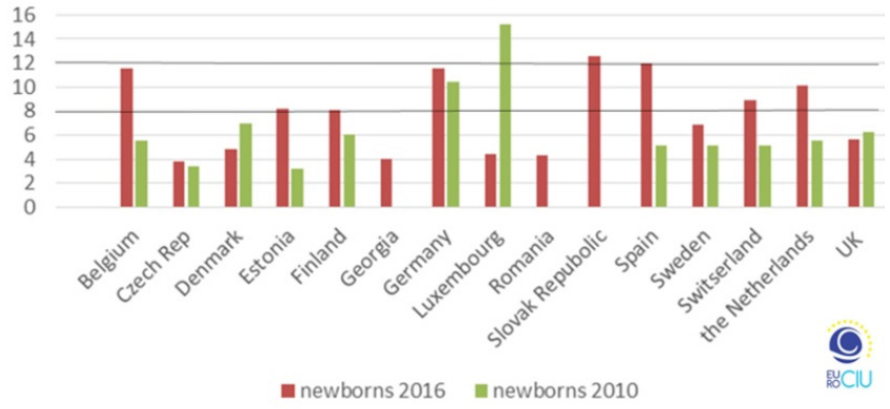
Indications in case of unilateral deafness

- In France, there is no reimbursement for asymmetric hearing loss nor single sided deafness. (Measurements for bilateral hearing lsos are done in the best ear.)
- In the Netherlands, there is no reimbursement for asymmetric hearing loss nor single sided deafness. (Measurements for bilateral hearing lsos are done in the best ear.)
- In Germany, measurements for CI are done for each ear separately, so CI can also be indicated in asymmetric hearing loss and single sided deafness.
- In Switzerland, CI can be indicated in single sided deafness, when speech understanding <50% with monosyllables in free field, at 65 dB SPL in noise, with hearing aids and with covered ear on the other side.
- In Spain, CI can be indicated in adults in case of unilateral deafness but only when associated with incapacitating tinnitus (Severe-profound sensorineural hearing loss; Speech performance tests with silent two syllables at 65 dB SPL in optimum conditions without lip reading assistance <50%; Score of >58 in the Tinnitus Handicap Inventory; Tinnitus causing disability related with or caused by hearing loss and not by other causes; Duration of tinnitus >1 year)
- In Spain, CI can be indicated in children in case of unilateral deafness, for children up to 12 years (Severe-profound hearing loss with a duration of hearing loss under 12 years)

7.12.3 Volume of CI per newborn and inhabitant

A survey conducted for Euro-CIU shows that in Belgium, per 10 000 newborns, between 11 and 12 children received a CI (can be unilateral or bilateral) in 2016. Belgium ranks amongst the highest-volume (per newborn) countries, approaching the volume of Germany, Slovak Republic and Spain. Compared to 2010 there was a considerable increase in Belgium, a trend also observed in many other countries.[131]

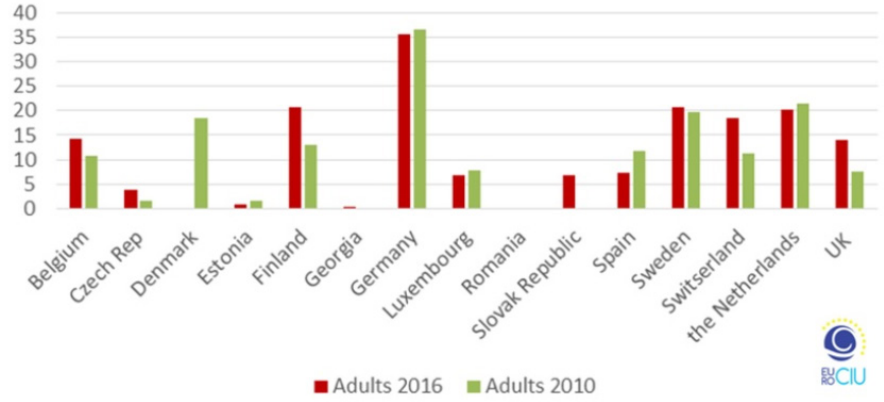
Figure 21 – Number of children receiving (one or two) CI per 10 000 newborns in 2010 and 2016



Source: De Raeve[131]

The same survey shows that a bit less than 15 adults per million inhabitants received a CI in Belgium. For adults Belgium ranks lower than countries like Germany (with 35 per million), Finland, Sweden and the Netherlands (three countries with about 20 per million).

Figure 22 – Number of adults receiving (one or two) CI per million inhabitants in 2010 and 2016

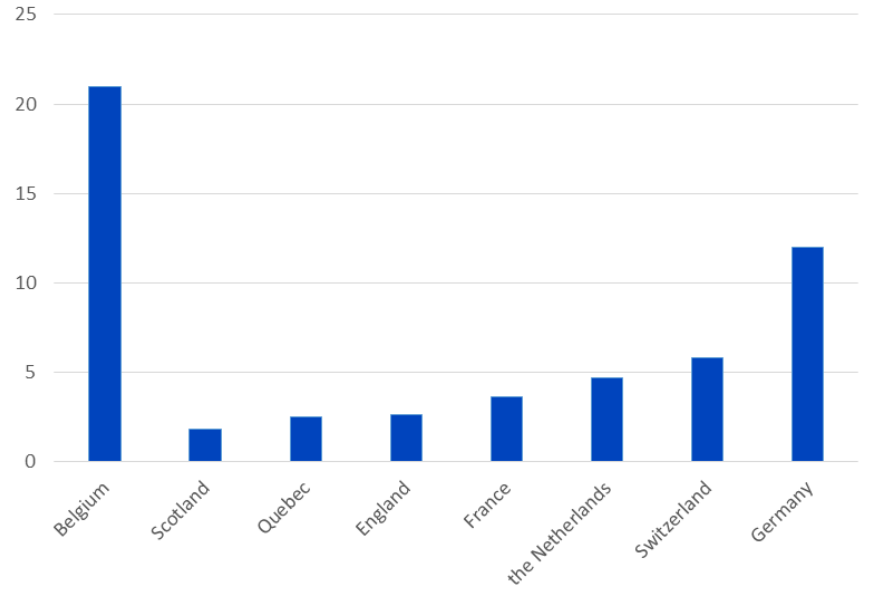


Source: De Raeve[131]

7.12.3.1 Organisation of CI

Figure 28 shows the number of CI centers per 10 million inhabitants in the analysed set of countries. With 24 centres performing CI in Belgium (21 per 10 million inhabitants), Belgium ranks highest. Germany follows Belgium but with a considerably lower rate of 12 centers per 10 million inhabitants. Further down the ranking are Switzerland with around 6 centers per 10 million inhabitants, the Netherlands with nearly 5 centers per 10 million inhabitants and France with less than 4 centers per 10 million inhabitants.

Figure 23 – International comparison of number of CI centers per 10 million inhabitants



- In the Netherlands, 8 centers implant CIs (~ 4.7 centers per 10 million inhabitants; 1.8 per 10 000 km^2).
- In France, 24 centers perform CI implants (~3.6 centers per 10 million inhabitants; 0.4 per 10 000 km^2).
- In Germany, nearly 100 centers perform CI implants (~12 centers per 10 million inhabitants; 2.8 per 10 000 km^2).
- In Switzerland, 5 centers perform CI implants (~5.8 centers per 10 million inhabitants; 1.2 per 10 000 km^2).
- In Quebec (province of Canada), since recently 2 centers implant CIs (~2.5 centers per 10 million inhabitants; 0.01 per 10 000 km^2).

- In England, 17 centers perform CI implants (~2.6 centers per 10 million inhabitants; 1.3 per 10 000 km^2).
- In Scotland, a single center performs CI implants (~ 1.8 centers per 10 million inhabitants; 0.1 per 10 000 km^2).
- In Luxembourg, patients are referred to Germany, Belgium or France for CI implantation. For the fitting and in case of problems with the implant, they have to return to the center where they got the implant. Recently, for the first time the activation of the processor of a CI (implanted in France) and the post-implant follow-up has taken place in Luxembourg. In mean term horizon, the hospital foresees to offer a full service for CI in Luxembourg.

Organisation of CI: minimum volume per center

- In the Netherlands, the lowest volume center implanted 32 implants in 2017.
- In France, conditions for minimal activity are imposed: centers for adults must have a forecasted yearly number of implantations > 20. Centers for children have a forecasted yearly number of implantations > 10. Centers for adults and children have a forecasted yearly number of implantations above 20, amongst which minimum 10 in children.
- In Germany, a minimum volume of examinations is imposed to implant CI: > 1000 examinations in routine audiometry; > 100 specialised audiology examinations (e.g. evaluation of CI indication)
- In Spain, it is recommended in the guideline that a centre implants more than 30 CI per year.
- In Quebec (province of Canada), there is an average of about 125 implantations per center.
- It may be considered best practice to determine minimum of patients that are examined, instead of minimum number of CIs, not to induce a risk of putting too many CIs.

7.12.4 Pricing of CI

- Price in France is fixed by government at 13 650 € (including taxes, but only for the implant, the sound processor is around € 6 000) from July 1st 2020. The government agreed a price-volume agreement with the manufacturers for bilateral CI implantation in adults: they are funded up to 100 units per year. If this number is exceeded, a 25% price discount applies to all bilaterals.
- Current price in Belgium is € 15 983 for the full kit (implant and sound processor).
- Prices in the Netherlands are negotiated between the manufacturers and the hospitals (unknown).

7.12.5 Registration of CI patients

In Germany, France, the Netherlands and Switzerland, all CI patients must be registered in a detailed database. The registry includes medical complications, the care trajectory and outcome results (e.g. to inform future patients). In Germany, France and Switzerland, the registration is centralised in a national database.

7.12.6 Upgrade term for sound processor

- In the Netherlands, the sound processor can be upgraded after 5 years.
- In France, the sound processor can be renewed after 5 years, but only in case of defect or reduced performance.
- In Germany, the sound processor can be upgraded, upon prescription of a physician, on the condition of a minimum 10% hearing improvement on 2 measures, minimum after 5 to 6 years.

7.13 Cross-country comparison and key points for BCD

Reimbursement level of BCD

- In France, BCD since recently is fully reimbursed (implantable as well as non-implantable part).
- In the Netherlands, BCD is fully reimbursed (implantable as well as non-implantable part). Patients have to pay for accessories.
- In Germany, BCD is fully reimbursed (implantable as well as non-implantable part). Patients have to pay for the batteries.

Reimbursed indications for BCD

- In the Netherlands, a national guideline has been developed on BCDs upon initiative of the Dutch Association of ENT and Head and Neck. The guideline details the indications for BCD in different types of hearing losses: bilateral conductive hearing loss, mixed hearing loss, unilateral conductive hearing loss, unilateral perceptive hearing loss.
- In France, BCDs listed on the LPPR for the following indications: conductive or mixed hearing loss for which middle ear surgery cannot be realised and for which traditional hearing aids by airway or bone is ineffective or impossible (unilateral implant) and for unilateral neurosensorial hearing loss which is severe or worse.
- In Germany, the hearing implant (partially or fully implantable MEI, active or passive (transcutaneous or percutaneous) bone conduction hearing aids) should be the optimal choice given the medical and audiological factors to provide the best possible rehabilitation. Patients with single sided deafness, who cannot get a CI (missing or destroyed vestibulocochlear nerve) and who cannot satisfying results with conventional CROS/BiCROS hearing aids can be an indication for bone conduction hearing aids.

Reimbursement of active tBCD

Bonebridge is already reimbursed in a range of European countries. It is fully reimbursed in Germany, the UK, Spain as well as in Austria, Portugal, Norway and Sweden, both for unilateral and bilateral applications. It is partially reimbursed in Switzerland. A case-by-case request is required in Germany, Switzerland, Spain and Portugal. Bonebridge is not yet reimbursed in the Netherlands and France

7.14 Cross-country comparison and key points for MEI

Indications for MEI

- In the Netherlands, at UMC St Radboud Nijmegen, all patients who received a semi-implantable MEI so far were patients with chronic otitis.
- In France, MEIs are reimbursed in case of conductive or mixed hearing loss, unilateral or bilateral, in children and adults, after failure or impossibility of middle ear surgery, traditional hearing aids by airway or by bone, BCD.
- In Germany, the hearing implant (partially or fully implantable MEI, active or passive (transcutaneous or percutaneous) bone conduction hearing aids) should be the optimal choice based on the medical and audiological factors to provide the best possible rehabilitation. The indication criteria for hearing implants are fulfilled in patients in whom a conventional hearing aid either due to medical or audiological reasons cannot be used, and if by using an implantable hearing aid long-term rehabilitation can be expected. They can be indicated in conductive and mixed hearing loss. A special case are patients with single sided deafness, who cannot get a CI (missing or destroyed vestibulocochlear nerve) and who cannot obtain satisfying results with CROS/BiCROS, they can be an indication for bone conduction hearing aids. Another special case can be dysplasia.

Reimbursement of Carina (fully implantable MEI)

- Carina is not reimbursed in France. It is reimbursed in Germany (by a case-based lump sum of about 14 000 €).
- According to the HTA of HQ Ontario, Carina is not used or promoted for clinical practice in Canada. It has been used only in research. In September 2018, its Health Canada licence was discontinued.

8 LIST OF OPTIONS AND EVALUATION OF EACH OPTION

Since December 2019 the criteria for cochlear implants (CI) in Belgium have been broadened. This was a major step forward in making CIs more accessible to the Belgian population, yet stakeholders agree that further improvements are still possible. In this chapter we present a long list of options to further improve the reimbursement of all hearing devices (so also a small part on the conventional hearing aids) but we will mainly focus on the hearing implants, so not only CI but also middle ear implants (MEI) and bone conduction devices (BCD). The options pertain to reimbursed indications, used tests, reimbursed devices, level of reimbursement as well as to conditions imposed to the centres performing the procedures. To keep some congruence throughout the report, this chapter starts with a small note on the conventional hearing aids, and continues with the improvement options for BCD. It then gives possible future options for CI. Consequently the chapter turns to MEI. The chapter finishes with proposals regarding the conditions imposed on the centres for performing the implantations and a 'various' section with proposals to improve reimbursement regarding procedures and materials related to hearing implants

This list of options is the result of a triangulation of methods (as described in the introduction section 1.2).

We focussed on 3 main topics (i.e. active tBCD, second CI in adults with bilateral severe-profound hearing loss, and CI in SSD in adults and children) that are discussed throughout the chapters. Besides these topics, other 'improvement points' were given by the experts and are also listed in this list of options and briefly evaluated when possible.

Note that the 'input from the interviews' is mainly based on 'opinions' of experts in the field and stakeholders, and should be seen in that light and interpreted with care.

Also, in general, the included scientific studies were characterized by heterogeneity, small sample sizes, and rather low quality. The retrieved results should therefore be interpreted with care.

This chapter integrates the other chapters of this report. Therefore, for details (amount of reimbursement, amount of patients in studies, comparators, etc.) and complete referencing we refer to the according chapters.

8.1 Reimbursement of conventional hearing aids

Conventional hearing aids (CHAs) were considered out of scope for this report for several reasons, however, the current reimbursement situation was listed in chapter 3 (as the non-implantable part of a BCD is also part of the agreement committee of audiciens and insurance institutions) and during the interview round, input of the experts was given and suggestions were reported here.

Input from the interviews

- People over 65 years receive lower reimbursement despite the fact that they can be still active in society, or work. Besides having an active life, one should also take into account the fact that 'understanding' and 'stereophonic hearing' leads to a more independent life. Often older patients with hearing loss are more dependent of others and isolated. They often need help from other care givers, which brings extra side costs for health care. Also, persistent hearing loss at an older age leads faster and more often to dementia, as shown in literature.[132]
- A national screening towards hearing loss could be useful to detect hearing loss especially in a population older than 50 years. It is seen that in most persons suffering hearing loss, it takes up to 7 years to detect and provide adequeate hearing solutions. Moreover, when hearing loss is left untreated it could induce social isolation, dementia, etc.
- There is a fully refunded device available. The quality of this device towards hearing gain is rated 'good'.
- Patients often request/receive extra features in their device, which augments the out of pocket payments. Devices over € 2 000 per ear is common.
- When a patient 'chose' a CHA, the audicien may suggest up to 3 devices. However, which is suggested first or if a fully reimbursed one is suggested is not clear and not obligated.
- The RIZIV/INAMI requested the manufacturers to devide their devices into 4 categories according the 'technology level'. Specific descriptions of the categories are not given. The goal of this would be to implement differentiated reimbursement levels.
- Expertmeeting: the reimbursement for the conventional hearing aids should also be reviewed. In many cases, patients have high out of pocket expenditures.

Clinical evidence

In general, the hearing technology is evolving rapidly. There are many devices on the Belgian market. It is not possible to find evidence for specific devices, nor for the levels of technology. It is nearly impossible to base a decision tree on evidence in this case. Therefore, this was considered out of scope for this report.

8.2 Reimbursement of bone conduction devices

8.2.1 Increased reimbursement for the non-implantable bone conduction devices

Input from the interviews

- In February 2019 RIZIV-INAMI increased the reimbursement for the sound processor for implantable BCDs; this was not the case for non-implantable BCDs (BCDs without bone anchoring but with headband or magnet). Despite the increased reimbursement, interviewed experts find that out-of-pocket expenditures for the patient remain too high, for implantable BCDs but especially for the non-implantable BCDs. Note that an implantable BCD can only be implanted when the skull bone is thick enough, therefore children get a non-implantable BCD. Also some adults may require a non-implantable BCD for medical reasons.
- In the case of children, because of the low reimbursement for non-implantable BCDs, parents sometimes postpone the intervention with headband (and thus a solution for hearing loss) until the child is old enough to get an implantable BCD, which is better reimbursed. However, early intervention is important for the development of the child. Also for implantable BCDs some patients decline the intervention for financial reasons. These patients cannot wear a conventional hearing aid and are not eligible for a CI, so they are left untreated.
- Stakeholders therefore plead for, at least, an increased reimbursement for non-implantable BCDs, to the same level as (the recently increased reimbursement) for implantable BCDs, but preferably for a full reimbursement for all BCDs (both non-implantable and implantable), as is the case for the other hearing solutions:
    - For conventional hearing aids, there is the possibility to buy a fully reimbursed device. For BCD devices this possibility does not exist. The sound processor of the BCD device is reimbursed like a conventional hearing aid, with a supplement, but this supplement is not sufficient to cover the higher price of the BCD sound processor. Also CIs and MEIs are fully reimbursed.
    - In case of implantable BCDs, in the past some patients have had the costs reimbursed by their hospitalisation insurance as the implantation requires hospitalisation. In case of non-implantable BCDs, however, there is no hospitalisation and thus no such possibility to get reimbursement from the hospitalisation insurance.
    - Hearing solutions for children should be fully reimbursed up to 12 years irrespective of unilateral or bilateral hearing loss.
- What should taken into account in the future is that more MRI assessements will be conducted. With a pBCD, the experts indicate, there is no limitation and image shattering is very low. However in tBCD's is seen that there can be a large shadow making MRI assessment difficult. This should be also taken into account.

Input from the international comparison

- In France, since november 2019, the BCD (both the implant and the sound processor) is fully reimbursed by the national health insurance. The sound processor can be renewed every 2 years.
- Also in Germany, the BCD (both the implant and the sound processor) is fully reimbursed. Patients only have to pay for the batteries.
- Same situation in the Netherlands where the BCD is fully reimbursed (non implantable as well as implantable). It is financed on the basis of 'Diagnose-Behandel-Combinatie' (DBC) codes within the hospital payment system. A patient can on average after 5 years be eligible for replacement of the sound processor.
- Finally also in NHS England the BCD is free of charge for patients.

Input for budget impact calculations

- The price of the implantable part is fixed by government and is fully reimbursed at € 1 128,34 (first fixation point) and € 317,28 (second fixation point, this code is rarely used). For the sound processor, patients get a base reimbursement as for a traditional hearing aid. On top of this, patients with BCD with headband or magnet get an extra reimbursement of € 99,66; patients with bone anchored hearing aid get a higher extra reimbursement (for details see chapter 3).
- In 2018, 212 sound processors for BCD were reimbursed in Belgium.
- If the sound processors for BCD would be fully reimbursed, it is estimated that the RIZIV-INAMI budget would increase by around € 658 400:
    - Cost per unit: Given that the majority of sound processors are for patients in the category 18-64 years, we assume an extra reimbursement of around € 2 900 and € 3 500 for a processor for BCD with and without bone anchoring respectively.
    - Volume: Based on the volume of 2018 (212 reimbursed sound processors for 149 reimbursed implants (€ 2 900), assuming 63 sound processors without bone anchoring (€ 3 500)). The total cost for full reimbursement of all BCDs would be around € 658 400.

8.2.2 *Reimbursement of the implantable part of passive transcutaneous and percutaneous bone conduction devices*

A trend exists to implant tBCDs over pBCDs. The reimbursement for the implantable part of passive tBCDs was augmented in February 2019.[133]

Input from the interviews

- For now, no specific reimbursement criteria are listed for the implantable part of the BCDs.
- The insurance companies state that for full reimbursement of the devices, the pricing of the manufacturers should be lowered.
- BCDs (and every hearing solution) should be fully reimbursed for children.
- The price of the implant is fixed by the government.

8.2.3 *Reimbursement of active transcutaneous bone conduction devices*

Note that in the category of active tBCDs, Bonebridge (MED-EL) so far is the only product on the Belgian market, but Cochlear recently obtained FDA clearance (December 2019) for an active tBCD system, named Osia. When we refer to active tBCDs we refer to the category as a whole, not to any brand specifically. So far no request has been introduced to RIZIV-INAMI for reimbursement of the Bonebridge, but Cochlear is attempting to submit a request for Osia.

Input from the interviews

- For now, no specific reimbursement criteria are listed for the implantable part of the BCDs.
- Experts indicate that a conductive component of 30 dB provides the best results. However, there are cases in which wearing a CHA is not possible, and in which cannelplasty or meatoplasty is not sufficient. In these cases, a BCD can be implanted although the conductive component is less. A try out with a non-implantable BCD (e.g. softband) could be informative on weather a BCD could improve hearing in these cases.

- Several ENT specialists stipulate another point of inequality in reimbursement of BCDs, notably the lack of reimbursement for active tBCDs. For some ENTs this is the highest priority on the list of changes to be made to the current reimbursement. According to them, Bonebridge is very effective; some of the experts indicated that studies show that Bonebridge is worn more hours per day compared to pBCDs (an average of 4 hours was reported in a recent presentation).[134] Also in Zernotti et al, 2016[135] wearing time was significantly longer for Bonebridge compared to Sophono.[135] It has a higher fitting comfort and has no risk of infection as the skin is left intact. The active tBCD is particularly important for a population of patients who will never be helped with conventional hearing aids, CI nor MEI, for which a BCD is the preferred treatment but because of adverse events of the passive tBCD such as skin irritation, the active tBCD is the only good solution.
- The reimbursement criteria of active tBCDs overlap with those of passive tBCDs (e.g. Baha Attract), notably conductive and mixed hearing loss with a bone conduction (BC) threshold ≤45 dB as well as SSD. According to the experts both options should be reimbursed below the BC threshold of 45 dB as sometimes still preference is given to passive tBCDs, e.g. when one expects that the BC threshold will deteriorate in the coming years.
- The reimbursement criteria of active tBCDs and MEIs are the same for conductive and mixed hearing loss. For the demarcation of indications between active tBCDs and MEIs, active tBCDs can be considered the same way as passive tBCDs. In case of conductive or mixed hearing loss MEI can only be reimbursed when a trial with a BCD with headband does not give sufficient improvement. This reimbursement limitation for MEI can remain unchanged, also when active tBCDs would be reimbursed, as when a trial with a BCD with headband does not give improvement, an active tBCD will likely not be an optimal solution either. So the condition for MEI remains that it is only an option when BCD (be it passive or active) is not expected to give an improvement.
- From a clinical point of view it would be logical to classify active tBCD as other BCDs. Active tBCD should be a direct (not a second order) option at the same level of other BCDs. Active tBCD should not be reserved to only those patients in whom passive tBCDs are contra-indicated or not rendering sufficient gain.
- For the distributor however it is not clear how to classify Bonebridge in the current reimbursement framework:
  - Bonebridge is a BCD as such, so indeed it would be logical to classify and reimburse it as BCD, however it has a considerably higher price than the currently reimbursed BCDs. The price of the Bonebridge approximates the price of a MEI (€ 9 371). Furthermore, as Bonebridge works without bone anchoring, it would not be eligible for the recently introduced supplemental reimbursement for BCDs with bone anchoring.
  - On the other hand it would be contradictory to reimburse it as MEI as the reimbursement criteria for MEI stipulate that they can only be reimbursed when there is a contra-indication for BCD, Bonebridge notably being a BCD.

  Therefore the manufacturer also considers another option, which is to have it reimbursed as a new separate category.
- According to RIZIV-INAMI, there is a clear procedure to request a reimbursement for an active tBCD, as there is for any implant: the distributor can submit a request to the Commission Reimbursment of Implants and Invasive Medical Devices. If a higher reimbursement is requested than for a passive tBCD, while targeting the same indications, then this has to be justified and an added value and/or cost-effectiveness has to be presented in the request. Alternatively, equivalence can be claimed and the same reimbursement as for a passive tBCD can be requested. For that, the RIZIV-INAMI endorses MED-EL to contact them, look at the possibilities and support them for submit a request file.

- Concerning BCD's for SSD, experts indicated that reimbursement for BCD's and MEIs should be excluded for SSD since a BCD does not restore binaural hearing wich is aimed to and there are better options available.
- When comparing devices in scientific literature, one should make sure that Bonebridge and pBCD's from the same generations are assessed.

Input from the clinical literature

In July 2018 the Bonebridge received FDA clearance in patients ≥ 12 years with conductive or mixed hearing loss as well as single-sided deafness. Osia 2 obtained FDA clearance in December 2019.

In our clinical review, evidence was only found for the Bonebridge, not Osia. Two reviews were retrieved and discussed: one review[2] assessed the active tBCD in conductive and mixed hearing loss and single sided deafness, while the other (a very recent review and meta-analysis) assessed the active tBCDs in general.[18] Improved audiometric thresholds and intelligibility for speech in quiet and noise is reflected in high levels of subjective satisfaction reported by the users of a Bonebridge via several questionnaires in all three types of hearing loss (compared to no treatment often within the same patient). Towards sound localization, no conclusions can be drawn since the samples were too small. The limitations of the research (included studies in the reviews) should be emphasized: testing methodologies and language varies (important for the results of word recognition scores) across study sites in various countries; the level of evidence was low comprising mainly cohort and case-control studies leading to potentially biased conclusions. Therefore, caution in drawing conclusions in the overall performance of the device of treatment has to be taken.

Towards safety of the devices, a lower complication rate (6-9%) with minor events was seen for the active tBCD compared to passive tBCDs (18-29%) and pBCDs (5-17%). Based on current evidence, the Bonebridge is a valuable and safe treatment option.[60] There is a need for more rigorous reporting of AEs in hearing implants, as Schwab indicates a guideline for assessing and reporting AEs in hearing solutions is under development.[60]

Input from the economic literature

In our economic review we identified one economic evaluation, conducted in Canadian setting, comparing active tBCDs with 'no intervention' (i.e. unaided) for each of the indications conductive-mixed hearing loss and SSD. The study examined bone conduction implants (BCDs and MEI) as a class of devices as a whole but assumed active tBCD to be the most commonly used device in this class in adults in Canada and therefore based the reference case on this device.

The study concluded active tBCD might be cost-effective in the indication of conductive and mixed hearing loss, but likely not in SSD, where CI was found to be more cost-effective. However the input data used in the model, especially on quality-of-life, remain too limited to be conclusive.

<u>Active tBCD in conductive and mixed hearing loss</u>

- For quality-of-life improvement from active tBCD in conductive and mixed hearing loss, the study used data from an Ontarian hospital in 33 adults. With HUI-3, the hospital reported a utility increment of 0.07 (on a scale from 0 – death, to 1 – perfect health) for active tBCD compared to unaided. No other data on quality-of-life measured by generic instruments were available.
- The resulting QALYs gained by active tBCD compared to no intervention, calculated over a 10 year horizon, amounted to 0.30 in adults.
- The resulting cost per QALY was CAN$ 74 155/QALY in adults.

<u>Active tBCD in SSD</u>

- For quality-of-life improvement from active tBCD in SSD, the study used data from the same Ontarian hospital in 17 adults. The hospital reported a small utility increment of 0.01 for active tBCD compared to unaided with HUI-3, a figure four times smaller than for conductive and mixed hearing loss. Note that this increment seems to be on the conservative side as an older study comparing Baha to unaided in SSD (in 11 adults) reported a utility increment of 0.11 with HUI-3, whilst results of active tBCD would expected to be equal, if not better.

- Based on this data, total QALYs gained over a 10 year horizon amounted to 0.06 in adults compared to no intervention.
- With a resulting ICER of CAN$ 408 350/QALY in adults, the authors conclude that active tBCDs are unlikely to be cost-effective in adults with SSD. In this population, CI appears more cost-effective (see further). Yet, sensitivity analysis demonstrates that when a higher utility increment is used, a much more favourable ICER is obtained. Note that for children similar conclusions are drawn but the analysis is based on pBCD.

The choice of 'no intervention' as comparator in the Canadian study may have led to rather conservative results, as the extra cost compared to 'no intervention' is considerably higher than compared to an alternative intervention. In the Belgian context, for many patients, active tBCD constitutes an alternative to passive tBCD or middle-ear surgery. Therefore for these patients the relevant comparator could be considered to be passive tBCD, the current treatment. Also compared to passive tBCDs, active tBCDs are expected to lead to improved quality-of-life, mostly because of lower complications (the QALYs gained though will likely be lower than in the Canadian comparison, with no intervention), but they also come at a higher price, although some savings can be realised by the lower complication rate. No data have been reported on the net cost compared to passive tBCDs and there is not sufficient data available to precisely balance the gains against the costs.

In the Belgian setting, incremental costs of active tBCD compared to passive tBCD in initial phase (comprising implant, sound processor and hospitalisation, assuming costs for hospitalisation being equal) are estimated at € 5 500 per ear. This cost is calculated from the healthcare payer perspective so includes both costs paid by public healthcare payer and the patient. However, given the small number of QALYs gained (<0) the ICER will still be rather high, despite the relatively limited incremental cost. A price reduction for active tBCD would obviously improve its cost-effectiveness. Since cost-effectiveness ratios calculated with HUI-3 are not strictly comparable to ratios calculated with EQ-5D in other clinical domains, and since there is no formal ICER threshold in the Belgian decision-making context, further research is required on quality-of-life (e.g. HUI-3) to obtain more robust data.

Input from the international comparison

- Bonebridge is already reimbursed in a range of European countries. It is fully reimbursed in Austria, Germany, the UK, Spain, Portugal, Norway and Sweden, both for unilateral and bilateral applications. It is partially reimbursed in Switzerland. A case-by-case request is required in Germany, Switzerland, Spain and Portugal. Bonebridge is not yet reimbursed in the Netherlands and France.
- In Ontario (Canada) Bonebridge is not yet reimbursed (nor for SSD nor for conductive or mixed hearing loss), but a positive recommendation for reimbursement was formulated by HQ Ontario for conductive and mixed hearing loss (based on the above mentioned studies). For SSD, according to the Ontario Cochlear Implant Program, CI is designated as implant of choice, unless CI is contraindicated, e.g. in case of cochlear nerve aplasia or inner ear contraindicated for implantation (e.g. prior surgical removal of an acoustic neuroma). When CI is contraindicated, active tBCD becomes the implant of preference.
- Osia 2 is FDA cleared in the US since December 2019 and reimbursed. It is also approved in Canada (not yet reimbursed). Osia 1 is reimbursed in Germany after ENT's advice.

Input for budget impact calculations

- Volume: Financially, reimbursing active tBCDs would partly imply a shift in volume from passive tBCDs to active tBCDs. Within the group of patients with bone conduction threshold <45 dB, who are potential candidate for both active and passive tBCDs, it is estimated that about half of them would be candidate for an active tBCD. (This equals the percentage that previously was candidate for Baha Attract, the passive transcutaneous solution, versus the Baha Connect, the percutaneous solution.) If we estimate that around 50% of the patients who are candidate for BCDs have a bone conduction threshold <45 dB, then we roughly estimate a volume of 25% of patients who are currently

implanted a BCD, i.e. around 37 patients. There may be some extra patients who currently reject the option of passive tBCD but who instead are interested in an active tBCD.

- Unit cost and budget impact: The impact of this shift on the budget depends on the reimbursement level for the active tBCD. As stated above, the price of Bonebridge (the implant itself) is considerably higher than of a passive BCD. The price of Bonebridge is comparable to the price of MEI, € 9 371. The price of a passive tBCD is around € 5 500 (implant of € 1 128.34 + sound processor of around € 4 400).
    - If the implant and processor of an active tBCD would be reimbursed as for passive tBCD without bone anchoring, likely there would not be a large impact on the budget. However this would leave a considerable out-of-pocket payment for the patient of around € 6 700 (<18 yrs) - € 7 400 (18-64 yrs) - € 7 500 (≥65 yrs).
    - If the active tBCD would be fully reimbursed, the expected impact for the budget of RIZIV-INAMI (for both the implants and speech processors), would be around € 277 587 (= 37 patients x (€ 9 371 minus current reimbursement of passive tBCD of around € 1 869 for 18-64 yrs)).
    - Besides the higher cost of the implant, active tBCD likely will also have higher procedural costs than other BCDs. Data show that the costs for hospitalisation, the surgical procedure, other procedures performed during the hospital stay and drugs administered during that stay for a BCD are around € 1 162, whereas for MEI (Vibrant Soundbridge) they are around € 3 218. This would result in an additional impact on the budget of RIZIV-INAMI.

8.2.4 Adaptation of hearing gain test for bone conduction devices in children

Input from the interviews

- In order to be eligible for reimbursement of BCDs, like for traditional hearing devices, the audiologist has to demonstrate a hearing gain of 5 dB tonal or 5% vocal. However, especially in case of unilateral hearing loss and especially in children, it is difficult to demonstrate this improvement, because the patient overhears with the better ear and the effect of the better ear is difficult to mask. The same problem is seen with CROS devices.
    - Interviewed audiologists therefore recommend to switch to subjective questionnaires such as PEACH (Parents' Evaluation of Aural/Oral Performance of Children), CHILD (Children's Home Inventory for Listening Difficulties), TEACH (Teachers' Evaluation of Aural/oral Performance of Children), etc. (see Appendix 3.3).
    - Another option that was suggested is to adjust the set up for the speech audiometry and turn the worse ear towards the loudspeaker.

Input from the international comparison

In France and the Netherlands there is no strict criterion on minimum hearing gain for reimbursement of BCDs or conventional hearing aids, nor for children or adults. This is also the case in Germany, only when the patient wants to renew the hearing aid sooner than the standard renewal term, a minimum improvement of 10% is requested. In NHS England, the patient has to show benefit in speech tests but no further precision is made as to how big this benefit should be; this holds for both children and adults.

8.2.5 *Ensure that the mandatory trial period for BCD is complied to*

Input from the interviews

- Although it is mandatory to let the patient try out a BCD with headband before definite implantation of BCD, not all centres appear to follow this rule. Experts stress that this try out is important as roughly 50% of their patients reject BCD implantation after the trial period; this percentage corresponds to what is reported in literature.[136] The fact that this mandatory rule is not followed highlights the need for action to be taken in terms of quality-assurance.
- RIZIV-INAMI has the right to perform controls in the hospitals if rules are followed. If they are not followed, a refund of any reimbursements can be demanded.

8.3 Reimbursement of MEI

Note that since mid May 2020, the fully implantable MEI Carina is no longer available on the Belgian market.

Input from the interviews

- During the interviews, most experts see no need to adapt the criteria for MEI. MEI is reimbursed only when a conventional hearing aid or BCD renders too limited gain or is contra-indicated. However a non-implantable BCD can be tested, but no test can be executed with a MEI before implantation. In their opinion, technology of these latter devices has significantly improved over the last period while especially a fully implantable MEI takes complex surgery of about 6 to 8 hours and a new operation is required in case of misplacement or defect. Moreover, a reintervention may be needed under certain circumstances.
- Currently the amplification capacity of MEI is limited. In the future, however, they will likely become stronger and in case fully implantable systems would be on the market and reimbursed, then patients might want to choose for a fully implantable MEI for aesthetic reasons. Experts stress that reimbursement should in that case stay reserved for medical indications, not for aesthetic preferences. If the problem would arise in the long run, then perhaps a system could be developed where the patient has to ask the medical opinion of 2 ENT specialists (who do not work together), to be sure that the implant is not selected for aesthetic reasons only.
- The experts indicated during the expert meeting that no reimbursement for a contralateral MEI is foreseen. They stated that in certain specific cases, it should be made possible to have two reimbursed MEIs. The contralateral MEI should comply with the same conditions for reimbursement as the first MEI. The RIZIV-INAMI said the distributor (MED-EL) should submit a request and show that there is sufficient evidence of the effectivity of a contralateral MEI.
- Moreover, experts are of the opinion that MEI's (and BCD's) should be full reimbursed in children. In adults only in bilateral or specific cases in which the contralateral ear should comply to the same conditions as the first MEI.
- During the expert meeting it was questioned why the reimbursement criteria were so specific for MEI, it's to say some seem not completely feasible in clinical practise. Specifically, it was questioned why the air bone gap should be > 30 dB, why not 20 dB or less? With the new criteria, the bone conduction threshold is following the CE marking (user manual) in all types of hearing loss.

Input from the clinical literature

- Concerning a possible overlap between BCD and MEI for conductive hearing loss, as stated in the reimbursement criteria, it are exactly the same indications for passive BCD, active BCD and MEI (for conductive and mixed hearing loss). However, as indicated by the experts, MEIs are only implanted in a very specific patient population, after careful counselling, in case no other solution can be given or a BCD is not indicated. This is also confirmed in the literature.[56, 57] So the 'selection' is not made by the reimbursement criteria but is made by the multidisciplinary team and ENT specialist. It is seen that this approach

of a more broaden reimbursement criteria, and letting the specialised ENT and multidisciplinary team evaluating the options, works also.

- The currently reimbursed semi-implantable MEI (i.e. Vibrant Soundbridge), was subject of investigation in most studies and shown to improve speech perception in noise, quality of life, and patient satisfaction. Fully implantable MEIs were less investigated, but patient satisfaction was relatively good.[137] Also, the safety profile of the semi-implantable MEI was more favourable[60], reporting complication rates up to 40%, while the rates with the fully implantable MEIs were generally higher (46 to 84%). Moreover, the surgical procedures of fully implantable MEIs are more complex and surgery has to be redone every time there is an error, refitting, battery change, etc.
- As for BCDs, a MEI should be reimbursed in children up to 12 years old (independently of unilateral or bilateral hearing loss). In adults full reimbursement is only necessary when they have a **bilateral** problem, and when hearing loss became suddenly and recent, but in that case full reimbursement is really necessary.

Input from the international comparison

- In France MEI is not reimbursed for sensorineural hearing loss. For conductive or mixed hearing loss, just like in Belgium, it is reimbursed only when BCD is impossible or fails. It is reimbursed in case the patient does not achieve enough benefit from conventional hearing aids or BCDs and middle ear surgery.
- Indications for MEI in the Spanish guidelines include that the patient has not achieved sufficient benefits from other hearing systems. This, together with reconstructive surgery of the ossicular chain, should be the first-line choice Indications encompass patients with sensorineural, conductive or mixed hearing loss.
- The German guidelines mention that there is an overlap of indications and spectrum of use of BCD and MEI, but do not stipulate that MEI can only be implanted when BCD is contra-indicated or renders too limited gain. The guideline states that the patient should be thoroughly counselled about the existing implants, in order to be able to make an informed decision.

It is experienced that the reimbursement criteria for MEI in Belgium are rather (too) specific, compared to other countries and that in practice they do not always seem feasible as indicated by the experts. As we look to the international comparison, it is seen that changes towards reimbursement could be considered based on the following criteria:

- Patient does not achieve sufficient benefits from other hearing systems
- Reconstructive surgery of the ossicular chain/middle ear surgery does not deliver sufficient result/not possible
- In case of sensorineural, mixed, and/or conductive hearing loss (not more specified by criteria)

8.4 Reimbursement of CI

8.4.1 Expansion of reimbursement to bilateral CI in patients above 12 years: according to selected criteria

Input from the interviews

- To start with, there have been multiple patients with the Usher syndrome (deaf with progressive loss of vision) (above the age of 12 years) that have obtained reimbursement for bilateral CI by the Special Solidarity Fund. According to experts, deaf-blindness is certainly considered as justified indication to obtain reimbursement for bilateral CI above the age of 12.
- Also besides the indication of deaf-blindness, ENT specialists advocate expanding reimbursement to bilateral CI above the age of 12, but the patients have to be thoroughly selected. At least the same criteria should apply as for the first CI (on residual hearing) and some other clinical points could be taken in consideration such as different assessments, timing of deafness, and duration of hearing loss.

- Experts see clear added value of bilateral implantation as their aim is to let the person hear 'normal', which means recovering binaural hearing. Binaural hearing improves listening in noisy situations, the orientation of sound, the feeling of safety, maximal integration, communication, reduces (side effects of) isolation, and reduces the effort it takes to listen. ENT specialists already have implanted Belgian adult patients bilaterally who paid for it themselves. Moreover, binaural hearing is reimbursed if it considers hearing aids.
- Bilateral CI for adults would be a major improvement for several patients who want binaural hearing. It should not be forgotten that opening the option for reimbursement does not mean that every patient will opt for it. If the ENT and team will find that the best option for the patient, the patient still can decide to wear CHA instead of getting implanted. Every case should be looked at individually.
- It was asked to update and change the contence of the kit for CI implantation.

Input from the clinical literature

One systematic literature review was retrieved (within an HTA) assessing bilateral cochlear implantation in adults and children from inception to March 2017.[33] We limited our research question to adults. The review retrieved 10 original publications of which 3 RCTs (2 reporting on the same trial of 38 patients), the other trial randomized 24 patients in a wait-list control design. There were 6 prospective observational studies using the patients as their own controls and one cohort analysis of a RCT (sample sizes ranging between 15 and 40 adults).

The authors, when comparing bilateral CI to unilateral CI in adults with severe to profound sensorineural bilateral hearing loss found (i) a high level of evidence for improvements in sound localization, (ii) a moderate level of evidence for improvements in speech perception in noise and subjective benefits of hearing, (iii) a low to moderate level of evidence for speech perception in quiet, and (iv) a low level of evidence for tinnitus and quality of life (inconclusive results).

A number of points should be taken into account when interpreting the summarized results. The test measures used across the studies differ largely (different tests, test configurations, outcome measures, ranges of follow up, etc.) making direct comparison between studies very difficult. There was heterogeneity in methods, study design, patient characteristics (e.g. imbalanced patient characteristics included in the observational groups), reporting of results, and ears implanted. Moreover, when patients with bilateral CI serve as their own control by switching from one CI it does not represent true unilateral hearing.

Towards CI, relatively low rates of (mainly minor) adverse events were reported (<20%), thus the devices are considered relatively safe.

Input from the economic literature

- Five economic evaluations have been conducted in recent years (we searched from 2014 onwards) to calculate the cost-utility of BCI compared to UCI in adults. Four of them conclude BCI is cost-effective or borderline cost-effective compared to UCI.
- Cost-utility results vary considerably in function of utility questionnaire used and costs reported, as well as the time horizon (age of patients). The younger the patients, the better the cost-effectiveness. Simultaneous BCI is more cost-effective than sequential BCI because of its lower costs.
- Regardless of utility instrument used, it is the first CI that gives the largest improvement. The gain of the second CI is estimated to represent 11.5% of the total increment going from no CI to BCI.
- When the generic EQ-5D instrument is used, as recommended by the Belgian, the impact of BCI compared to UCI is so small that BCI turns out not cost-effective. Using HUI-3, also a generic instrument, BCI has been found cost-effective in some but not all studies. In contrast to EQ-5D, HUI-3 contains questions on hearing and speech. In the described studies it is considered a more suitable instrument than EQ-5D for economic evaluations on hearing related disorders. Note that some experts indicated that these generic QoL questionnaries are not

sensitive enough to measure specific differences with regards to a number of hearing related aspects.

- Using the HUI-3, the long-term incremental health effect of BCI over UCI fluctuates around 1 QALY. Compared to other generic instruments (except for EQ-5D) HUI-3 still appears to be on the conservative side.
- Long-term incremental costs of BCI compared to UCI in Belgian setting are estimated at € 54 823 for sequential BCI and € 52 956 for simultaneous BCI. These costs are from the healthcare payer perspective and include cost of the CI, hospitalisation, pre- and post-operative costs (up to 25 years postoperative). No potential societal gains (e.g. from increased labour market participation) have been deducted.

Input from the international comparison

In Germany, bilateral implantation is reimbursed in children as well as adults and the same criteria hold for the contralateral ear as for the first ear. In France, bilateral implantation in adults is indicated in the following circumstances:

- when there is short term risk of bilateral cochlear ossification, whatever the cause, in particular bacterial meningitis or bilateral temporal bone fracture, **or**
- when there is clear impact on social life and work, **or**
- when there is a loss of autonomy in elderly persons.

Of note is that France agreed a price-volume agreement with the manufacturers for adult bilateral CIs. If adult bilateral CIs exceed 100 units per year then a 25% price discount is applied to all bilaterals (defined as those bilaterals that are implanted <6 months after the first CI).

In Switzerland, bilateral implantation is reimbursed in children and in adults in case of postlingual deafness and when there is an expected positive impact on the patient's ability to maintain or get to work, to be independent and to take up activities with responsibility. In Switzerland in the year 2016, 182 unilateral implantations (78% of patients) and 52 bilateral implantations took place (in adults and children; a bilateral implantation takes place in 22% of patients); most bilateral implantations were done sequentially.

In the Netherlands, Spain and NHS England, bilateral implantation remains restricted to a small selection of adult patients:

- In the Netherlands, bilateral implantation is only reimbursed until the age of 5, until the age of 18 under certain conditions and in deaf adults when they are also blind.
- In Spain, bilateral implantation in adults is only indicated when the patients also have a severe visual impairment or a disease involving bilateral labyrinth obliteration.
- In NHS England, bilateral CI is covered in adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

In Ontario (Canada) bilateral implantation in adults is not publicly funded, but they have been funded for a limited number of adults by research grants in whom significant improvement in education and/or employment opportunities were expected, according to the following absolute and relative indications (can be consulted in the Ontario report).[68]

The Ontario CI Program furthermore specified that contralateral CIs should be limited to 10% of the total funding target for unilateral CIs in adults. Annually this means 10% of about 270 funded unilateral CIs.

Input for budget impact calculations

Volume

- According to ENT specialists the financial impact on the RIZIV-INAMI budget is not expected to be very high as only a minority of patients would go for a second implant. As long as the patient still has some residual hearing, he or she may prefer not to be implanted in that ear.
- Belgian data for the years 2016-2018 show that in childeren, for whom bilateral CI is reimbursed until the age of 12 for bilateral hearing loss, 62% (127 of 205) get bilateral implantation. In the years 2016-2018,

there were 488 unilateral implantations in patients ≥12 yrs. With the recent lowering of thresholds, the volume of unilateral implantations however is expected about to double. If we estimate a volume of 10% contralateral implantations compared to unilateral implantations in patients ≥12 yrs (a percentage comparable to Ontario), we calculate a volume of around 17 (calculation based on old threshold volume) to 34 (based on new threshold) contralateral implantations per year. It is clear however that these are very rough estimations.

Unit cost and budget impact

- This would imply an estimated budget impact for RIZIV-INAMI of 17 to 34 patients x minimum € 16 000 (implant + procedure) per patient = € 272 000 to € 544 000. Pay attention however, that there are also extra ENT consultations (paid by RIZIV-INAMI and patient), extra rehabilitation sessions (paid by RIZIV-INAMI and patient when done by speech therapist outside ambulatory centre for rehabilitation, and paid by the regions otherwise) and extra costs for hospitalisation (paid by the Federal Public Service/patient).

Especially for persons that are still active on the labour market, ENT specialists argue that the financial investment is likely gained back very rapidly through increased social security contributions from higher participation in the labour market.

8.4.2 Expansion of reimbursement for CI in SSD: according to selected criteria

Input from the interviews

- **CI in prelingual SSD in children** (note that all congenital hearing loss is prelingual, but not all prelingual hearing loss is congenital)
  - **Opinions of interviewed ENT specialists diverge** on this topic. We interviewed specialists with a more “progressive” view, stating that it has been clearly demonstrated that SSD has negative consequences on cognitive development (e.g. due to listening fatigue) but also on social interactions. They find it also unfair that children with severe-profound bilateral hearing loss can have bilateral implantation whereas children with SSD cannot have a single implantation.
  - However, some specialists are more “conservative”, stating that they experience that children with SSD (and good mental status) also develop very well without CI and even in the same way as their normal hearing peers. Moreover, an advantage of not being implanted is that the children are not stigmatised and medicalised for the rest of their life. There are also other options like CROS and FM systems which can provide a sufficient solution for a child with SSD in classroom situations.
  - If one wants to intervene in children with prelingual SSD it has to be done early, perhaps even before 18 months to fully capture the benefits of binaural hearing as it is actively developed in the first two life years, during the prelingual phase. So if CI is implanted too late, binaural hearing can no longer be developed. But at the same time one should also take into account that deafness (depending on the pathology) could restore itself spontaneously in infants (an example is auditory neuropathy which is self reversing in one thirth of the patients). When implanting a CI is done too early, this possibility of spontaneous recovery is prohibited (also residual hearing is irreversibly lost).

- Most experts state that currently there is no sufficient evidence yet to balance between the advantages and disadvantages. For that, they refer to the Belgian multicentric study named CICADE (cochlear implantation for children and one deaf ear), which is currently ongoing and for which no final concluding results have been published yet (publication of results expected by 2024). Participating centres are UZ Leuven, UZ Antwerpen, UZ Gent and St. Augustinus Antwerpen. This study examines the negative consequences of SSD on speech and language development as well as cognitive development and the potential added value of CI in children. ENT specialists however also point to possible limitations of the study as the children with CI get more support by speech therapists than the non-implanted children, and this could lead to bias in the results (if implanted children perform better, is it not partly related to the extra support?). Even when the study results will be known it is likely that it will remain a difficult balancing between the pros and cons of CI in children with SSD. It could well be the case that e.g. in certain subgroups, like children who are cognitively weaker, would get the most advantage from CI. Also in acute or chronic causes (e.g. acoustic neuroma, viral neuropathy, etc.) where the other ear is at risk of future deterioration, a CI should be considered.
- There are some experts who plea for fully reimbursement for the few children with congenital prelingual SSD until the age of 3 years, since the first results of the CICADE study are promissing but definite results will be available in 5 to 10 years. They feel, if requested, these children should be able to be implanted.
- It is clear that, in case of reimbursement, careful assessment and counselling of the child and its parents is extremely important to create realistic expectations and to provide clear information about the pros and cons of the implantation (heavy surgical operation, intensive rehabilitation, loss of residual hearing, etc.). A complex trade-off has to be made, between what a child gains and what a child might risk.
- ENT specialists estimate that, in case of reimbursement, the financial investment would be very limited as there is only a very limited number of cases of children with SSD per year and many of them even would drop out because the nerve does not work well enough to be implanted with CI. Specialists estimate a volume of around 10 to 20 patients per year.
- When screening is done in babies (before week 6) by K&G/ONE, the evoqued potentials should be tested again the day after (second test, in presence of general practictioner). If this test is neither good, the parents and baby are refered to a specific ENT center (recognized by K&G/ONE). However, no real independent information is given towards patient organisations, possible treatments, reimbursement, etc.
- In Antwep University Hospital, experts implanted CI in SSD already 15 years ago and CE marking was obtained. Also Germany does it already and the results are very positive towards binaural hearing. In well-selected cases, CI can have added value towards binaural hearing.

- **CI in acquired postlingual SSD, either acute or progressive, in adults or children**
  - Patients with SSD are currently proposed two options: conventional hearing aids, BCD and/or CROS; patients mostly opt for a CROS device, the non-invasive option. ENT specialists however see patients who are not satisfied with any of these options after having tested them, and who prefer a CI, despite the fact that they have to fully pay for it. In patients with unilateral hearing loss, specialists experienced that BCD has around 50% non-users (similar to what was reported in literature). This high percentage is not acceptable according to the specialists. In this indication CI is seen to give better results. The big advantage of CI compared to BCD or CROS is that one can hear in stereo. Though it is no perfect stereo (the sound differs and there is a certain delay in time), it can be an added value to the patient. Still, CI will not be the solution for all SSD in adults and **patient selection will mainly have to be done**

on the basis of tinnitus suppression, the duration of SSD , needs in professional life or the presence of other pathologies:

- Adults with acquired SSD often suffer from tinnitus when becoming deaf on one side. As CI suppressess the tinnitus, the experts agree that the gain of a CI is especially attained in those who have SSD in combination with tinnitus. A specialist mentioned to have participated in a successful Canadian study on CI in adults with SSD with tinnitus, who received thorough follow-up (patients had to wear the CI continuously throughout the day to develop maximum plasticity of the brain). In this study patients made very good progression with CI. Experts also referred to research from the University Hospital of Antwerp that showed that this patient group appears to benefit from a CI.
- In adults with acquired postlingual SSD, a CI can also deliver some gain in terms of hearing, it remains limited. The functional gain that can be reached with a CI in this population depends on
  - the duration of deafness: the shorter the duration of deafness, the better the results with a CI and therefore, when CI is indicated, implantation should be done as soon as possible, and not longer than 10 years after the onset of SSD
  - whether the patient has worn hearing aids since then: the shorter the time the ear has not been stimulated, the better
  - patient's professional life or activities: e.g. in persons who frequently participate in meetings a CI can help to reduce listening fatigue; in militarians, CI can help for sound localization; etc.
  - if there are other pathologies (e.g. acute or chronic causes in which the other ear is also at risk of future deterioration).
- So also here good patient selection is paramount and the pros and cons have to be balanced.
- Note that in adults with prelingual SSD, CI is not indicated as binaural hearing was not developed.

Input from the clinical literature

Effectiveness of current treatment modalities for SSD

Current reimbursed treatment modalities for SSD (i.e. Conventional Hearing Aids (CHAs), Contralateral Routing of Sound systems (CROS) and Bone Conduction Devices (BCDs)) do not restore binaural hearing. This was confirmed by literature indicating that sound localization (for which binaural hearing is needed) was not improved. Although we did not retrieve studies comparing the effectiveness of the current reimbursed therapies with each other, BCDs report more generally improved outcomes. Based on very heterogeneous, small sample sizes and low level of evidence studies, BCDs seem to improve objective audiometry outcomes, to have a medium-effect on subjective hearing related qualtiy of life outcomes, and to present a limited effect on speech audiometry outcomes (depending upon the localization of noise). Similar results were described for passive and active transcutaneous BCDs.

Effectiveness of CI in SSD

In contrast, cochlear implantation (CI) may overcome the limitations of CROS and BCD, as binaural input can be restored. Literature confirms that CI in SSD might improve speech perception in noise, sound localization, hearing-specific quality of life, and speech and language development (in children). However, only 6 reviews were retrieved from our search with only 1 review investigating children with CI and SSD. Thus few original articles (with weak level of evidence i.e. case reports or case series, small sample sizes ranging from 1 to 25 in adults and 1 to 13 in children, high heterogeneity in testing methologies, etc) were available and therefore it is not possible to draw definite conclusions based on the evidence from literature.

Effectiveness of CI in SSD with tinnitus

To relieve symptoms of tinnitus in SSD, hearing solutions (such as CIs) can only be considered an option when severe-profound hearing loss is also present. We retrieved five reviews but all included mainly the same articles ranging from 30 to 161 patients in 5 to 13 studies. In patients suffering from tinnitus in SSD (as well as AHL), a suppresion of tinnitus and general improvement was achieved with CI. Of note, a minority of patients do report worsned symptoms of tinnitus but in none of the retrieved reviews a patient was described in who tinnitus commenced with CI. Good selection of the patients (including a try out with a conventional hearing aid) and adequate counselling (in order to have realistic expectations) is needed.

Input from the economic literature

- A single economic evaluation has been conducted in recent years (we searched from 2014 onwards) to calculate the cost-utility of CI in SSD compared to no intervention. The study, conducted in Canadian setting, concludes CI is cost-effective in children as well as adults.
- Using the HUI-3, the long-term incremental health effect of CI in SSD over no intervention was reported to approach 2.8 QALYs on a time horizon of 25 years. Note that this is nearly three times as much as what was reported for BCI compared to UCI. However, utility data are based on a single older study in 11 adults only. Further research on quality-of-life is required to obtain robust data, preferably differentiated according to indication (SSD with tinnitus, SSD without tinnitus, SSD in children).
- Long-term incremental costs of CI compared to unaided in Belgian setting (including preprocedural, procedural and postprocedural costs) are estimated at € 54 823. Whether the gains can justify this cost all depends on the improvement in quality-of-life, for which there is very limited data so far. Since cost-effectiveness ratios calculated with HUI-3 are not strictly comparable to ratios calculated with EQ-5D in other clinical domains, and since there is no formal ICER threshold in the Belgian decision-making context, further research is required on quality-of-life (e.g. HUI-3) to obtain more robust data.
- Same as for BCI one can expect that the younger the patients, the better the cost-effectiveness.

Input from the international comparison

- CI is currently not reimbursed or covered for SSD in France, the Netherlands nor NHS England.
- In Switzerland CI is reimbursed for SSD under the following conditions:
  - speech understanding score <50% on monosyllable test in free field, at 65 dB SPL in noise, with hearing aids and with covered ear on the other side;
  - objective and subjective unsatisfactory hearing rehabilitation with CROS or BCD;
  - duration of SSD < 10 years.
- In Spain CI is reimbursed for SSD only in case of incapacitating tinnitus.
- Also in Germany CI is reimbursed for SSD. According to the German guideline on implantable hearing aids of 2018, BCD only has to be considered in SSD when patients do not fulfill the indication for a CI (missing or destroyed vestibulocochlear nerve) and when no satisfying results can be achieved with conventional CROS/BiCROS hearing aids. We deduce that CI gets preference over BCD in SSD, if CI is not contra-indicated. CI implantation in SSD follows the same general rules as for bilateral hearing loss as stipulated in the 'Weissbuch'. The indication has to be decided by the surgeon, based on findings of interdisciplinary case discussion:
  - Patients who are expected to reach better hearing and speech understanding with CI than with other hearing aids.
  - The auditory nerve and pathway must be functional, on the basis of pre-examinations.
  - On average in all postlingual patients with unilateral CI, there should be an expected improvement of monosyllabic speech test result of ≥ 20%-points at the end of the follow-up therapy.

- According to current knowledge, from audiologic point of view, a result of ≤60% on a monosyllabic speech test result, performed with hearing aids and at 65 dB, is an indication for CI.
- Postlingual patients (after speech acquisition), either deaf or with residual hearing, are as a rule eligible for CI. In prelingual deaf adults, selected individual cases can be eligible for CI, when there are signs of loudspoken language acquisition.
- Children who are prelingual deaf or perilingual deaf or with residual hearing should get an implant as soon as possible (in the first life year).
- In case of suspicion of suppurative labyrinthitis, a CI should be implanted as soon as possible.

- In Canada (Ontario), CI has recently been recommended to be reimbursed for SSD. Following the Ontario CI Program's candidacy guidelines, there are three clinical indications for CI in adults with SSD:
  - SSD due to acute or chronic causes (e.g. auto-immune disease, idiopathic viral neuropathy, acoustic neuroma or other intracranial tumors) where the other ear is at risk of future deterioration
  - SSD from subacute or chronic inner ear disease, where other forms of sound amplification have been unsuccessful (i.e. CROS aids, bone-conduction hearing aids)
  - A duration of deafness <10 years.

For children with SSD, CIs have been funded through hospital global budgets. In children with SSD, important factors to be taken into account are the duration of deafness (<4 years) and etiology of hearing loss (e.g. meningitis).

Input for budget impact calculations

Volume of children with SSD who qualify for a CI

ENT specialists estimate that, in case of reimbursement, the financial investment would be very limited as there is only a very limited number of cases of children with SSD per year and many of them would drop out because the nerve does not work well enough to be implanted with CI. Specialists estimate a volume of around 10 to 20 patients per year in Belgium.

According to the thesis of Sangen (2019)[42], an estimated 5 to 10 newborns with SSD would qualify for a CI each year in Flanders, out of a total estimated 20 to 25 newborns with unilateral profound hearing loss and removing those patients with syndromal and neurological etiologies as these do not qualify for a CI.

Volume of adults with SSD who qualify and opt for a CI

No estimations are available on the patient volume in this group for Belgium. If we would estimate that the volume of adults would be slightly higher than the volume of children (cfr Swiss registry), we arrive at a volume of around 12 to 25 patients per year in Belgium. However these are very crude estimates.

8.4.3 Minor adaptation of the criteria for CI implantation

8.4.3.1 Adaptation of threshold level for CI in asymmetric hearing loss

Input from the interviews

- Whilst the criteria for bilateral hearing loss have changed, the criteria for CI in asymmetric hearing loss remained unchanged. For asymmetric hearing loss, the threshold level for the worst ear remained at 85 dB and for the best ear at 60 dB. ENT specialists advocate a lowering of the threshold at the worst ear to 70 dB, in accordance with the lowered threshold for bilateral hearing loss. Considering the new criteria for bilateral hearing loss, this group would become relatively small, but still existent, so it is worthwhile to keep it as separate category. Some ENT specialists plead for a further lowering (from 60 dB to 50 dB) of the threshold at the best ear, notably for children with progressive hearing loss in order to obtain the best speech and language development; this would mean that not more children are treated but that they are treated earlier. Other ENT specialised also suggest to simplify the options and put single sided deafness together with asymmetrical hearing loss in the same group (and thus not taken into account anymore the contralateral 'best' ear).
- There is a small group of children between 12 and 18 year that suffer progressive hearing loss. Because of this hearing loss, they may have a CI already implanted before the age of 12 but the contralateral ear may deteriorate slowly progressive (after the age of 12). In the case of fast fibrosis (e.g. after meningitis) there is reimbursement until 18 year, but not in children with this rare progressive form of hearing loss. Progressive hearing loss for which these children between 12 and 18 years could receive reimbursement for their contralateral CI is requested.
- If CI in children would be reimbursed for congenital SSD, and threshold levels decrease in congruence with the new criteria, this category would be obsolete.

Input for budget impact calculations

In the year 2018 20 out of 319 CIs were attested for asymmetric hearing loss (amongst which 10 in patients <8 yr and 10 in patients 8-12 yr). Note that this number can also include patients with asymmetrical hearing loss and threathening ossification as subcodes for ossification and neuropathy were created after 2018. With the lowering of threshold for bilateral hearing loss, this number of persons in this category is expected to diminish. No data are available on how many extra patients would be eligible when the criteria for asymmetric hearing loss would be relaxed.

8.4.3.2 Adaptation of the criteria based on threatening ossification

Input from the interviews

- During the expert meeting, the example was given of persons of any age that present with profound unilateral hearing loss because of meningitis with commencing fibrosis. The experts say that currently nothing is done with these patients except for letting them ossificate.

8.4.3.3 Adaptation of criteria for bilateral CI in auditory neuropathy and bilateral assymetrical ossification to include adults

Input from the interviews

- Currently bilateral CI in auditory neuropathy is only reimbursed in children and adolescents of maximum 18 years old. According to some ENT specialists, reimbursement of bilateral CI should also be possible in adults with auditory neuropathy, as this disease may as well develop later in life. It is seen in literature that auditory neuropathy is a term that is used for a wide array of different causes of sudden hearing loss. It is seen that CI is effective if the disorder is located at the synaptic -sensory part of the cochlea (which than is bypassed by the CI)(see figure in clinical part), but CI is less/not effective when auditory neuropathy is caused by lesions in other parts of the hearing pathway. Thus, in case it could be shown that (post)synaptic auditory neuropathy is present, CI will probably be effective and could be reimbursed in adults (bilateral).

- Some centres consider any change in the reimbursement criteria for auditory neuropathy as low priority as they have never encountered a patient in this situation.
- Based on future research, reimbursement criteria for auditory neuropathy could be reformulated based on the localisation of the lesion causing the hearing loss as this impacts CI performance.

Input from the clinical literature

- The 'hearing loss category' auditory neuropathy spectrum disorder is too heterogeneous to make definitive statements about outcomes with CI.
- A more nuanced perspective based on the site of lesion in order to estimate the effect of CI in auditory neuropathy (selection of poor and good performers) is needed especially in children and adults in whom auditory neuropathy occurs in the post-lingual period.

Input from the international comparison

In most countries analysed (France, the Netherlands, Germany, NHS England) reimbursement of CI does not depend on etiology and no specific exceptions are made for auditory neuropathy.

Budget implications

No data are available on the number of adults with auditory neuropathy that could benefit from a CI. In France, last year, there were 3 patients who received reimbursement.

8.4.3.4 Reimbursement of CI in a single ear in adults, regardless of whether it is the first or contralateral implanted ear

Input from the interviews

In the past there have been patients with bilateral hearing loss who paid for the first CI themselves as they preferred not to wait until they met the threshold for reimbursement. Years later now, these patients may have reached the threshold for reimbursement but they are still not eligible for reimbursement of CI on their second ear as it concerns the second implanted ear, not the first implanted ear and with strict application of the nomenclature, the criteria for the 'contralateral' ear are applicable, including the age limit of 12 year. The reimbursement should be applied no matter if the patient already has one implant (self-payed) or not.

Budget implications

No data are available on the number of persons in this situation.

8.4.3.5 Additional restriction for late (unilateral) implantation of prelingually deaf adults

Input from the interviews

Interviewed persons mention the problem of a small group of non-users. Prelingually deafened adults who get a CI do not always perform very well. Most implantees who are non-users are within this group. For instance, a deaf adult who communicates with sign language and knows little spoken language will not recognize the sounds, may get headache from the CI and eventually leave the sound processor off. A number of factors may help predict the outcome, like the level of language development and the level of lipreading (which also stimulates the auditory cortex, whereas sign language stimulates the visual cortex). In order to avoid non-users, patients have to be very carefully selected. Some teams seem to select well, but a nonselected patient may switch to another centre where patient selection is less stringent and get a CI anyway. These practices should be avoided. It concerns a small group. Note that the group of late implanted prelingually

deafened adults also will get smaller over time as more children got CI at early age since the start of reimbursement in Belgium in 1994.

Input from the international comparison

In France, guidelines state that there is in general no indication for first implantation in adults with prelingual deafness.

According to the German Weissbuch, postlingual patients, either deaf or with residual hearing, are as a rule eligible for CI. In prelingual deaf adults, however, only selected individual cases can be eligible for CI, when there are signs of loudspoken language acquisition.

In Switzerland, bilateral CI is not indicated in prelingual deaf adults.

8.4.4 Modification or elaboration of tests for CI

8.4.4.1 Inclusion of speech-in-noise and localisation test, if CI reimbursement would be extended

Input from the interviews

Current reimbursement thresholds for unilateral implantation in Belgium are set for tonal audiometry, speech-in-quiet and BERA test. For an optimal patient selection for bilateral implantation or implantation in single sided deafness, also tests would need to be done on speech perception in noise and localization of sound. Although there is no scientific consensus yet on which speech-in-noise and localisation test should be used, audiologists could propose one.

Input from the international comparison

There are only limited examples in other countries to learn from when it comes to speech-in-noise tests. In our analysed sample of countries, speech-in-noise tests have not found their way yet to the criteria for reimbursement or coverage. The 'Veldnorm' in the Netherlands does not include criteria on a speech-in-noise test, although Dutch centres in practice may use them for patient selection. In France, the reimbursement criteria formulated by HAS are based on a speech-in-quiet test. Also in the German Weissbuch criteria are based on a speech-in-quiet test. Similar for NHS England, where criteria stipulated by NICE do not include a speech-in-noise test. In Switzerland, the criteria for CI in SSD are based on a speech-in-noise test, but this is not the case for the criteria for CI in bilateral hearing loss.

The study of Vickers et al. (2016)[130] showed that speech-in-noise tests are nevertheless frequently used in the clinical evaluation of the patient by the centres: 41% of respondents use speech-in-noise tests (17% words in quiet and noise; 12% words and sentences in quiet and noise; 12% sentences in quiet and noise), the remaining respondents only use speech-in-quiet tests. The answers in the study of Vickers correspond to the patient clinical evaluation tests applied by the individual centres, not necessarily to the criteria as imposed by the reimbursement rules at country level.

8.4.5 Facilitation and quality-assurance of fitting and rehabilitation for CI

Input from the interviews

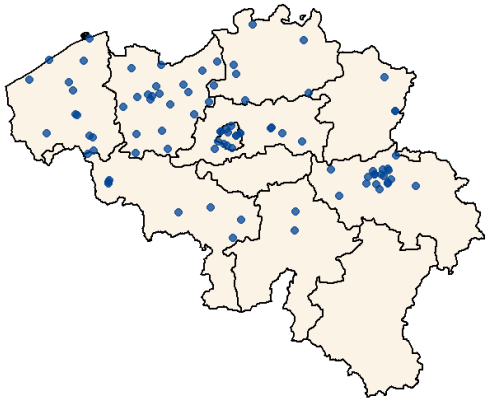
- Some CI-teams understand by rehabilitation only fitting of the device and not auditory training or multidisciplinary support. We have to define in detail what is meant by rehabilitation and we have to come to a 'standard of care for rehabilitation' (as we have a standard of care for selection of candidates, fitting, surgery, etc.). One limitation is that there are little clinical evidence studies (level 3 or higher) available on rehabilitation. This is confirmed by a French Guideline which states "There are at present no randomized studies with sufficient power demonstrating benefit for cognitive function with aural rehabilitation by cochlear implantation, but several longitudinal observational studies reported that hearing-impaired subjects showed better cognitive prognosis in case of hearing rehabilitation (level of evidence: 2)".[132] Currently, rehabilitation is based on evidence of good practice. More clinical studies (preferably RCTs) should be conducted on auditory training and multidisciplinary rehabilitation. But in reimbursement

criteria, the need for rehabilitation and its multidisciplinary character could be more highlighted.

- CI-teams and rehabilitation centres not only have to prove their quality on selection, surgery and fitting but also on rehabilitation.
- There should be an expantion of the budget available for rehabilitation in CI as it is very important for the whole CI implantation outcome.
- Currently there is no reimbursement for fitting or troubleshooting (cable problems, spare parts, etc.) and it is the goodwill and investment of the CI centres (for now). If it were small numbers, we were able to cover for the costs, but nowadays we opened 'a shop in repair' with fixed hours and this will only expand in the future. Spare materials cost a lot, and this is not only a problem that is experienced by CI centres but also by schools (audiologists in school settings who do troubelshooting on request of the patient, or other more local audiologists, etc.). They do not receive any financial input from the cochlear implants.
- Rehabilitation is mandatory irrespective of the first or second implant. It is also explicitly set in the legislation that the patient should be oriented towards rehabilitation and that this should be discussed with the patient before cochlear implantation. However, not all patients appear to be well informed about the rehabilitation before the implantation. According to some experts interviewed, at some centres the rehabilitation process should be more discussed with the patient beforehand and the patient's willingness should be better taken into account in the selection and preparation process.
- According to some experts interviewed, only few centres have real good knowledge on and the available resources to conduct auditory training and rehabiliation after CI and the expectations are sometimes set too low. Sometimes only fitting is considered, or training stops when the patient understands speech in the exercise sessions, but simply practising at a desk is not representative yet for the challenges in daily life, like listening in rumour, in meetings, or other situations at work or like using CI in combination with lipreading or other hearing aids. Functioning well in these types of settings requires more advanced auditory training. Further according to experts, speech therapists in other countries can be certified in auditory-verbal therapy. A quality label for speech therapists in Belgium who specialise in this domain would be useful.
- Following the reimbursement criteria, fitting of the CI and rehabilitation should be executed in a nursing unit with a specialised unit for ENT diseases that includes a multidisciplinary team with at least 1 FTE speech therapist, 1 FTE audiologist, and one FTE ENT or another specilized centre for ENT diseases that has a similar multidisciplinary team. Although the multidisciplinary aspect is highly supported by the experts, a more practical inconvenience is the accessibility of these centres since in some cases the patient has to travel long distances for the fitting of the device and rehabilitation (multiple times per week). There is an inequal distribution of (multidisciplinary) centres for ambulatory rehabilitation (CAR). In Flanders, for example, there are around 17 recognized CARs in two provinces (East and West Flanders), while in the province of Limburg you only have 2 centres, which takes some patients a ride of at least 40 minutes. Also in the other provinces there are less centres (Figure 24). To overcome the problem of accessibility towards fitting and rehabilitation some solutions could be listed:
    - One solution could be that in these regions with less opportunities for multidisciplinary rehabilitation, local certified speech therapists perform the rehabilitation of these CI patients (this is an option already outlined in the reimbursement criteria and the C-Form-I-01). Ideally, these speech therapists, should have a recognition or specific specialisation to be able to rehabilitate CI users. However, currently there is no such educational (post-graduate) course in Belgium. Although, in other countries (U.S.A., U.K., Australia, etc) there exist courses to become 'Auditory Verbal Therapist' and it is seen that more and more European countries evolve to this education as well.

- Another solution that could be looked at is the option of remote health care in audiologie i.e. fitting (tele-fitting) and remote rehabilitation (tele-rehabilitation and speech therapy) for CI-users.

Figure 24 – Distribution of centers for ambulatory revalidation in Belgium



- It is seen that when a patient receives a CI by an ENT working in a hospital that is easy to access by the patient (local), but without multidisciplinary rehabilitation and fitting centre attached, the patient sometimes has to travel far for the after-care, for which patients than drop-out (some local hospitals than work together with hospitals who have a recognized centre for rehab but this is not the closed by as such, it can be 50km further). Experts indicated that patients state that if they decide to go to a centre nearby for fitting (other than (adviced by) their implant centre), they are requested to pay about €50 to swap team. Also in practice it is seen that it is very difficult for a patient to go to another centre for fitting. For rehabilitation (auditory training), it is somewhat easier to switch, especially when the centre does not have a fitting team. The pain point is that people are usually not informed of this beforehand (this falls under the responsibility of the ENT specialist).
    - A solution can be found in setting up networks between hospitals and CAR centres.
- Another topic that was raised during the expert meeting (during the COVID-19 pandemic) is the topic of remote health care in audiology. I was questioned if some parts of selection, fitting and rehabilitation can be delivered remotely from a distance. The experts stated that a lot possibilities are discovered during this period, that have the potential to enhance accessibility (which is still a big issue), delivery of health care, and also help to reduce the costs. It is questioned if this topic could be more outlined and it is stated that research in the near future could be conducted to be able to perhaps reach reimbursement for these interventions in the future (as currently done for live consultation or therapy). In order to be able to provide some information on this specific question on tele-audiology, we performed a pragmatic quick search of available literature of which the results are outlined in Appendix 3.5:

What has been done in Belgium? Input from the experts.

- Teleconsultation is available and reimbursed for speech therapists.[138]
- During the COVID-19 period, tele-fitting was executed by some experts (especially in adults).
- The manufacturers of CI have software available for tele-fitting at a distance (however, at this moment, there is still a person available at the patient-side).
- Practically: it should be possible in the near future to conduct CI-fitting from the hospital side, while the patient goes to a local CAR (where someone experienced in fitting is available) where the fitting software is connected correctly to the CI. As such, live-fittings could be switched with tele-fittings.
- Tele-rehabilitation for audiologic training in Belgium is still in the pipeline. However, during that past months, telerehabilitation sessions were offered to CI users. Some limitations were seen such as obstructions in communication through videoconference. From the professionals side it all works fine, but from the CI-user side, extra

implementations are sometimes needed such as speech-to-text interpreting, or automated speech recognition systems.

- Parents of deaf children received tips and tricks through videoconference, in order to be able to guide their child better.
- In other countries (as also seen in literature especially in countries were large distances should be covered such as the USA), remote auditory training is already longer implemented and more often applied, especially when the speech therapists have an education as Auditory Verbal Therapist.

8.5 Conditions imposed to centres

8.5.1 Towards networking for quality assurance

Current regulation stipulates that the implantation of MEI and CI has to be done in a specialised unit for otolaryngology that has a multidisciplinary team with at least 1 FTE Ears-Nose-Throat (ENT) doctor, 1 FTE speech therapist and 1 FTE audicien/audiologist. This team is in charge of the clinical and audiometrical evaluation pre-implantation, the implantation, the adjustment of the aid and the audiological and medical follow-up. These services should provide assistance at all times.

Input from the interviews

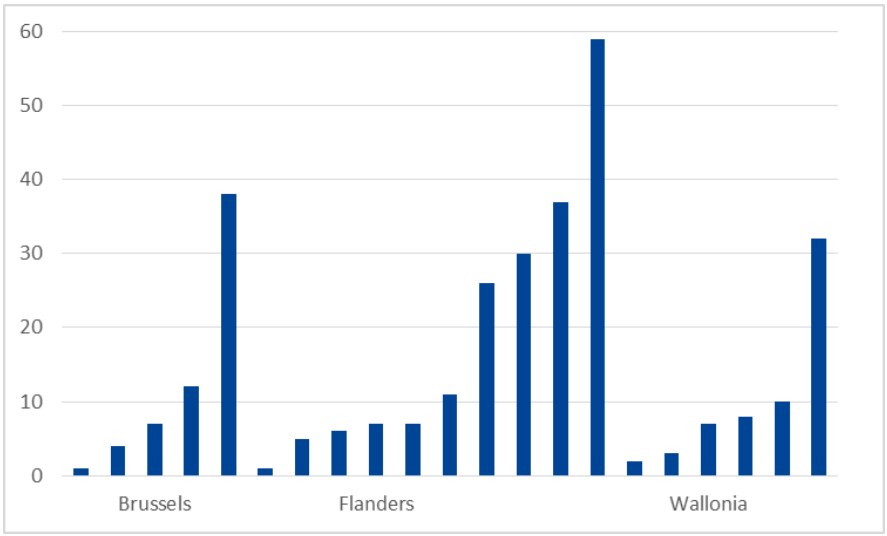
- In the Netherlands centres participate in a visitation and accreditation process, covering aspects such as the possibility to guarantee continuity of care, comprehensiveness and multidisciplinarity of the team, continuous training, research, as well as a minimum yearly volume. Experts generally agree that it is not the minimum volume as such that matters, but rather the full package of quality assurance.
- Considering CI, patient selection and counseling are of primordal importance, and should idealy be done by a multidisciplinary team consisting out of an audiologist, speech therapist, psychologist, ENT, social nurse, etc. Motivation and expectation of the patient should be evaluated and if needed adjusted. This is currently done in specialised centres for ambulatory rehabilitation (CAR), which work according the principle of best practices.
- Patients need to visit a centre for ambulatory rehabilitation once or twice a week. Accessibility and reachability of these centres for counseling, fitting, rehabilitation, etc. is therefore essential.
- Many experts argue for a limitation of the number of centres, some stating that 10 centres in theory would be sufficient for Belgium, while others argue for a sufficient amount of centres as to guarantee accessibility. Common ground amongst experts is that alternatives should be worked out for centres where only around 2 CIs are performed per year, as in this case it is hard to build up sufficient experience and to guarantee life-long follow-up for a patient at the implanting centre. Another point of agreement is that further proliferation of centres is not needed or desired. Rather than centralisation, networking is mostly regarded as the more viable option in the current setting, with referral patterns within the networks.
- Note that historically the criteria for CI were relatively strict in Belgium (cfr. Reimbursement ≥ 85 dB HL up until August 2019). Therefore, the amount of centres should be seen in this light and caution is warranted in making comparisons with e.g. The Netherlands.

Data on Belgian centres

Centres implanting CIs

- In 2018, 21 hospitals performed CI. The volume per hospital varied from minimum 1 to maximum 59. The average number of CIs was 15 and the median 7.
- With the relaxation of reimbursement criteria for CI in 2019, the volumes per centres are expected to increase considerably.

Figure 25 – Number of CIs by hospital in 2018

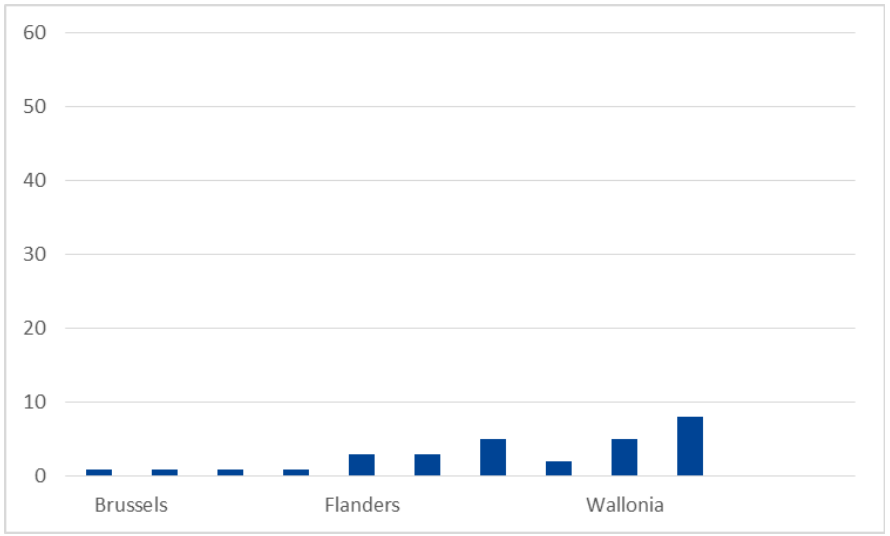


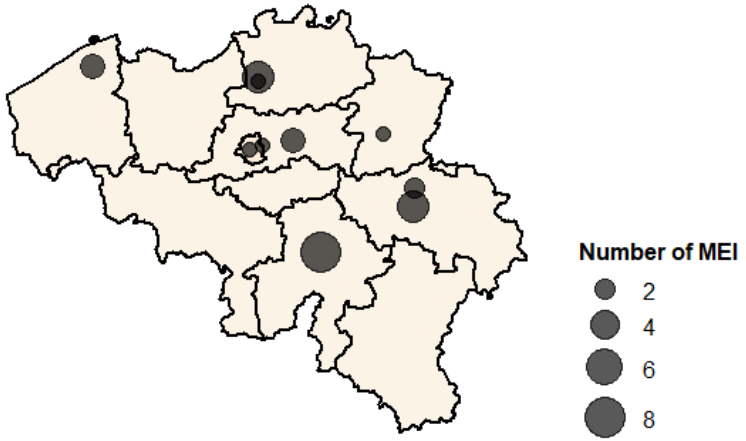


Centres implanting MEIs

10 hospitals performed MEI in 2018. The volume per hospital varied from1 to 8. The average and median number of implants was 3.

Figure 26 – Number of MEIs by hospital in 2018

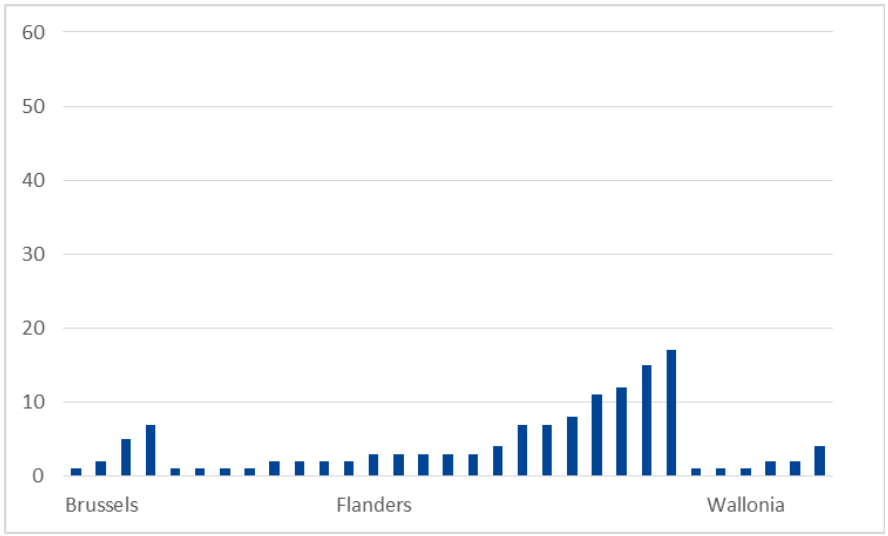


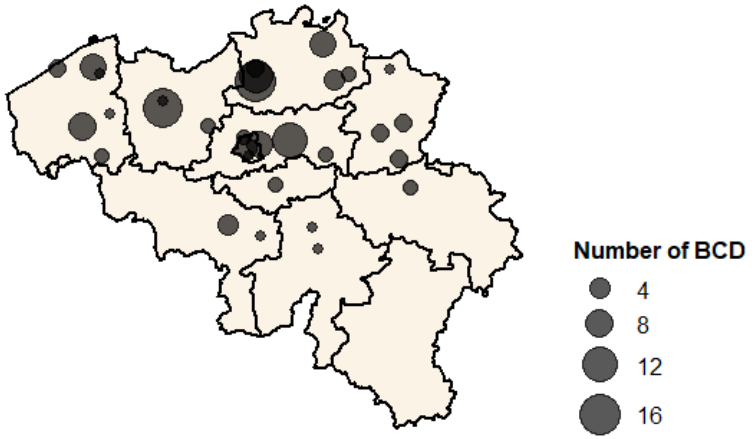


Centres implanting BCDs

31 hospitals performed BCDs in 2018. The volume per hospital varied from minimum 1 to maximum 17. The average number of implants was 4 and the median 3.

Figure 27 – Number of BCDs by hospital in 2018



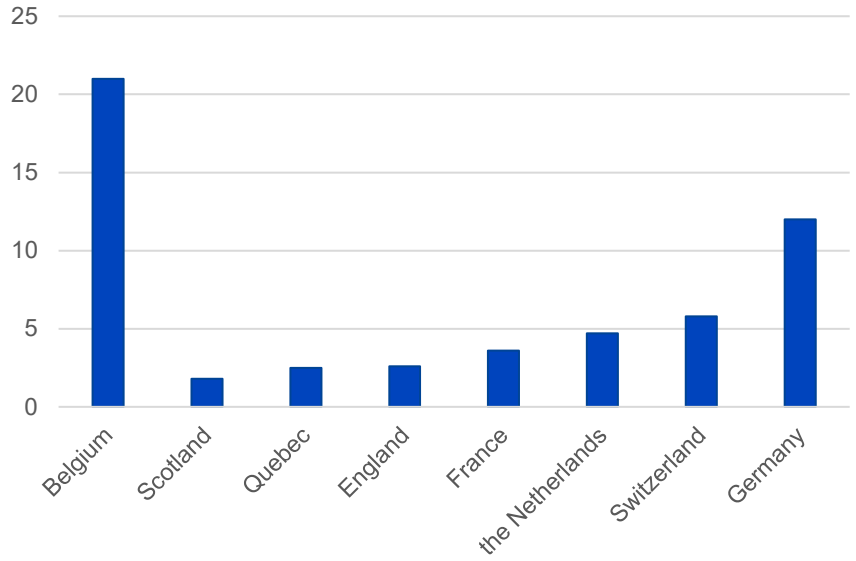


Data from the international comparison

Organisation of CI care

Figure 28 shows the number of CI centres per 10 million inhabitants in the analysed set of countries. With 24 centres performing CI in Belgium (21 per 10 million inhabitants), Belgium ranks highest. Germany follows Belgium but with a considerably lower rate of 12 centres per 10 million inhabitants. Further down the ranking are Switzerland with around 6 centres per 10 million inhabitants, the Netherlands with nearly 5 centres per 10 million inhabitants and France with less than 4 centres per 10 million inhabitants. At the bottom rank England, Quebec and Scotland with less than 3 centres per 10 million inhabitants.

Figure 28 – International comparison of number of CI centres per 10 million inhabitants



In terms of minimum volume of CIs per centre we observe the following:

- In France, conditions for minimal activity are imposed: centres for adults must have a forecasted yearly number of implantations > 20. Centres for children have a forecasted yearly number of implantations > 10. Centres for adults and children have a forecasted yearly number of implantations above 20, amongst which minimum 10 in children.
- In Germany, a minimum volume of examinations is imposed to implant CI: > 1000 examinations in routine audiometry; > 100 specialised audiology examinations (e.g. evaluation of CI indication). It may be considered best practice to determine minimum of patients that are examined, instead of minimum number of CIs, not to induce a risk of putting too many CIs.
- In the Netherlands, the lowest volume centre implanted 32 implants in 2017.
- In Spain, it is recommended in the guideline that a centre implants more than 30 CIs per year.
- In Quebec province of Canada, there is an average of about 125 implantations per centre.

Note that when comparing the minimum volume per centre internationally, we have to take into consideration that the criteria for reimbursement of CI also vary between countries.

By many interviewed experts, the Dutch Veldnorm is considered best practice. It details minimum requirements for CI teams, a list of quality indicators and provides a guide for the visitation and accreditation process of the CI centres. Every five years, a CI team gets visitation by a multidisciplinary commission. A new team has to get visitation as quick as possible and then after two years. According to the Veldnorm a CI team comprises minimum

- Two clinical physicist-audiologists with ample experience in audiology, conventional hearing rehabilitation and CI care
- Two ENT specialists with experience in CI
- One rehabilitation therapist
- One psychologist with experience in psychological consequences of hearing loss and deafness
- One speech therapist/hearing therapist
- One social worker
- One administrative worker
- One clinical linguist/speech pathologist or specialised speech therapist.

Every ENT specialist operates a minimum of 15 patients per year. The CI team actively participates in research which results in scientific publications and presentations at scientific meetings and congresses.

Also in Germany, a Weissbuch was drafted with guidelines for quality assurance of CI centres. Similarly for Spain a guideline was made.

Organisation of BCD care

According to the Dutch guideline on BCDs of 2018, patient care for BCD benefits from 'sufficient concentration'. Hospitals with only a few BCD patients per year and/or without multidisciplinary embeddedness provide less good perspectives. This holds all the more for BCD care in children and in mentally retarded. Children with microtia are by preference treated at a centre with specific expertise in microtia.

According to the Dutch guideline, other advantages of concentration are that

- it can lead to certain scale effects and more cost-effectiveness in purchasing and maintaining stock of materials and in organisation of consultation hours, hospitalisations and surgery centre.
- it can have advantages for evaluation of care and scientific research.

8.5.2 A Belgian or international registry for hearing implants?

Input from the interviews

- Many ENT specialists support the approach of France, the Netherlands and Switzerland, where all patients are kept in a mandatory registry and which also includes patient outcomes. Not only the number of cochlear implants in children and adults for the different hospitals is registered but also the number of re-implantations as well as other relevant outcomes. However, they also stress that mandatory registration requires funding. Specialists generally agree that registration, analysis and research is also what society expects, and in order to maintain transparency (some parts of the dataset) might be made publicly available (e.g. yearly report in Switzerland of all data on implantable devices). Centres have to look critically at their results, analyse them and preferably also publish on them.
- It is clear that voluntary registers will not work and thus financing would be mandatory.
- Some specialists mention the need for a national database with data on rare indications, like e.g. rare neuropathies, how the patient was treated and what were the results; such a 'library' could be very useful in the treatment of rare cases.

Input from the international comparison

Abroad, indeed successful examples of nationally based registries can be found in France and Switzerland. The Swiss registry includes all patients implanted since the first in 1977, over the 5 Swiss centres performing CI. Besides demographic data (gender and age of the patient) and etiology, subjective and objective evaluation scores (Speech recognition performance (V08; C12; Freiburger), categories of auditory performance (CAP), speech intelligibility rating (SIR), LittlEars Auditory Questionnaire) are captured in the registry. Outcomes are presented in publicaly available reports on regular basis.

According to the Dutch Veldnorm, CI teams keep track of patient data including complications. The CI teams have to register both "hard" and "soft failures" of implanted CIs.

8.5.3 Precise rules versus more flexibility in criteria? (a topic linked to organisation of care)

Input from the interviews

- Some ENT specialists call for more flexibility in reimbursement criteria for CI, as is the case for BCD. They refer to the way some other implants, like pacemakers, or hip prostheses, are reimbursed in Belgium, that is to say, when the implantation follows a medical decision, they are reimbursed. However, they acknowledge the fact that also other examples exist of procedures or implants, where reimbursement is restricted by rules.
- ENT specialists calling for more flexibility directly link it to a more centralised provision of care, where centres have to obtain accreditation, to the example of France or the Netherlands. In these

countries it are the heads of the centres that stipulate the centre guidelines within the boundaries of the national guidelines, and guard that they are followed in their centre.

- When more flexibility would imply volume limits, which is sometimes seen in other countries, then most interviewed specialists still prefer precise reimbursement rules.
- At the minimum, in order to avoid numerous applications to the Special Solidarity Fund, specialists would find it more practical to give the centres certain flexibility and a dedicated budget to perform a limited number exceptional interventions per year, so that they do not have to submit a request to the Special Solidarity Fund every time.
    - We retrieved data from the Special Solidarity Fund that 12 applications for cochlear implants were submitted in the year 2019, most of which pertained to contralateral implantation in deaf blind patients.

Input from the international comparison

- In the Netherlands, the clinical teams have flexibility to determine their criteria; however insurers agree with hospitals on the maximum number of CIs implanted per year. In function of the quotum, the hospital gets a budget and within the budget limits it gets the flexibility to decide on the patient selection. One of the consequences is that children get preference over adults, which has lead to waiting lists for adults, up to 11 months.
- In France, clinical teams also have certain flexibility in the interpretation of the criteria, like for bilateral implantation in adults (impact on social life and work, loss of autonomy, etc.). There are no volume limitations, the social security funds an unlimited amount of CIs. In an attempt to keep the budget within limits, for adult bilateral CI a price-volume agreement has been agreed with the manufacturers, as mentioned above.
- Also in Germany, clinical teams have flexibility in patient selection. The volume of CIs is uncapped, but not unlimited as the total budget of most hospitals is frozen.
- According to the international survey of Vickers et al. (2016) [130], besides Germany, also in Italy and Australia the clinical teams have considerable flexibility to determine if a patient is an appropriate candidate for CI.

8.6 Expansion of reimbursement – various options raised by the experts

8.6.1 Expansion of reimbursement for frequency modulation (FM) systems for unilateral hearing loss?

Input from the interviews

- Different options exist for supporting children with unilateral hearing loss. The children can for instance get preferential seating in the classroom. Another option is a frequency modulation system. With frequency modulation systems the teacher wears a microphone and the student wears a receiver. These FM systems are not reimbursed by RIZIV-INAMI, they are reimbursed by the federated instances for persons with a handicap[d], however as the latter only intervene when a person is recognised for having a handicap, they are in practice rarely reimbursed.

[d] Vlaams Agentschap voor Personen met een Handicap (VAPH), Agence Wallonne pour l'Intégration des Personnes Handicapées (AWIQ), Personne Handicapée Autonomie Recherchée" (PHARE), "Office pour une vie autodéterminée de la région germanophone" (OVA)

- Especially in SSD it was stated that children who have a normal mental capacity but suffer severe unilateral hearing loss, would have the same capabilities and develop in the same way as their normal hearing peers when they receive the correct support such as frequency modulation systems in classroom settings.

8.6.2 Creation of nomenclature for facialis monitoring?

Input from the interviews

- Some experts pointed to the lack of nomenclature for facialis monitoring, yet, facial nerve injury is one of the most severe complications of hear implant surgery. Moreover, a need for reimbursement of the navigation software (preparing images before surgery) is raised. Moreover, in future, more and more high technology monitoring will be applied with a kind of image monitoring before the surgery. This software is already reimbursed for sinus/nerve surgical procedures but not for hearing implantation.
- Also it was already suggested the revise nomenclature for (1) NIM facialis monitor in otological surgery and (2) neuronavigation supplement in rhinology and otology.
- Now new evidence can also be introduced to the commission by the sugraons and the scientific organisation can also file a demand to the commission to adapt the conditions for reimbursement.

8.6.3 Public availability of Bluetooth protocols

Input from the interviews

- It is requested by the audiologists (towards the manufacturers) if Bluetooth protocols can be made publicaly available. A user manual and special compatible device is needed to connect sound processors to BCDs or CIs or hearing aids with a divece through bluetooth to know how/what fits. If there is a renewal of a hearing aid/sound processor, we have to swap our procedures, and the device for compatibility should be bought (€50-450). If the protocols are made publically available (via smartphone, pc, etc.), and have direct connectivity, we do not need to buy expensive devices. To the VAPH, reimbursement can be requested (but not for patients over 65y).

8.6.4 Harmonization of payment for simultaneous as well as sequential cochlear implantation

Input from the interviews

- During the expert meeting, the remark was made that the surgery for simultaneous cochlear implantation is only payed half for the second CI. The surgery is executed under the same narcosis, but the patient is repositioned, other hygenic materials are implied, etc. In fact it are two similar (sequential) surgical procedures (twice the time, both the same complexity, etc.) executed at once under the same narcosis but material and resources costs are equivalent. It is requested to revise nomenclatur K500 to be able to apply it for each ear.

Input from the literature

Before, it was questioned if simultaneous cochlear implantation in children (and adults) was feasible and safe compared to sequential cochlear implantation. An overview of the available studies was made by Ngui et al. 2017[139] in which was found that bilateral simultaneous CI implantation is recommended in bilateral profoundly deafened paediactric and adult patients in order to obtain optimal hearing and speech outcomes. Also in more recent studies[140-142], better outcomes were seen with simultaneous cochlear implantation in a paediatric population and simultaneous implantation is even stated to be the gold standard.[140]

Data analysis

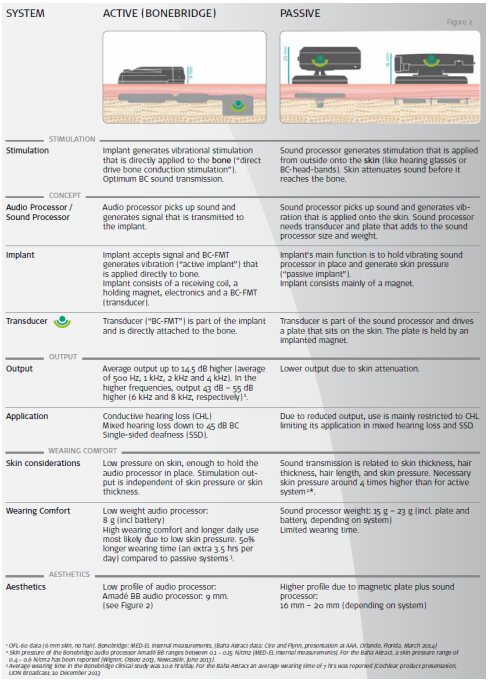
In 2018, for the sequential implantation of a CI the median honorarium of the ENT was € 1 191.45 € (34 deliveries) while for simultaneous implantation of a CI they received € 1 787.18€ (17 deliveries) which is a difference of € 595.72 if sequentially implanted.

APPENDICES

APPENDIX 1. APPENDIX TO THE CLINICAL BACKGROUND

Appendix 1.1. Difference between an active transcutaneous BCD (Bonebridge) and a passive transcutaneous BCD

Figure 29 – Active transcuteaneous BCD (Bonebridge) versus passive transcutaneous BCD



SYSTEM	ACTIVE (BONEBRIDGE)	PASSIVE
STIMULATION		
Stimulation	Implant generates vibrational stimulation that is directly applied to the **bone** (“direct drive bone conduction stimulation”). Optimum BC sound transmission.	Sound processor generates stimulation that is applied from outside onto the **skin** (like hearing glasses or BC-head-bands). Skin attenuates sound before it reaches the bone.
CONCEPT		
Audio Processor / Sound Processor	Audio processor picks up sound and generates signal that is transmitted to the implant.	Sound processor picks up sound and generates vibration that is applied onto the skin. Sound processor needs transducer and plate that adds to the sound processor size and weight.
Implant	Implant accepts signal and BC-FMT generates vibration (“active implant”) that is applied directly to bone. Implant consists of a receiving coil, a holding magnet, electronics and a BC-FMT (transducer).	Implant’s main function is to hold vibrating sound processor in place and generate skin pressure (“passive implant”). Implant consists mainly of a magnet.
Transducer	Transducer (“BC-FMT”) is part of the implant and is directly attached to the bone.	Transducer is part of the sound processor and drives a plate that sits on the skin. The plate is held by an implanted magnet.
OUTPUT		
Output	Average output up to 14.5 dB higher (average of 500 Hz, 1 kHz, 2 kHz and 4 kHz). In the higher frequencies, output 43 dB – 55 dB higher (6 kHz and 8 kHz, respectively)[1].	Lower output due to skin attenuation.
Application	Conductive hearing loss (CHL) Mixed hearing loss down to 45 dB BC Single-sided deafness (SSD).	Due to reduced output, use is mainly restricted to CHL limiting its application in mixed hearing loss and SSD.
WEARING COMFORT		
Skin considerations	Low pressure on skin, enough to hold the audio processor in place. Stimulation output is independent of skin pressure or skin thickness.	Sound transmission is related to skin thickness, hair thickness, hair length, and skin pressure. Necessary skin pressure around 4 times higher than for active system[2,3].
Wearing Comfort	Low weight audio processor: 8 g (incl battery) High wearing comfort and longer daily use most likely due to low skin pressure. 50% longer wearing time (an extra 3.5 hrs per day) compared to passive systems[3].	Sound processor weight: 15 g – 23 g (incl. plate and battery, depending on system) Limited wearing time.
AESTHETICS		
Aesthetics	Low profile of audio processor: Amadé BB audio processor: 9 mm. (see Figure 2)	Higher profile due to magnetic plate plus sound processor: 16 mm – 20 mm (depending on system)

[1] CHL 60 data (4 mm slits, no hair), Bonebridge: MED-EL internal measurements, (Baha Attract data: Cro and Flynn, presentation at AAA, Orlando, Florida, March 2014)
[2] Skin pressure of the Bonebridge audio processor Amadé BB ranges between 0.1 – 0.25 N/cm2 (MED-EL internal measurements). For the Baha Attract, a skin pressure range of 0.4 – 0.6 N/cm2 has been reported (Mojrzik, Closs 2015, Newcastle, June 2015)
[3] Average wearing time in the Bonebridge clinical study was 10.6 hr/day. For the Baha Attract an average wearing time of 7 hrs was reported (Cochlear product presentation, LION Broadcast, 10 December 2015)

Source: MED-EL

APPENDIX 2. APPENDIX TO THE REIMBURSEMENT

Appendix 2.1. Hearing aids and non-implantable part of bone conduction devices

Table 58 - Reimbursed hearing aids and BCD (non-implantable part) by brand and supplier in Belgium

Brand	Supplier	Minimum characteristics for digital hearing aids	Superpower ≥ 80dB	BCD
Audina	Kuulo	X		
Audika (oticon)	Prodition Audmet B.V.	X		
Audio Service	Sivantos B.V. Biotone Technologie SAS Omikron Hearing SA Audi Partner SARL	X	X	
Beltone	GN Hearing Benelux B.V.	X		
Bernafon	Audmet B.V. Prodition Omikron Hearing SA	X	X	
BHM	Kuulo	X	X	X
Bruckhoff	Veranneman			X
Cochlear	Cochlear Europe Ltd			X
Hansaton	Hoortoestel Benelux Kuulo	X	X	
Interton	Kuulo	X	X	
Lapperre (Phonak)	Sonova Belgium N.V.	X	X	
MED-EL	MED-EL BE			X
Microson	Hoortoestel Benelux	X		
NovaSense (oticon)	Audmet B.V.	X	X	
NovaSense (unitron)	Sonova Belgium N.V.	X	X	

Oticon	Audmet B.V. Prodition AGC Audio	X	X	
Oticon Medical	Audmet B.V. Prodition	X		X
Otomag™	Medtronic N.V.			X
Phonak	Sonova Belgium N.V. AGC Audio	X	X	
Resound	GN Hearing Benelux B.V. GN Hearing SAS	X	X	
Siemens	Veranneman Sivantos B.V. AGC Audio	X	X	
Sebotek	Kuulo	X		
Selectic (oticon)	Audmet B.V.	X		
Selectic (phonak)	Sonova Belgium N.V.	X		
Siemens (signia)	Veranneman	X	X	
Signia	Sivantos B.V. AGC Audio Veranneman	X	X	
Sonic	Audmet B.V. Prodition	X		
Starkey	Kuulo Starkey France SARL Kind Horen	X	X	
Unitron	Sonova Belgium N.V.	X	X	
Vista (Unitron)	Sonova Belgium N.V.	X	X	
Widex	Veranneman AGC Audio	X	X	

Source: RIZIV/INAMI[26]

APPENDIX 3. APPENDIX TO THE CLINICAL REVIEW

Appendix 3.1. Search for Systematic Reviews

Appendix 3.1.1. Search strategy and results for Cochrane

Date	10 Sep 2019	
Database	Cochrane@Wiley.com	
Search strategy		
#1	[mh ^"hearing aids"]	251
#2	[mh "Neural Prostheses"]	148
#3	[mh ^"cochlear implantation"]	81
#4	[mh ^"Auditory Brain Stem Implantation"]	0
#5	#1 or #2 or #3 or #4	416
#6	(auditory NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	922
#7	(auditive NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	3
#8	(cochlear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	484
#9	(middle-ear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	47
#10	(brain-stem NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	21
#11	(otorhinolaryngology NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	43
#12	(ear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	389
#13	(hearing NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	962
#14	ear mold?:ab,ti,kw	11
#15	("bone conducti*" NEAR/3 device?):ab,ti,kw	0
#16	(implant* NEAR/3 neuroprosthes*):ab,ti,kw	4
#17	(neural NEAR/3 prosthes*):ab,ti,kw	9
#18	((BAHA or BAHAs or BAHS or BAHSs or BAHI or BAHIs or BAHD or BAHDs or BCHI or BCHIs) NEAR/5 (cochlea* or implant* or device* or system*1)):ab,ti,kw	20

#19	((Ponto or Carina or Sophono) NEAR/5 (cochlea* or implant* or device*)):ab,ti,kw	9
#20	(Bonebridge* or Soundbridge*):ab,ti,kw	11
#21	softband:ab,ti,kw	4
#22	#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21	2410
#23	#5 or #22	2410
#24	[mh "Hearing Disorders"]	1703
#25	(hearing NEAR/3 disorder?):ab,ti,kw	366
#26	dysac?usis:ab,ti,kw	3
#27	(distorted NEAR/3 hearing):ab,ti,kw	1
#28	parac?usis:ab,ti,kw	0
#29	tinnitus:ab,ti,kw	2233
#30	hypoacus*:ab,ti,kw	28
#31	(hearing NEAR/2 loss):ab,ti,kw	2355
#32	(hearing NEAR/2 impairment):ab,ti,kw	1227
#33	deafness:ab,ti,kw	994
#34	deaf?mutism:ab,ti,kw	0
#35	#25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34	5573
#36	#24 or #35	5597
#37	[mh ^"Bone-Anchored Prosthesis"]	3
#38	[mh ^"Prostheses and Implants"]	595
#39	[mh ^"Electrodes, Implanted"]	384
#40	[mh ^"Implantable Neurostimulators"]	30
#41	[mh ^"ossicular prosthesis"]	24
#42	#37 or #38 or #39 or #40 or #41	1029
#43	implant*:ab,ti,kw	33302
#44	prosthes*:ab,ti,kw	12508
#45	porp:ab,ti,kw	5

#46	torp:ab,ti,kw	12
#47	electrodes:ab,ti,kw	3330
#48	(ossicular NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	37
#49	(bone-anchored NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti,kw	58
#50	#43 or #44 or #45 or #46 or #47 or #48 or #49	42248
#51	#42 or #50	42248
#52	#36 and #51	461
#53	#23 or #52	2474
#54	[mh ^"bone conduction"]	59
#55	[mh ^"Osseointegration"]	344
#56	#54 or #55	397
#57	(bone* NEAR/3 (conduct* or anchor* or integrat*)):ab,ti,kw	415
#58	(osseointegrat* or osseo integrat*):ab,ti,kw	623
#59	#57 or #58	1007
#60	#56 or #59	1007
#61	#51 and #60	733
#62	#36 and #61	60
#63	#53 or #62	2474
#64	#63 with Cochrane Library publication date Between Jan 2014 and Jan 2019	1104
Comments	Cochrane Database of Systematic Reviews **19**	

Appendix 3.1.2. Search strategy and results for Embase

Date	10 Sep 2019	
Database	Embase.com	
Search strategy		
#1	'hearing aid'/exp	27119
#2	'neuroprosthesis'/exp	15879
#3	'cochlear implantation'/de	3133
#4	'auditory brain stem implantation'/de	69
#5	#1 OR #2 OR #3 OR #4	29843
#6	(auditory NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	7616
#7	(auditive NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	50
#8	(cochlear NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	16803
#9	('middle ear' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	1270
#10	('brain stem' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	768
#11	(otorhinolaryngology NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	60
#12	(ear NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	5314
#13	(hearing NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	16034
#14	'ear mold$':ab,ti,kw	75
#15	('bone conducti*' NEAR/3 device$):ab,ti,kw	235
#16	(implant* NEAR/3 neuroprosthes*):ab,ti,kw	169
#17	(neural NEAR/3 prosthes*):ab,ti,kw	836
#18	((baha OR bahas OR bahs OR bahss OR bahi OR bahis OR bahd OR bahds OR bchi OR bchis) NEAR/5 (cochlea* OR implant* OR device* OR system*)):ab,ti,kw	390
#19	((ponto OR carina OR sophono) NEAR/5 (cochlea* OR implant* OR device*)):ab,ti,kw	100

#20	bonebridge*:ab,ti,kw OR soundbridge*:ab,ti,kw	378
#21	softband:ab,ti,kw	48
#22	#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21	36438
#23	#5 OR #22	42637
#24	'hearing disorder'/exp	151945
#25	(hearing NEAR/3 disorder$):ab,ti,kw	3686
#26	dysac$usis:ab,ti,kw	55
#27	(distorted NEAR/3 hearing):ab,ti,kw	12
#28	parac$usis:ab,ti,kw	15
#29	tinnitus:ab,ti,kw	14163
#30	hypoacus*:ab,ti,kw	1095
#31	(hearing NEAR/2 loss):ab,ti,kw	55698
#32	(hearing NEAR/2 impairment):ab,ti,kw	11893
#33	deafness:ab,ti,kw	26258
#34	deaf$mutism:ab,ti,kw	39
#35	#25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34	91795
#36	#24 OR #35	167737
#37	'prostheses and orthoses'/de	16082
#38	'electrode implant'/de	2522
#39	'implantable neurostimulator'/de	678
#40	'middle ear prosthesis'/exp	926
#41	#37 OR #38 OR #39 OR #40	20105
#42	implant*:ab,ti,kw	523834
#43	prosthes*:ab,ti,kw	102604
#44	porp:ab,ti,kw	230
#45	torp:ab,ti,kw	282

#46	electrodes:ab,ti,kw	85249
#47	(ossicular NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	763
#48	('bone anchored' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	994
#49	#42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48	655266
#50	#41 OR #49	663555
#51	#36 AND #50	14135
#52	#23 OR #51	44192
#53	'bone conduction'/de	5095
#54	'osseointegration'/de	1803
#55	#53 OR #54	6865
#56	(bone* NEAR/3 (conduct* OR anchor* OR integrat*)):ab,ti,kw	8388
#57	(osseointegrat*:ab,ti,kw OR osseo:ab,ti,kw) AND integrat*:ab,ti,kw	1155
#58	#56 OR #57	9223
#59	#55 OR #58	13452
#60	#50 AND #59	6492
#61	#36 AND #60	1110
#62	#52 OR #61	43648
#63	#62 AND [2014-2019]/py	12832
#64	#63 NOT [medline]/lim	3867
#65	#64 NOT ('conference abstract'/it OR 'conference paper'/it OR 'conference review'/it)	1846
#66	'meta-analysis'/exp OR 'meta-analysis' OR 'systematic review'/exp OR 'systematic review'	410043
#67	#65 AND #66	**54**
#68	'clinical pathway'/exp	8114
#69	'clinical protocol'/exp	94969
#70	'consensus'/exp	63324

#71	'consensus development'/exp	23459
#72	'practice guideline'/exp	510591
#73	'position statement':ab,ti OR 'position statements':ab,ti OR 'policy statement':ab,ti OR 'policy statements':ab,ti OR 'practice parameter':ab,ti OR 'practice parameters':ab,ti OR 'best practice':ab,ti OR 'best practices':ab,ti	42955
#74	standards:ti OR guideline:ti OR guidelines:ti	122711
#75	((practice OR treatment* OR clinical) NEAR/5 guideline*):ab	99105
#76	consensus*:ti OR cpg:ti OR cpgs:ti	33903
#77	((critical OR clinical OR practice) NEAR/2 (path OR paths OR pathway OR pathways OR protocol*)):ab,ti	28390
#78	recommendat*:ti	45927
#79	(care NEAR/2 (standard OR path OR paths OR pathway OR pathways OR map OR maps OR plan OR plans)):ab,ti	92977
#80	(algorithm* NEAR/2 (screening OR examination OR test OR tested OR testing OR assessment* OR diagnosis OR diagnoses OR diagnosed OR diagnosing)):ab,ti	9559
#81	(algorithm* NEAR/2 (pharmacotherap* OR chemotherap* OR chemotreatment* OR therap* OR treatment* OR intervention*)):ab,ti	13354
#82	#68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77 OR #78 OR #79 OR #80 OR #81	854015
#83	#65 AND #82	87
#84	#83 NOT #67	**78**
Comments	SR exported from line #67 Guidelines exported from line #84	

Appendix 3.1.3. Search strategy and results for Medline (Ovid)

Date	10 Sep 2019	
Database	Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to September 09, 2019>	
Search strategy		
1	hearing aids/	8338
2	exp Neural Prostheses/	9997
3	cochlear implantation/	6168
4	Auditory Brain Stem Implantation/	111
5	1 or 2 or 3 or 4	20134
6	(auditory adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	5816
7	(auditive adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	24
8	(cochlear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	14544
9	(middle-ear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	1035
10	(brain-stem adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	588
11	(otorhinolaryngology adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	46
12	(ear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	4340
13	(hearing adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	12929
14	ear mold?.ab,ti,kf.	63
15	("bone conducti*" adj3 device?).ab,ti,kf.	198
16	(implant* adj3 neuroprosthes*).ab,ti,kf.	129
17	(neural adj3 prosthes*).ab,ti,kf.	581
18	((BAHA or BAHAs or BAHS or BAHSs or BAHI or BAHIs or BAHD or BAHDs or BCHI or BCHIs) adj5 (cochlea* or implant* or device* or system*1)).ti,ab,kf.	313
19	((Ponto or Carina or Sophono) adj5 (cochlea* or implant* or device*)).ti,ab,kf.	72
20	(Bonebridge* or Soundbridge*).ti,ab,kf.	305
21	softband.ab,ti,kf.	40
22	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	30575

23	5 or 22	33551
24	exp Hearing Disorders/	84075
25	(hearing adj3 disorder?).ab,ti,kf.	4439
26	dysac?usis.ab,ti,kf.	44
27	(distorted adj3 hearing).ab,ti,kf.	8
28	parac?usis.ab,ti,kf.	15
29	tinnitus.ab,ti,kf.	11032
30	hypoacus*.ab,ti,kf.	756
31	(hearing adj2 loss).ab,ti,kf.	44504
32	(hearing adj2 impairment).ab,ti,kf.	9091
33	deafness.ab,ti,kf.	21741
34	deaf?mutism.ab,ti,kf.	32
35	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	74987
36	24 or 35	109041
37	Bone-Anchored Prosthesis/	55
38	"Prostheses and Implants"/	44891
39	Electrodes, Implanted/	19444
40	Implantable Neurostimulators/	522
41	ossicular prosthesis/	1444
42	37 or 38 or 39 or 40 or 41	65771
43	implant*.ab,ti,kf.	382800
44	prosthes*.ab,ti,kf.	83424
45	porp.ab,ti,kf.	198
46	torp.ab,ti,kf.	214
47	electrodes.ab,ti,kf.	75032
48	(ossicular adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	622
49	(bone-anchored adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf.	874

50	43 or 44 or 45 or 46 or 47 or 48 or 49	499222
51	42 or 50	525372
52	36 and 51	12469
53	23 or 52	34772
54	bone conduction/	3213
55	Osseointegration/	9596
56	54 or 55	12721
57	(bone* adj3 (conduct* or anchor* or integrat*)).ti,ab,kf.	6825
58	(osseointegrat* or osseo integrat*).ti,ab,kf.	9405
59	57 or 58	15629
60	56 or 59	21931
61	51 and 60	15289
62	36 and 61	1132
63	53 or 62	34772
64	limit 63 to yr="2014-2019"	9854
65	('systematic review'.ti. or 'meta-analysis'.pt. or 'meta-analysis'.ti. or 'systematic literature review'.ti. or 'this systematic review'.tw. or 'pooling project'.tw. or ('systematic review'.ab,ti. and review.pt.) or 'meta synthesis'.ti. or 'meta synthesis'.ti. or 'integrative review'.tw. or 'integrative research review'.tw. or 'rapid review'.tw. or 'consensus development conference'.pt. or 'practice guideline'.pt. or 'drug class reviews'.ti. or 'cochrane database syst rev'.ja. or 'acp journal club'.ja. or 'health technol assess'.ja. or 'evid rep technol assess summ'.ja. or 'jbi database system rev implement rep'.ja. or ('clinical guideline' and management).tw. or (('evidence based'.ti. or evidence-based medicine/ or 'best practice'.ti. or 'best practices'.ti. or 'evidence synthesis'.ab,ti.) and (((review.pt. or diseases category/ or behavior.mp.) and behavior mechanisms/) or therapeutics/ or 'evaluation studies'.pt. or 'validation studies'.pt. or guideline.pt. or pmcbook.mp.)) or ((systematic or systematically or critical or 'study selection' or ((predetermined or inclusion) and criteri*) or 'exclusion criteri*' or 'main outcome measures' or 'standard of care' or 'standards of care').tw. and ((survey or surveys or overview* or review or reviews or search* or handsearch).tw. or analysis.ti. or critique.ab,ti. or appraisal.tw. or (reduction.tw. and (risk/ or risk.tw.) and (death or recurrence).mp.)) and ((literature or articles or publications or publication or bibliography or bibliographies or published or pooled data or unpublished or citation or citations or database or internet or textbooks or references or scales or papers or datasets or trials or meta-analy* or (clinical and studies)).tw. or treatment outcome/ or 'treatment outcome'.tw. or pmcbook.mp.))) not (letter or 'newspaper article').pt.	365045
66	64 and 65	**359**

67	exp clinical pathway/	6380
68	exp clinical protocol/	161350
69	exp consensus/	11185
70	exp consensus development conference/	11547
71	exp consensus development conferences as topic/	2737
72	critical pathways/	6380
73	exp guideline/	32465
74	guidelines as topic/	38405
75	exp practice guideline/	25630
76	practice guidelines as topic/	111835
77	health planning guidelines/	4043
78	(guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.	41516
79	(position statement* or policy statement* or practice parameter* or best practice*).ti,ab,kf,kw.	30171
80	(standards or guideline or guidelines).ti,kf,kw.	103640
81	((practice or treatment* or clinical) adj guideline*).ab.	37005
82	(CPG or CPGs).ti.	5516
83	consensus*.ti,kf,kw.	24099
84	consensus*.ab. /freq=2	23354
85	((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol*)).ti,ab,kf,kw.	18857
86	recommendat*.ti,kf,kw.	38314
87	(care adj2 (standard or path or paths or pathway or pathways or map or maps or plan or plans)).ti,ab,kf,kw.	53595
88	(algorithm* adj2 (screening or examination or test or tested or testing or assessment* or diagnosis or diagnoses or diagnosed or diagnosing)).ti,ab,kf,kw.	7024
89	(algorithm* adj2 (pharmacotherap* or chemotherap* or chemotreatment* or therap* or treatment* or intervention*)).ti,ab,kf,kw.	9105
90	or/67-89	580843
91	64 and 90	239

92	91 not 66	**209**
Comments	**SR exported from line 66** Guidelines exported from line 92	

Appendix 3.2. Description of the retrieved articles

Table 59 – Description of the Objectives, Methods, Search Results, Quality Assessment, and Conclusions of the Articles Included in the Clinical Evidence Review

Author, year	Objective(s)	N (Databases); Search period; Included articles (n)	Quality assessment: result	Conclusion(s)
Appachi et al., 2017[34]	SR to characterize auditory outcomes of hearing rehabilitation options in children with unilateral HL.	5 (Pubmed, Embase, Medline, CINAHL, Cochrane); up until 4/1/2016; 20	RoB Newcastle Ottawa Scale: 4.9 = moderate	Data evaluating functional and objective auditory outcomes following hearing amplification in children with unilateral HL are limited. However, most of the studies reviewed suggest improvement in these measures with bone conduction hearing devices in the setting of moderate to profound unilateral HL. No conclusion can be drawn on the benefit of CROS hearing aids. In patients with mild to moderate unilateral HL, frequency modulation systems seem to benefit children in the educational setting. Although evidence is limited, conventional hearing aids also seem to benefit these children, and further studies are needed to elucidate this benefit.
Bezdjian et al., 2017[65]	SR to delineate the Sophono device's functional improvement and perioperative outcomes.	2 (Pubmed, Embase); 1975-8/2016; 8	Critical appraisal checklist (DoE & RoB): exclusion of 5 articles based on high RoB. Included articles: low-moderate RoB & high DoE.	The Sophono™ transcutaneous bone conduction device shows promising functional improvement, no intra-operative complications and minor post-operative skin related complications. If suitable, the device could be a proposed solution for the rehabilitation of hearing in children meeting eligibility criteria. A wearing schedule must be implemented in order to reduce magnet-related skin complications.
Blasco & Redleaf, 2014[44]	Review of the available literature to understand if CI in unilateral sudden deafness improves tinnitus, sound localization, and speech comprehension.	3 (Medline, Embase, Cochrane); up until 6/2013; 9	None reported	CI in sudden SSD with a normal functioning contralateral ear might prove to be an effective therapy. Tinnitus is reduced as is the signal-to-noise ratio, which still allows 50% speech discrimination. All patients felt that they localized sound better, and most

				felt that they understood speech better. Further studies should be conducted to compare the success of hearing rehabilitation of cochlear rehabilitation and traditional modalities such as contralateral routing of signal and bone-anchored hearing aids.
Bruchhage et al., 2017[56]	SR of the safety, efficacy/effectiveness and cost-effectiveness, as well as patient satisfaction of the Vibrant Soundbridge (active MEI) in SNHL.	5 (Cochrane, Medline, Embase, CRD, TRIP); up until 12/2012; 24	Checklist from the Evidence Analysis Library, Academy of Nutrition and Dietetics. Oxford Centre for Evidence-Based Medicine (CEBM): level IV (n=14), level III (n=9)	The VSB turns out to be a highly reliable device which significantly improves perception of speech in noisy situations with a high sound quality and can be a safe tool in surgically experienced hands. Nonetheless, more standard operating procedures to compare functional outcomes or measure subjective qualities of VSB device performance are necessary to increase the validity of measured data.
Cabral et al., 2016[47]	To analyse the influence of CI in patients with SSD with regards to sound localization, speech perception, tinnitus and, quality of life.	4 (Pubmed, Embase, Cochrane, Lilacs); up until 2/2015; 11	None reported; CEBM: level IV (n=2), level II (n=9)	Although some studies have shown encouraging results on CI and SSD, all fail to provide a high-level of evidence. Larger studies are necessary to define the tangible benefits of CI in SSD.
Cooper et al., 2017[37]	SR on currently available passive transcutaneous bone conduction hearing implants with regard to complications audiological outcomes, and quality of life scores.	4 (Medline, Embase, Scopus, Cochrane); up until 4/2017; 26	None reported	Passive transcutaneous BCDs are a viable alternative to percutaneous devices in a carefully selected group of patients. These devices have demonstrated good audiological outcomes, low morbidity, and high patient satisfaction.
Dimitriadis et al., 2016[66]	SR of the indications, surgical techniques, and audiological, clinical and functional outcomes of the BAHA attract device.	4 (Pubmed, Scopus, Cochrane, Google scolar); not reported but exclusion of articles published before 2013 (commercialisation of BAHA attract); 10	None reported	The functional and audiological results presented so far in the literature have been satisfactory and the complication rate is low compared to the skin penetrating BCDs. Further robust trials will be needed to study the long-term outcomes and any adverse effects.
Ernst et al., 2016[57]	SR (and meta-analysis) of the safety and effectiveness of the Vibrant Soundbridge (VSB) in comparison to no intervention, BCDs, and middle ear surgery plus hearing aids for adults and children with CHL or MHL.	5 (Pubmed, Medline, Embase, CRD, Cochrane); 1/2006-4/2014 (articles on VSB & Bonebridge); 36	CEBM: level IV (n=18), level III (n=11), level II (n=1) Checklist from the Evidence Analysis Library, Academy of Nutrition and Dietetics.	As demonstrated in the literature, the VSB as an active device offers an effective alternative for patients with various middle ear pathologies, particularly with MHL and failed previous tympanoplasties when classical ossiculoplasty could not provide enough functional gain. This new strategy in hearing rehabilitation has led to an improved quality of hearing and life.

Health Quality Ontario 2018[68]	HTA evaluating the potential benefits and harms of having cochlear implants in both ears (bilateral cochlear implantation) as opposed to unilateral cochlear implantation (SR).	7 (Medline, Embase, Cochrane central register of controlled trials, Cochrane database of systematic reviews, CRD HTA, NHS EED, DARE); up until 3/2017	Cochrane risk-of-bias tool for RCT and the ROBINS-I for non-randomized studies GRADE	Based on evidence of moderate-high quality, we found that bilateral cochlear implantation improved hearing in adults and children with severe-profound sensorineural hearing loss.
Health Quality Ontario 2020[6]	HTA on safety and effectiveness of implantable devices for single sided deafness and conductive or mixed hearing loss (review of reviews).	5 (Medline, Embase, Cochrane database for systematic reviews, HTA database, NHS EED); up until 1/2018	ROBIS: moderate GRADE	Based on evidence of moderate quality, cochlear implantation and bone conduction implants improve functional and patient-important outcomes in adults and children with single sided deafness and conductive or mixed hearing loss.
Kahue et al., 2014[58]	SR of the safety and efficacy of the 3 FDA approved MEI systems currently in use for SNHL.	2 (Medline, Cochrane); not reported; 17	CEBM	The majority of studies evaluating the safety and efficacy of MEIs are retrospective in nature with limited follow-up. To date, no prospective randomized controlled trial exists comparing contemporary air conduction hearing aid performance and MEI outcomes. Based on available data for patients with SNHL, functional gain and word recognition improvement seems similar between CHAs and MEIs, whereas patient-perceived outcome measures suggest that MEIs provide enhanced sound quality and eliminate occlusion effect.
Kim et al., 2017[38]	SR of the efficacy towards speech recognition in noise, sound localization, and some subjective outcomes, of bone-anchored hearing aids (BAHAs) in SSD.	3 (Cochrane, Medline, Embase); up until 8/2015; 14	Scottish Intercollegiate Guidelines Network (SIGN) checklist	This SR has indicated that BAHAs may successfully rehabilitate patients with SSD by alleviating the hearing handicap to a certain degree, which could improve patients' quality of life. This report has presented additional evidence of effective auditory rehabilitation for SSD and will be helpful to clinicians counselling patients regarding treatment options for SSD.
Kitterick et al., 2015[39]	SR (and meta-analysis) examining the impact of hearing-assistive devices on the health-related QOL of adults with SSD as measured using generic and disease-specific instruments.	5 (Pubmed, Embase, Medline, Cochrane, DARE); up until 26/2/2014; 20	CEBM: IV (n=21), IIIb (n=2), Ib (n=1)	A synthesis of the current evidence for the impact of hearing assistive devices on HRQoL in adults with SSD suggests that, when measured using disease-specific instruments, the average effect of ACDs on HRQoL is small and BCDs have a medium effect. CIs are associated with a larger effect size, but one which should be considered a medium effect due to being derived from within-subject comparisons of HRQoL

				before and after implantation. The review identified the SSQ as a disease-specific instrument that is sensitive to the impact of CROS and restorative hearing-assistive devices on HRQoL. Few studies have measured the impact of these devices using generic instruments, but data from those that have suggest that generic instruments such as the HUI3 are sensitive to changes in the HRQoL of adults with SSD.
Kitterick et al., 2016[36]	To assess the nature and quality of the evidence for the use of hearing instruments in adults with unilateral severe to profound SNHL.	6 (Pubmed, Embase, Medline, Cochrane, CINAHL, DARE); up until 11/2/2015; 30	Downs & Black risk of bias checklist: low to moderate quality	Devices that reroute sounds from an ear with a severe to profound hearing loss to an ear with minimal hearing loss may improve speech perception in noise when signals of interest are located toward the impaired ear. However, the same device may also degrade speech perception as all signals are rerouted indiscriminately, including noise. Although the restoration of functional hearing in both ears through cochlear implantation could be expected to provide benefits to speech perception, the inability to synthesize evidence across existing studies means that such a conclusion cannot yet be made. For the same reason, it remains unclear whether cochlear implantation can improve the ability to localize sounds despite restoring bilateral input. Prospective controlled studies that measure outcomes consistently and control for selection and observation biases are required to improve the quality of the evidence for the provision of hearing instruments to patients with unilateral deafness and to support any future recommendations for the clinical management of these patients.
Liu et al., 2017[40]	SR on the audiological and/or QoL benefits of a BCD in children with congenital unilateral CHL or SNHL.	3 (Pubmed, Medline, Embase); 1/1/1977 (first implanted BCDs) -7/1/2016; 9	None reported	Given the potential benefits of a BCD along with the fact that it can be safely trailed using a headband, it is reasonable to trial a BCD in children with congenital SSD. Should the trial offer audiological and/or QoL benefits for the individual child, then BCD implantation can be considered.

Magele et al., 2019[18]	To critically assess (SR & meta-analysis) the current literature on safety, efficacy and subjective benefit after implantation with an active transcutaneous BCD.	2 (Pubmed, Cochrane); 1/2012 (commercialisation BCDs)-31/10/2018; 39	Quality and scientific validity: MEDDEV 2.7/1 rev. 4 CEBM: IV-V (n=9), IV (n=27), III-IV (n=3)	The device's transcutaneous technology results in a minor event incidence rate of one in 9.9 person-years and a major incidence rate of one in 148.9 person-years. Based on the audiological outcomes, high patient satisfaction as well as the low complication rate, the authors recommend the active transcutaneous bone conduction hearing device as a safe and effective treatment for patients suffering from hearing loss within the device's indication criteria (CHL and/or MHL or SSD).
Peter et al., 2019[50]	SR with descriptive data analysis about the influence of CI on tinnitus in patients with SSD.	5 (Pubmed, Embase, Web of Science, Cochrane, Google Scolar); up until 29/1/2018; 13 (exclusion of 4 based on quality assessment)	GRADE, DoE & RoB (Cochrane): moderate-high DoE and moderate RoB	This review shows a clear improvement of tinnitus complaints after CI in patients with SSD. Therefore, tinnitus might be considered as an additional indication for CI in SSD.
Peters et al., 2015[35]	SR on the clinical outcomes of BCD and CROSS for patients with SSD.	4 (Pubmed, Embase, Cochrane, CINAHL); up until 7/4/2014; 6	Critical appraisal checklist (DoE & RoB): moderate-high DoE and low-moderate RoB	No high level of evidence studies compare BCD and CROS in patients with SSD. Literature showed no beneficial effect of BCD or CROS regarding speech perception in noise and sound localization. Subjective speech communication demonstrated a moderate improvement with BCD and CROSS. High evidence studies comparing all treatment options for SSD should be conducted.
Peters et al., 2016[41]	SR on CI for children with unilateral HL.	4 (Pubmed, Embase, Cochrane, CINAHL); up until 29/6/2015; 5	Critical appraisal checklist (DoE & RoB): low-moderate DoE and high RoB	No firm conclusions can be drawn on the effectiveness of CI in children with unilateral HL, due to heterogeneous findings, small sample sizes, and the lack of high Level of Evidence studies. Based on the findings of the SR, CI may be an effective treatment option in children with unilateral HL.
Oliveira et al., 2014[59]	To review the outcomes of the fully implantable middle ear devices Carina and Esteem regarding the treatment of HL.	4 (Pubmed, Embase, Scielo, Cochrane); 2000-2014; 22	None reported	There are still some problems to be solved, mainly related to device functioning and price. Due to the relatively few publications available and small sample sizes, we must be careful in extrapolating these results to a broader population. Additionally, none of all these studies represented level-high levels of evidence (i.e. RCTs).

Sprinzl and Wolf-Magele, 2016[2]	Safety and effectiveness of the Bonebridge for patients with CHL or MHL and SSD.	4 (Pubmed, Cochrane, Medline, Embase); up until 6/2014; 29 (17 trials, 12 presentations)	National Health and Medical Research Council levels and grades of evidence	The transcutaneous BCD system Bonebridge provides a valuable and stable audiological benefit to patients suffering from CHL or MHL and SSD. With its active transcutaneous design, the Bonebridge offers a lower complication rate to percutaneous systems and higher and more reliable hearing gain compared to other transcutaneous or percutaneous systems. Moreover, the fast activation of the implant system enables the recipient of the system to benefit in a short time frame postoperatively from the intervention.
van Zon et al., 2015[45]	SR on clinical outcomes of CI for patients with SSD or asymmetrical HL	4 (Pubmed, Cochrane, CINAHL, Embase); up until 10/12/2013; 15	Critical appraisal checklist (DoE and RoB): moderate-high DoE and moderate RoB	There are no high-level-of-evidence studies concerning cochlear implantation in patients with SSD or asymmetrical HL. Current literature suggests important benefits of CI regarding sound localization, QoL, and tinnitus. Varying results were reported for speech perception in noise, possibly caused by the large clinical heterogeneity between studies. Larger and high-quality studies are certainly warranted.
Vlastarako et al., 2014[46]	Critical review of evidence on CI efficacy in SSD and/or unilateral tinnitus.	1 (Medline); up until 5/2013; 17	Evidence-based guidelines for categorization of medical studies: level II (n=6), level III (n=2), level IV (n=4)	The criteria for CI candidacy are changing to include wider patient populations; however, the determination of implant candidacy is ultimately based on the best knowledge and judgement of the managing physician. Although the outcomes of the 108 SSD implantees in the literature have certain weaknesses (e.g. short follow-up, various evaluation protocols), the overall quality of evidence supports a wider use of CI in SSD following appropriate selection and counselling (overall strength of recommendation B). It remains to be seen if the long-term follow-up of large number of patients in well conducted high quality studies will confirm the results.

HL: Hearing Loss, RoB: Risk of Bias, DoE: Directness of Evidence, SR: Systematic Review, BCD: Bone Conduction Device, MEI: Middle Ear Implant, CI: Cochlear Implant, SNHL: Sensorineural Hearing Loss, MHL: Mixed Hearing Loss, CHL: Conductive Hearing Loss, SSD: Single Sided Deafness, BAHA: Bone Anchored Hearing Aids, VSB: Vibrant Soundbridge, QoL: Quality of Life, CHA: Conventional Hearing Aid, CROS: Contralateral Routing Off-Signal, HUI-3: Health Utility Index 3; RCT: Randomized Controlled Trial, SSQ: Speech, Spatial, and Qualities of Hearing Scale.

Table 60 – Description of the Primary studies, Included Population, Intervention, Comparator, and Outcomes of the Articles Included in the Clinical Evidence Review

Author, year	Primary studies (n); patients/ears* (n)	Population		Intervention (n, primary studies)	Comparator	Outcomes		
		Child/Adult; mean age (range of mean age) [range]	Description of the population's HL	Device type (Brand)	Device type (Brand), or test conditions	Auditory (functional, objective, subjective, QoL)	Tinnitus	Safety / Adverse events
Appachi et al., 2017[34]	12; 213	Child	Mild to profound, congenital or not specified, unilateral or bilateral (although the objective was limited to unilateral HL), SSD, AHL, SNHL, CHL, or MHL.	Passive tBCD, 7 studies (≠) Non-surgical, 5 studies (CHA, frequency modulation/CROS, combination)	No treatment	X		
Bezdjian et al., 2017[65]	8; 86	Child/Adult: 17.2y [5-71y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented uni- or bilateral CHL (79.1%), MHL (1.2%), SNHL (7.0%), other (12.7%).	Passive tBCD (Sophono)	No treatment	(X)		X
Blasco & Redleaf, 2014[44]	8*; 35	Adult: 47y [22-70y]	Sudden SSD = sudden, unilateral, severe to profound HL: PTA > 70 dB (worst ear), and PTA < 25 dB (best ear)	CI (≠)	/	X	X	
Bruchhage et al., 2017[56]	24; 679	Adult: [18-86y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented mild to severe, uni- or bilateral SNHL.	Active MEI (VSB)	No surgical intervention, unaided, active MEI Esteem, active MEI Carina	X		X
Cabral et al., 2016[47]	12; 137	/	Patients with SSD or unilateral HL.	CI (≠)	/	X	X	

Author, year	Primary studies (n); patients/ears× (n)	Population		Intervention (n, primary studies)	Comparator	Outcomes		
Cooper et al., 2017[37]	26 ; 482×	Child/Adult	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented uni- or bilateral CHL, MHL, SSD, or was not described.	Passive tBCD (Sophono (n=319) & BAHA Attract (n=163))	No treatment	X		X
Dimitriadis et al., 2016[66]	10; 89	Child/Adult: (10.7-65y)[5-67y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented uni- or bilateral CHL (40%), MHL (20%), unilateral HL (40%), or was not described.	Passive tBCD (BAHA Attract)	No treatment	(X)		X
Ernst et al., 2016[57]	19; 294 13; 666 4; 43	Child/Adult	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented uni- or bilateral MHL or CHL.	Active MEI (VSB)	No treatment BCDs Middle ear surgery with CHA	X		X
Health Quality Ontario 2018[68]	24 (child n=14; adult n=10) Adults: RCT (n=3): n=50 in each group (unilateral and bilateral CI) Observational studies (n=7): n=208 Children: Observational studies (n=14): n>1000	Child [0-17.9y] / Adult [18-87y]	Severe to profound bilateral sensorineural hearing loss	Unilateral CI	Bilateral CI	X	X	X

Author, year	Primary studies (n); patients/ears× (n)	Population		Intervention (n, primary studies)	Comparator	Outcomes		
Health Quality Ontario 2020[6]	20 systematic reviews	Child/Adult	Single sided deafness, mixed hearing loss, conductive hearing loss	BCD, MEI, CI	No treatment, CHA, BCD	X	X	X
Kahue et al., 2014[58]	17; 503×	Adult: 58.2y	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented mild to profound/deafness, uni- or bilateral, SNHL.	Active MEI (3 FDA approved MEIs: Vibrant Soundbridge (n=211), Soundtec Direct (n=190), Esteem (n=102))	Non aided or best aided	X		X
Kim et al., 2017[38]	14; 296	Child/Adult: (12.6-64y)	Patients with SSD£ or unilateral HL.	BAHA‡ (≠, not specified probably pBCD)	No treatment, normal control, other intervention (CROS)	X		X
Kitterick et al., 2015[39]	24; 461	Adult	Unilateral, severe-profoundα/deafness, SNHL	≠ devices: CHD, BCD, CI	No treatment; placebo devices	X (QoL)		
Kitterick et al., 2016[36]	30; 556	Adult	Unilateral, severe-profoundα/deafness, SNHL	≠ devices: CHD, BCD, CI	No treatment; placebo devices; between interventions (CHA vs. BCD)	X		X
Liu et al., 2017[40]	9; 112	Child: (4.4-12.4y)[3, 18]	Congenital unilateral deafness: • Sensorineural deafness: profound SNHL ≥ 90 dB HL (only 1 included study on 8 patients) • Conductive deafness: maximum CHL 60 dB HL	BCD (≠)	No treatment	X		

Author, year	Primary studies (n); patients/ears* (n)	Population		Intervention (n, primary studies)	Comparator	Outcomes		
Magele et al., 2019[18]	39; 487	Child/Adult: 35.6±16.9y [5-80y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented severe to profound/deafness uni- or bilateral CHL (62%), MHL (14%), SSD (11%) or not reported (13%).	Active tBCD (Bonebridge)	No treatment; other therapies for CHL, MHL or SSD	X		X
Peter et al., 2019[50]	13; 153	Adults (40-53.8y)	SSD$^{\alpha}$+tinnitus or AHL$^{\beta}$+tinnitus	CI (≠)	No treatment		X	
Peters et al., 2015[35]	5; 91	Adults (43.6-60.2y)	SSD$^{\alpha}$ or AHL$^{\beta}$	BCD & CROS	No treatment	X		
Peters et al., 2016[41]	5; 22	Child: ±8y (one pt was 19.5y old)	Unilateral HL: unilateral severe-profound SNHL (worst ear), no HL (better ear) Asymmetrical HL: unilateral severe-profound SNHL (worst ear), moderate HL (better ear)	CI	No treatment	X		
Oliveira et al., 2014[59]	22; 244	Adults: [18-88y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented HL (not specified).	Active MEI (Carina (n=10) & Esteem (n=134))	No treatment, CHA, inactivated device	X		X
Sprinzl and Wolf-Magele, 2016[2]	18; 190	Child/Adult [8-74y]	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented uni- or bilateral CHL, MHL or SSD.	Active tBCD (Bonebridge)	/	X		X
van Zon et al., 2015[45]	9; 112	Adults: (43.3-57y)[22-82y]	SSD$^{\alpha}$, AHL$^{\beta}$	CI (≠)	No treatment, BCD, CROS	X	X	

Author, year	Primary studies (n); patients/ears* (n)	Population	Intervention (n, primary studies)	Comparator	Outcomes	
Vlastarakos et al., 2014[46]	17 (5 reporting on the same population); 108	/	Population was not selected based on type or degree of HL but on device. Therefore, the included population presented unilateral deafness (±tinnitus (n=42))	CI (≠)	X	X

**We excluded one case study of Hassepasse 2012, to make the other included studies more comparable, since that was the only case on a child. The presented numbers are thus without that case. † Only included if the groups could not be separated. Only the selection criteria were presented. £SSD defined as PTA > 90 dB, and speech discrimination < 20%, and normal hearing (PTA < 30 dB) in the opposite ear. ‡ BAHA devices used in these studies were Compact, Classic or Compact, Compact or Divino, Divino, Divino or Intenso, Intenso, Divino or BP100 and BP100. α Unilateral severe-profound HL defined as: PTA >70 dB HL in one ear with an air-bone gap ≤ 10 dB (from 1 to 4 kHz) and a PTA ≤ 30 dB HL (averaged across 0.5, 1, 2, and 4 kHz) in the other ear. βAHL defined as a PTA ≥ 70 dB in the poor ear, and the better ear has a threshold of PTA ≤ 50 dB or PTA < 70 dB (van Zon et al., 2015). (X) The outcome was described but selection was based on device and not on etiology of hearing loss. Thus it was impossible to retrieve the data to answer the research questions.*

HL: Hearing Loss, BCD: Bone Conduction Device, tBCD: transcutaneous Bone Conduction Device, pBCD: percutaneous Bone Conduction Device, MEI: Middle Ear Implant, CI: Cochlear Implant, SNHL: Sensorineural Hearing Loss, MHL: Mixed Hearing Loss, CHL: Conductive Hearing Loss, SSD: Single Sided Deafness, BAHA: Bone Anchored Hearing Aids, VSB: Vibrant Soundbridge, QoL: Quality of Life, CHA: Conventional Hearing Aid, PTA: Pure Tone Audiometry

Appendix 3.3. Overview of the applied evaluation tools across the articles to measure the outcomes

Table 61 – Tests, applied in the articles across the reviews, to assess tinnitus, objective and subjective auditory performance, and speech/language development.

Outcome	Test
Tinnitus	Visual Analogue Scale (VAS) : score 0 to 10. Tinnitus Questionnaire (TQ) : 52-questions Tinnitus Handicap Inventory (THI) : 25-questions Tinnitus Reaction Questionnaire (TRQ) : 26-questions Tinnitus Rating Scale (TRS) Tinnitus Annoyance Questionnaire (TAQ) : 13-questions Tinnitus Test
Speech recognition in quiet or noise: objective auditory performance	Speech Recognition Thresholds (SRT) Signal-to-Noise Ratio (SNR)† Leuven Intelligibility Sentence Test (LIST) Oldenburg Sentence Test (OlS or OLSA) Bamford-Kowal-Bench Speech in Noise test (BKB-SIN) Hochmair-Schulz-Moser (HSM) Hearing In Noise Test (HINT) Consonant-Nucleus-Consonant test (CNC) Consonant-Vowel-Consonant test (CVC) Speech in spatially separated sources (SISSS) Utrecht sentence test with adaptive randomized roving levels (U-STARR) Vrije Universiteit 98 sentences (VU-98) Texas Instruments Massachusets Institute of Technology (TIMIT) City University of New York (CUNY) Hearing In Noise Test – Children (HINT-C) Northwestern University – Children's perception of speech (NU-CHIPS) Phonetically Balanced Kindergarten (PBK) Freiburger Monosyllabic word test (FM) Fournier dissyllabic Quick-SIN Italian disyllabic word lists

	Göttinger kindersprachtest Danatale Phonetically balanced bisyllabic Finnish words Mainzer monosyllables Spanish bisyllables words and numbers lists R-SPIN Döring Basler Satz Ling 6 sound test
Subjective auditory performance / Quality of Life (QoL)	Speech, Spatial, and Qualities of Hearing Scale (SSQ; or it's short form, the SSQ-12) Glasgow Benefit Inventory (GBI) Glasgow Children's Benefit Inventory (GCBI) The Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire Hearing Device Satisfaction Scale (HDSS) Hough Ear Institute Profile (HEIP) Glasgow Hearing Aid Benefit Profile (GHABP) Hearing Handicap Inventory for the Elderly (HHIE) Hearing Handicap Inventory for Adults (HHIA) Bern Benefit in Single Sided deafness (BBSS) The Client Oriented Scale of Improvement Meaningful Use of Speech Scale Meaningful Auditory Integration Scale (MAIS) Satisfaction with Amplification in Daily Life questionnaire Client Oriented Scale of Improvement (COSI) Children's Home Inventory for Listening Difficulties (CHILD) International Outcome Inventory for Hearing Aids Health Utilities Index Mark 3 (HUI3) Spatial Hearing Questionnaire (SHQ) The Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Teachers' Evaluation of Aural/oral Performance of Children (TEACH) Auditory Behaviour in Everyday Life (ABEL) Screening Instrument For Targeting Educational Risk (SIFTER) 36-item Short Form Health Survey (SF-36)

	Other non-validated tests
Speech and language development	Categories of Auditory Performance II (CAP-II) Speech Intelligibility Rating (SIR)
Sound localization	Testing differs based on the positioning of the loudspeakers e.g. 15°, 30°, 60°.

Appendix 3.4. Effectiveness of hearing solutions in SSD

Table 62 – Summary of the results per systematic review on bone conduction devices (versus CROS or unaided) in single sided deafness in adults and children.

Author, Year	Type of BCD	Results
Objective Audiometry and Speech Perception in Noise		
Appachi et al., 2017[34]	Passive tBCD: Sophono[1] and BAHA[2]	Average improvement (significant): • PTA: 36[1]-41[2] dB • SRT: 38[1]-56[2] dB WRS improvement from 2-91 HINT mean scores (pre -> post): • @SNR 0 dB: 38%-42% -> 81%-82% • @SNR 5 dB: 76% -> 97% • @SNR 10 dB: 71%-95% -> 99%-100%
Cooper et al., 2017[37]	Passive tBCD: Sophono[1] and BAHA[2]	Average improvement: • PTA: 53.2±12.9 dB[1] - 22.6±4.8 dB[2] • SRT: 45.0±5.0 dB[1] - 56.0±21.0 dB[2]
Magele et al., 2019[18]	Active tBCD: Bonebridge	Average improvement: • PTA: 28.3 dB SPL [16.9, 41]* • WRS improvement of 16% (95%CI: -17.26, 49.26) • Speech perception in noise improvement especially when noise presented from the normal-hearing side and speech on the deaf side.
Sprinzl & Wolf-Magele, 2016[2]	Active tBCD: Bonebridge	Significant improvement • PTA: 20-40 dB improvement depending upon frequency • WRS: 18%-90% improvement

		• SRT: 34.5-32.3 dB improvement • SNR: 1.3-2.5 dB depending on where the noise originated.
Kim et al., 2017[38]	BAHA[1] (not specified) CROS[2]	Speech perception in noise (Significant) Improvement in SNR pre -> post, depending on where noise originated: • 0.63 -> -2.04[1] , -1.18[2] (BAHA > CROS) • -0.03 -> -2.02[1] (BAHA > CROS) • -4.58 -> -5.61[1] Improvement in dB SNR pre -> post: -3.8 -> -4.8[1] Improvement in dB pre -> post: 33.48 -> 36.12[1], 36.36[2]
Kitterick et al., 2015 & 2016[36, 39]	BCD (implanted and non-implanted, not specified)	Speech perception in noise, described in 4 articles, was improved, when noise was presented from the hearing ear.
Peters et al., 2015[35]	BCD (not specified) & CROS	The four articles describing SNR reported different numbers (no differences and significant improvements), depending on where noise originated. The unaided condition ranged between -7.1-2.2, CROS -3.4-1.0, BCD -5.5, 0.9. The word score was reported in one study and especially an (significant) improvement was seen with CROS when the sound was provided at the pore ear and noise at better ear.
Sound localisation		
Kim et al., 2017[38]	BAHA (not specified)	No (significant) difference pre -> post: 13-66% (mean score: 31%) -> 15-69% (mean score: 28%)
Kitterick et al., 2015 & 2016[36, 39]	BCD (implanted and non-implanted, not specified)	No changes were reported in sound localization when comparing BCDs with no treatment. No differences were seen between BCDs and CHAs.
Magele et al., 2019[18]	Active tBCD: Bonebridge	Currently, numbers are too small to draw conclusions on the benefit of sound localization.
Peters et al., 2015[35]	BCD (not specified) & CROS	No (significant) difference with BCD and CROS from unaided condition: 15-53% (CROS), 17-59% (BCD) vs. 18-61% (unaided) correct identification
Satisfaction / Hearing related QoL / Quality of hearing		
Sprinzl & Wolf-Magele, 2016[2]	Active tBCD: Bonebridge	Improved subjective benefits of hearing APHAB (pre -> post): • Ease of conversation: 20% -> 7% • Background noise: 69% -> 46% • Listening in reverberant condition: 43% -> 27% • Aversiveness of sound: 31% ->29%

		Improved patient satisfaction measured by HDSS and GBI (numeric data not shown)
Kim et al., 2017[38]	BAHA (not specified)	APHAB (unaided -> BAHA): • Ease of conversation: 24-59% -> 12-53% • Background noise: 33-79% -> 18-48% • Listening in reverberant condition: 41-65% -> 26-55% • Aversiveness of sound: 28-41% -> 30-45% GHABP: BAHAs were reported to improve hearing, but did not differ significantly from CROS. Positive score results were reported for tests of subjective satisfaction and benefit assessment: SSQ, GBI, BBSS, HHIE, QoL, and CHILD.
Appachi et al., 2017[34]	Passive tBCD: BAHA	Significant improvements CHILD-child scores (pre -> post): 3.36–4.49 -> 7.10–7.29 CHILD-parent scores (pre -> post): 3.43-4.60 -> 6.90-7.00
Kitterick et al., 2015 & 2016[36, 39]	BCD (implanted and non-implanted, not specified)	The APHAB score improved in 9 studies. A mixed effect meta-analysis of disease specific measures suggested that hearing assistive devices have a small to medium impact on HRQoL (SSQ, HUI-3)
Liu et al., 2017[40]	BCD (not specified)	Average VAS score for satisfaction was 9/10 GCBI had a positive score (median: +47.5) SSD questionnaire reported benefit in talking to one person among a group, listening to the television or radio, talking to a person sitting on the deaf side at a dinner table.
Magele et al., 2019[18]	Active tBCD: Bonebridge	Using APHAB, BBSS (average benefit 2.8), GBI (total score 15) and IOI-HA (benefit), some improvement was seen
Peters et al., 2015[35]	BCD (not specified) & CROS	Improved subjective benefits of hearing measured by APHAB (numeric data for unaided condition not shown) HUI3 showed equivalent (non-significant) improved outcomes for CROS and BCD compared to unaided condition. No significant, improved, differences were seen with SSQ.

*(t/p)BCD: (transcutaneous/percutaneous) bone conduction device, PTA : pure-tone average, SRT : speech reception threshold, HINT: hearing in noise test, SNR: signal-to-noise ratio, dB: decibel, CHILD: Children's home inventory for listening difficulties, APHAB: Abbreviated profile of hearing aid benefit, HDSS: Hearing device satisfaction scale, GBI: Glasgow benefit inventory, VAS: visual analogue scale, BAHA: bone-anchored hearing aid, CROS: contralateral routing of signal, GHABP: Glasgow hearing aid benefit profile, SSQ: speech, spatial, and qualities of hearing scale, BBSS: Bern benefit in single sided deafness, HHIE: hearing handicap inventory for elderly, QoL: quality of life, WRS: word recognition score, GCBI: Glasgow children benefit inventory, SSD: single sided deafness, HIU-3: Health utilities index mark 3. *meta-analysis of the functional gain in 3 studies investigating SSD.*

Table 63 – Summary of the results per systematic reviews on cochlear implants in single sided deafness in adults.

Author, Year	Articles (n); Patients (n)	Original articles	Results
Speech audiometry			
Kitterick et al., 2016[43]	6; NR	Vermeire 2009; Arndt 2011; Tavora-Vieira 2013; Hansen 2013; Jacob 2011; Punte 2013, Punte 2011	Speech perception in quiet: Two studies (Tavora Vieira & Arndt) reported a statistically significant improvement (only listening with the implanted ear, not both ears). Neither study reported equivalent outcomes when participants also had the use of their non-implanted ear. Speech perception in noise: Significant improvement in speech perception in noise in 3 studies (Vermeire, Arndt, Tavora-Vieira) (out of 4(Jacob)) when the implanted ear had a more favourable SNR. Only one study found significant benefits when both ears had a similar SNR (Tavora-Vieira). Speech perception was reported to be significantly better after CI compared with the preoperative use of both an ACD and BCD when either ear had a more favourable SNR (Arndt) Results from the spatial configuration that created a more favourable SNR at the normal ear were inconclusive. Heterogeneity in the assessment methodologies across studies meant that data could not be pooled for meta-analysis
Blasco & Redleaf, 2014[44]	3; 16	Vermeire 2009; Stelzig 2011; Tavora-Vieira 2013	Meta-analysis for measuring signal-to-noise ratio (SNR) necessary for 50% sentence understanding was executed. Used tests were LIST (noise presented at 65 dB SPL), Oldenburg Sentence Test (noise at 60 dB SPL), and BKB (noise at 65 dB SPL). Three different geometries of speech and noise presentation were assessed. Significant improvement was seen for both speech and noise presented to the front (S_0N_0) in only one study assessing 8 patients. No other significant results were found. A meta-analysis of the 3 studies with 15 patients demonstrated a summary mean decrease in SNR necessary for 50% sentence understanding after CI for S_0N_0. It decreased by 1.30 dB SPL ($I^2 = 84\%$). No significant differences were noted when sound was presented to the front and noise to the CI (S_0N_{CI}), nor when sound was presented to the front and noise to the normal hearing ear (S_0N_{HE}). Meta-analysis of 2 studies (12 patients) who used HSM sentence test (sentence understanding with speech and noise presented at 65 dB SPL) in S_0N_0 showed no significant difference although low heterogeneity ($I^2=0$).
Cabral et al., 2016[47]	7; 82	Vermeire 2009*; Stelzig 2011*; Tavora-Vieira 2013*; Arndt 2011*; Firszt 2012; Cardieux 2013; Buechner 2010	Different configurations have been used to assess overall speech understanding. *Only 4 showed consistent statistical data (using divergent parameters to measure outcome). Two (Arndt & Tavora-Vieira) found a significant improvement in speech understanding when $S_{CI}N_{NH}$ (considered the most challenging situation in daily life). Only Tavora-Vieira found statistical significant performance when S_0N_0. These results are encouraging since they can be attributed to the squelch effect, meaning that the auditory system is able to process binaural signals after CI.
Van Zon et al., 2015[45]	6; 68	Arndt 2010; Firszt 2012; Jacob 2011; Tavora-Vieira 2013; Vermeire 2009; Buechner 2010	Reported in 6 studies but all different tests and outcomes e.g. significant improvement in speech perception in noise (correctly repeated HSM 42.5% vs 14.5%, $p < 0.01$) if $S_{CI}N_{NH}$. Other configurations and tests might be not improved.
Vlastarakos et al., 2014[46]	7; 85	NR	Improvement in speech perception in noise when noise is from the front (n=3) or the deafened ear (n=4), when noise is coming either from the front (n=1) or from the normal hearing ear (n=5). The remaining study (level III evidence) found no difference. Statistically significant results were reported in four level

			II studies (n=50 patients). In all other signal-noise configurations the results were contradictory and thus inconclusive.
Sound localization			
Kitterick et al., 2016[43]	1; 11	Arndt 2011	Arndt et al (n=11) reported significant less localization error with CI compared to pre-implant condition (CROS, BCD, or unaided).
Cabral et al., 2016[47]	3; 26	Arndt, 2010; Firszt 2012; Cardieux 2013	Arndt et al (n=11) reported significant less localization error with CI compared to pre-implant condition (CROS, BCD, or unaided). In Firszt et al., in 7 out of 10 patients presenting with post-lingual HL, significant improvement was seen of a CI+CHA compared to CHA only, whereas in the three patients with pre- or perilingual deafness, no improvement was noticed. The last study noticed a significant improvement in bimodal scores in three out of five patients with CI compared to CHA only.
Van Zon et al., 2015[45]	3; 34	Arndt 2010; Firszt 2012; Jacob 2011	Different test setups were used but all assessed the localization error as outcome measure. Arndt et al. reported a significant reduction of the localization error after CI compared to the pre-implant condition (CROS, BCD or unaided). Jacob et al. tested at different time points and reported a reduction of localization error from 48° to 4° in CI-on versus CI-off condition (no statistics presented). Firszt et al. assessed data of postlingual deaf patients and prelingual deaf patients separately and showed that the localization error reduced significantly in the bimodal (CI + HA) post-implant condition versus HA-alone (better ear) in the postlingual deaf patients. This improvement was not found in the prelingual deaf patients.
Vlastarakos et al., 2014[46]	6; 63	NR	All studies reported improvement, only statistical significant in 25 patients (the other studies did not have statistical analysis)
Satisfaction / Hearing specific QoL			
Blasco & Redleaf, 2014[44]	4; 14 4; 16	Firszt 2012; Vermeire 2009; Hassepass 2013; Tavora-Vieira 2013	Subjective improvement (87%) while 2 patients (13%) reported worse speech comprehension after implantation (speech). Subjective improvement (100%) of sound localization was noted (spatial).
Kitterick et al., 2016[43]	3; NR	Vermeire 2009; Arndt 2011; Tavora-Vieira 2013	Significant benefits on subjective benefits of hearing measured by SSQ. A meta-analysis of this SSQ data from 3 studies found significant decreases in listening difficulty on the speech, spatial, and qualities subscale in CI versus unaided. One study reported also significant benefits on measures of hearing-related (SSQ) and health-related (HUI3) QoL after CI compared with ACD and/or BCD.
Van Zon et al., 2015[45]	4; 50	Arndt 2010; Firszt 2012; Tavora-Vieira 2013; Vermeire 2009	Significant improvement in subjective benefits of hearing measured by SSQ especially in the speech and spatial components. In some studies, other tests were used also reporting subjective benefits. In the prelingual group, significant improvement was seen in spatial subsection. In the postlingual group in speech and special subsections significant benefit was noted. The quality was improved but not significantly.

Vlastarakos et al., 2014[46]	5; 57	NR	Using a self-assessment questionnaire, four level II studies (n=43) reported significant improvements in especially the speech and spatial components of the SSQ. The quality of hearing component was not improved.

SNR: signal-to-noise ratio, dB: decibel, SPL: sound pressure level, CI: cochlear implant, HSM: Hochmair-Schulz-Moser, SSQ: speech, spatial, and qualities of hearing scale, CAP-II: categories of auditory performance II, SIR: speech intelligibility rating, CHA: conventional hearing aids, CROS: contralateral routing of signal

Appendix 3.5. Tele-audiology

Input from the literature

- The concept of tele-audiology is not new. It has been applied by many agencies and practices in developing countries to help the unserved and underserved populations and to overcome the shortage of audiologists. Worldwide, especially during the COVID-19 pandemic, it is questioned how tele-audiology can provide to clinical challenges associated with social distancing.[143] Tele-audiology practice is sometimes portrayed/practiced as an extension of conventional audiology practice, but in reality, it should be considered as a more flexible and innovative way of delivering hearing healthcare. There will still be a need for conventional audiology practices to manage more complex cases where medical diagnosis and intervention are involved, or where clients prefer face-to-face service. There are studies and evidence available and clinical data that aspects of tele-audiology are prevalent within different service models and that the outcomes are at least as beneficial to the recipients as the outcomes from delivery of conventional audiology services in conventional audiology clinics. In addition to potential improvements to client outcomes, tele-audiology is already starting to improve access to hearing health services, reduce costs, and deliver social and economic benefits to society.[144]
- As said, there are different aspects of tele-audiology. On the one hand there are the different stages (screening, assessment, coaching, adjustment, monitoring, assistance, aftercare, etc.) and on the other hand there are the different devices for which a different approach can be needed / different health care workers are needed for example CHA users or candidates will have difficulties reaching the audiologist to assess and select a device, but CI users need consistent follow up towards for example fitting of the CI and rehabilitation/auditory training.[143]
- Concerning implementation, different steps should be taken into account: patient candidacy (determine which patient is a good candidate), clinical education and training (of the hearing care professionals), technology infrastructure (which equipement is needed) and regulatory environment (is reimbursement foreseen).(Phonak ref) Moreover, the tele-audiology delivery model can be grouped into two models of which the first is applied with a satellite clinic or a physical location away from the main clinic and the second model exclusively relies on mobile technology outside of the clinic.[143]
- Since clinical literature on tele-audiology indicates a significant opportunity for telehealth applications in the practice of audiology, in 2014-2015, the American Academy of Audiology Tele-audiology Toolkit was launched. This kit is designed to provide tools and resources to help address this evolving service delivery model, while maintaining a successful and vital practice where the audiologist remains central in the provision of hearing health-care diagnosis and treatment practices. The kit will evolve and be updated as new information and research becomes available.[145]
- Concerning fitting of the CI and reachability of the centres, tele-fitting could be considered. In 2007, the technology was implemented for the first time.[146] In 2009, the Word Hearing Centre introduced the National Network of Teleaudiology to reduce the burden to patients, and it now consists of 21 co-operating centres in Poland and four abroad in the Ukraine (Odessa and Lutsk), Kyrgyzstan (Bishkek), and Belarus (Brest).[147] In Poland was shown that a nationwide platform for telefitting

for postoperative care for implanted patients using telemedicine seems to be a reliable alternative to standard model. It improves the quality of service provided to patients and saves substantial time and money.[148] Also in Odessa, over 95% of respondents were satisfied with telefitting and they found it a suitable alternative to standard fitting. Moreover, they felt that they had good contact by videoconference with the audiologist in Poland.[147] Another study showed that patients who were remotely fitted, were highly satisfied with the results.[149] Tele-fitting seems to save time and money, and patients seems to be satisfied with the procedures, so this could be an interesting step to take towards accessibility of the centres. Moreover, remote programming is effective and safe and was approved by the FDA on Nobember 17, 2017.[150]

- Concerning remote rehabilitation, little studies are published, but some examples are available such as the Home Rehabilitation Clinic in 2004 for children with hearing loss and CI.[146] A systematic review on the role of telemedicine in auditory rehabilitation showed practices took already place in several countries and that especially more investigation should be done towards cost-effectiveness and bandwidth limitations.[151] Very recently a feasibility and developmental study is published on therapist-guided telerehabilitation (Train2Hear) in adult CI users.[152]

APPENDIX 4. APPENDIX TO THE ECONOMIC REVIEW

Appendix 4.1. Search for HTA reports

Appendix 4.1.1. List of INAHTA member websites searched for HTA reports

AETS: *https://publicaciones.isciii.es/unit.jsp?unitId=aets*

AETSA: https://www.aetsa.org

AGENAS: https://www.agenas.gov.it/

AHRQ: https://www.ahrq.gov/

AHTA: https://www.adelaide.edu.au/ahta/

AHTAPol: http://www.aotm.gov.pl/

AQuAS: http://aquas.gencat.cat

ASERNIP-S: https://www.surgeons.org/research-audit/research-evaluation-inc-asernips

ASSR: http://assr.regione.emilia-romagna.it/

AVALIA-T: https://acis.sergas.gal/

CADTH: *https://www.cadth.ca*

CEDIT: *cedit.aphp.fr*

CEM: https://igss.gouvernement.lu/

CENETEC: https://www.gob.mx/salud/cenetec

CONITEC: http://conitec.gov.br/

CCCMeRC: http://cmerc.org/

DAHTA@DIMDI: https://www.dimdi.de/

DECIT-CGATS: http://www.saude.gov.br/sctie/decit

DEFACTUM: https://www.defactum.net/

G-BA: https://www.g-ba.de/

GÖG: https://goeg.at/

HAD-MSP: https://www.gub.uy/ministerio-salud-publica/

HAS: https://www.has-sante.fr/

HCT-NHSRC: http://www.nhsrcindia.org

HealthPACT: https://www2.health.vic.gov.au/

HIQA: *https://www.hiqa.ie*

HIS: http://www.healthcareimprovementscotland.org/

HQOntario: https://www.hqontario.ca/Evidence-to-Improve-Care

IACS: http://www.iacs.es/

IECS: https://www.iecs.org.ar/

IETS: http://www.iets.org.co/

IHE: https://www.ihe.ca/

INASanté: http://www.pacs.gov.tn/

INESSS: https://www.inesss.qc.ca/

IQWiG: https://www.iqwig.de

LBI-HTA: https://hta.lbg.ac.at/

MaHTAS: http://www.moh.gov.my

MTU-SFOPH: http://www.bag.admin.ch/hta

NIHR: https://www.nihr.ac.uk

NIPH: *https://www.fhi.no/*

OSTEBA: http://www.euskadi.eus/web01-a2ikeost/en/

RCHD-CS: www.rcrz.kz/

SBU: https://www.sbu.se/

UVT: https://www.policlinicogemelli.it/

ZIN: https://www.zorginstituutnederland.nl/

ZonMw: *https://www.zonmw.nl*

Other websites consulted

CHE: *https://www.york.ac.uk › che*

EUnetHTA: https://eunethta.eu/

NICE: *https://www.nice.org.uk*

Appendix 4.2. Search for recent primary economic evaluations

Table 64 – Search strategy and results for Cochrane.

ID	Search	Hits
	Date Run: 06/02/2020 17:34:36	
#1	[mh ^"hearing aids"]	261
#2	[mh "Neural Prostheses"]	152
#3	[mh ^"cochlear implantation"]	84
#4	[mh "Auditory Brain Stem Implantation"]	0
#5	#1 OR #2 OR #3 OR #4	430
#6	(auditory NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	562
#7	(auditive NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	4
#8	(cochlear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	491
#9	(middle-ear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	31
#10	(brain-stem NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	11
#11	(otorhinolaryngology NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	0
#12	(ear NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	289
#13	(hearing NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	920
#14	ear mold?:ab,ti	13
#15	((bone NEAR/2 conducti*) NEAR/3 device?):ab,ti	21
#16	(implant* NEAR/3 neuroprosthes*):ab,ti,kw	4
#17	(neural NEAR/3 prosthes*):ab,ti,kw	9
#18	((BAHA or BAHAs or BAHS or BAHSs or BAHI or BAHIs or BAHD or BAHDs or BCHI or BCHIs) NEAR/5 (cochlea* or implant* or device* or system*1)):ti,ab	21
#19	((Ponto or Carina or Sophono) NEAR/5 (cochlea* or implant* or device*)):ab,ti	11
#20	(Bonebridge* or Soundbridge*):ab,ti	11
#21	softband:ab,ti	4
#22	#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21	1984

#23	#5 or #22	2012
#24	[mh "Hearing Disorders"]	1837
#25	(hearing NEAR/3 disorder?):ab,ti	111
#26	dysac?usis:ab,ti	4
#27	(distorted NEAR/3 hearing):ab,ti	1
#28	parac?usis:ab,ti	0
#29	tinnitus:ab,ti	1932
#30	hypoacus*:ab,ti	23
#31	(hearing NEAR/2 loss):ab,ti	2056
#32	(hearing NEAR/2 impairment):ab,ti	538
#33	deafness:ab,ti	597
#34	deaf?mutism:ab,ti,kw	0
#35	#25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34	4529
#36	#24 or #35	5050
#37	[mh ^"Bone-Anchored Prosthesis"]	5
#38	[mh ^"Prostheses and Implants"]	607
#39	[mh ^"Electrodes, Implanted"]	390
#40	[mh ^"Implantable Neurostimulators"]	30
#41	[mh ^"ossicular prosthesis"]	24
#42	#37 OR #38 OR #39 OR #40 OR #41	1049
#43	implant*:ab,ti	30503
#44	prosthes*:ab,ti	4012
#45	porp:ab,ti	5
#46	torp:ab,ti	12
#47	electrodes:ab,ti	2950
#48	(ossicular NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	18
#49	(bone-anchored NEAR/5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)):ab,ti	59

#50	#43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49	35380
#51	#42 or #50	35740
#52	#36 and #51	393
#53	#23 or #52	2070
#54	[mh ^"bone conduction"]	63
#55	[mh ^"Osseointegration"]	354
#56	#54 or #55	410
#57	(bone* NEAR/3 (conduct* or anchor* or integrat*)):ti,ab	412
#58	(osseointegrat* or osseo integrat*).ti,ab,kf.	79
#59	#57 or #58	491
#60	#56 or #59	850
#61	#51 and #60	484
#62	#36 and #61	58
#63	#53 or #62	2070
#64	[mh ^"economics"]	43
#65	[mh ^"economics, medical"] or [mh ^"economics, pharmaceutical"] or [mh "economics, hospital"] or [mh ^"economics, nursing"] or [mh ^"economics, dental"]	799
#66	[mh /EC]	11188
#67	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf.	79
#68	[mh "costs and cost analysis"]	10196
#69	(cost or costs or costing or costly):ti	12581
#70	cost effective*:ti,ab	36440
#71	(cost* NEAR/2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)):ab	14375
#72	[mh ^"models, economic"]	234
#73	[mh ^"markov chains"] or [mh ^"monte carlo method"]	433
#74	(decision NEAR/1 (tree* or analy* or model*)):ti,ab	1356

#75	(markov or markow or monte carlo):ti,ab	1938
#76	[mh ^"quality-adjusted life years"]	1190
#77	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs):ab,ti	8379
#78	((adjusted adj (quality or life)) or (willing* NEAR/2 pay) or sensitivity analys*s):ab,ti	17527
#79	#64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77 OR #78	67938
#80	#63 and #79	102
#81	#80 with Cochrane Library publication date Between Jan 2018 and Feb 2020	48

Table 65 – Search strategy and results for Embase.

ID	Search	Hits
	20 Jan 2020	
#1	'hearing aid'/exp	27801
#2	'neuroprosthesis'/exp	16352
#3	'cochlear implantation'/de	3488
#4	'auditory brain stem implantation'/de	73
#5	#1 OR #2 OR #3 OR #4	29808
#6	(auditory NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	7779
#7	(auditive NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	50
#8	(cochlear NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	17365
#9	('middle ear' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	1298
#10	('brain stem' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	772
#11	(otorhinolaryngology NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	62
#12	(ear NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	5423
#13	(hearing NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	16483
#14	'ear mold$':ab,ti,kw	76
#15	('bone conducti*' NEAR/3 device$):ab,ti,kw	250

#16	(implant* NEAR/3 neuroprosthes*):ab,ti,kw	171
#17	(neural NEAR/3 prosthes*):ab,ti,kw	854
#18	((baha OR bahas OR bahs OR bahss OR bahi OR bahis OR bahd OR bahds OR bchi OR bchis) NEAR/5 (cochlea* OR implant* OR device* OR system*)):ab,ti,kw	406
#19	((ponto OR carina OR sophono) NEAR/5 (cochlea* OR implant* OR device*)):ab,ti,kw	102
#20	bonebridge*:ab,ti,kw OR soundbridge*:ab,ti,kw	395
#21	softband:ab,ti,kw	52
#22	#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21	37553
#23	#5 OR #22	43886
#24	'hearing disorder'/exp	155024
#25	(hearing NEAR/3 disorder$):ab,ti,kw	3747
#26	dysac$usis:ab,ti,kw	56
#27	(distorted NEAR/3 hearing):ab,ti,kw	12
#28	parac$usis:ab,ti,kw	15
#29	tinnitus:ab,ti,kw	14521
#30	hypoacus*:ab,ti,kw	1105
#31	(hearing NEAR/2 loss):ab,ti,kw	57276
#32	(hearing NEAR/2 impairment):ab,ti,kw	12172
#33	deafness:ab,ti,kw	26658
#34	'deaf mutism':ab,ti,kw OR deafmutism:ab,ti,kw	342
#35	#25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34	93968
#36	#24 OR #35	171103
#37	'prostheses and orthoses'/de	16212
#38	'electrode implant'/de	2616
#39	'implantable neurostimulator'/de	698
#40	'middle ear prosthesis'/exp	950
#41	#37 OR #38 OR #39 OR #40	20371

#42	implant*:ab,ti,kw	536074
#43	prosthes*:ab,ti,kw	104336
#44	porp:ab,ti,kw	234
#45	torp:ab,ti,kw	285
#46	electrodes:ab,ti,kw	89269
#47	(ossicular NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	773
#48	('bone anchored' NEAR/5 (implant* OR prosthes* OR device$ OR aid$ OR neuroprosthes* OR prosthetic* OR stimulat*)):ab,ti,kw	1025
#49	#42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48	672111
#50	#41 OR #49	680452
#51	#36 AND #50	14582
#52	#23 OR #51	45480
#53	'bone conduction'/de	5208
#54	'osseointegration'/de	2018
#55	#53 OR #54	7185
#56	(bone* NEAR/3 (conduct* OR anchor* OR integrat*)):ab,ti,kw	8612
#57	(osseointegrat*:ab,ti,kw OR osseo:ab,ti,kw) AND integrat*:ab,ti,kw	1184
#58	#56 OR #57	9466
#59	#55 OR #58	13920
#60	#50 AND #59	6774
#61	#36 AND #60	1248
#62	#52 OR #61	45281
#63	#62 NOT [medline]/lim	10511
#64	#63 NOT ('conference abstract'/it OR 'conference paper'/it OR 'conference review'/it)	639
#65	'economics'/de	237982
#66	'health economics'/exp OR 'pharmacoeconomics'/de	844088

#67	econom*:ti,ab,kw OR price:ti,ab,kw OR prices:ti,ab,kw OR pricing:ti,ab,kw OR priced:ti,ab,kw OR discount*:ti,ab,kw OR expenditure*:ti,ab,kw OR budget*:ti,ab,kw OR pharmacoeconomic*:ti,ab,kw OR 'pharmaco economic*':ti,ab,kw	513905
#68	'cost'/exp	345388
#69	cost:ti OR costs:ti OR costing:ti OR costly:ti	146621
#70	'cost effective*':ti,ab,kw	180263
#71	(cost* NEAR/2 (util* OR efficacy* OR benefit* OR minimi* OR analy* OR saving* OR estimate* OR allocation OR control OR sharing OR instrument* OR technolog*)):ab	124209
#72	'economic model'/de	1920
#73	'markov chain'/de OR 'monte carlo method'/de	42841
#74	(decision NEAR/1 (tree* OR analy* OR model*)):ti,ab,kw	26378
#75	markov:ti,ab,kw OR markow:ti,ab,kw OR 'monte carlo':ti,ab,kw	71658
#76	'quality adjusted life year'/de	25425
#77	qoly:ti,ab,kw OR qolys:ti,ab,kw OR hrqol:ti,ab,kw OR hrqols:ti,ab,kw OR qaly:ti,ab,kw OR qalys:ti,ab,kw OR qale:ti,ab,kw OR qales:ti,ab,kw	44461
#78	adjusted:ti,ab,kw AND near:ti,ab,kw AND (quality:ti,ab,kw OR life:ti,ab,kw) OR ((willing* NEAR/2 pay):ti,ab,kw) OR 'sensitivity analyses':ti,ab,kw OR 'sensitivity analysis':ti,ab,kw	57273
#79	#65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77 OR #78	1594861
#80	#64 AND #79	371
#81	#80 AND [2018-2020]/py	30

Table 66 – Search strategy and results for Medline (OVID).

ID	Search (Hits)
	Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to January 07, 2020>

1	hearing aids/ (8515)
2	exp Neural Prostheses/ (10334)
3	cochlear implantation/ (6468)
4	Auditory Brain Stem Implantation/ (114)
5	1 or 2 or 3 or 4 (20683)
6	(auditory adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (5924)
7	(auditive adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (24)
8	(cochlear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (14931)
9	(middle-ear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (1050)
10	(brain-stem adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (589)
11	(otorhinolaryngology adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (47)
12	(ear adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (4403)
13	(hearing adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (13251)
14	ear mold?.ab,ti,kf. (63)
15	("bone conducti*" adj3 device?).ab,ti,kf. **(210)**
16	**(implant* adj3 neuroprosthes*).ab,ti,kf.** (131)
17	(neural adj3 prosthes*).ab,ti,kf. (589)
18	((BAHA or BAHAs or BAHS or BAHSs or BAHI or BAHIs or BAHD or BAHDs or BCHI or BCHIs) adj5 (cochlea* or implant* or device* or system*1)).ti,ab,kf. (323)
19	((Ponto or Carina or Sophono) adj5 (cochlea* or implant* or device*)).ti,ab,kf. (72)
20	(Bonebridge* or Soundbridge*).ti,ab,kf. (311)
21	softband.ab,ti,kf. (42)
22	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 (31213)
23	5 or 22 (34232)
24	exp Hearing Disorders/ (85419)
25	(hearing adj3 disorder?).ab,ti,kf. (4478)
26	dysac?usis.ab,ti,kf. (44)
27	(distorted adj3 hearing).ab,ti,kf. (8)
28	parac?usis.ab,ti,kf. (15)
29	tinnitus.ab,ti,kf. (11250)

30	hypoacus*.ab,ti,kf. (761)
31	(hearing adj2 loss).ab,ti,kf. (45580)
32	(hearing adj2 impairment).ab,ti,kf. (9287)
33	deafness.ab,ti,kf. (22023)
34	deaf?mutism.ab,ti,kf. (32)
35	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 (76475)
36	24 or 35 (110835)
37	Bone-Anchored Prosthesis/ (90)
38	"Prostheses and Implants"/ (45359)
39	Electrodes, Implanted/ (19751)
40	Implantable Neurostimulators/ (551)
41	ossicular prosthesis/ (1469)
42	37 or 38 or 39 or 40 or 41 (66620)
43	implant*.ab,ti,kf. (390381)
44	prosthes*.ab,ti,kf. (84588)
45	porp.ab,ti,kf. (200)
46	torp.ab,ti,kf. **(217)**
47	electrodes.ab,ti,kf. (76715)
48	(ossicular adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (630)
49	(bone-anchored adj5 (implant* or prosthes* or device? or aid? or neuroprosthes* or prosthetic* or stimulat*)).ab,ti,kf. (898)
50	43 or 44 or 45 or 46 or 47 or 48 or 49 (508916)
51	42 or 50 (535248)
52	36 and 51 (12801)
53	23 or 52 (35469)
54	bone conduction/ (3277)
55	Osseointegration/ (9780)
56	54 or 55 (12967)
57	(bone* adj3 (conduct* or anchor* or integrat*)).ti,ab,kf. (6983)
58	(osseointegrat* or osseo integrat*).ti,ab,kf. (9625)
59	57 or 58 (15994)
60	56 or 59 (22345)
61	51 and 60 (15593)
62	36 and 61 (1171)

63	53 or 62 (35469)
64	economics/ (27118)
65	economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (41525)
66	economics.fs. (415523)
67	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (407315)
68	exp "costs and cost analysis"/ (231538)
69	(cost or costs or costing or costly).ti. (108023)
70	cost effective*.ti,ab,kf. (130206)
71	(cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab. (81839)
72	models, economic/ (9780)
73	markov chains/ or monte carlo method/ (38968)
74	(decision adj1 (tree* or analy* or model*)).ti,ab,kf. (17589)
75	(markov or markow or monte carlo).ti,ab,kf. (64479)
76	quality-adjusted life years/ (11740)
77	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (25551)
78	((adjusted adj (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (47356)
79	64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 (1023645)
80	63 and 79 (1017)
81	limit 80 to yr="2018-Current" (136)

Appendix 4.3. Utility instruments reported in this review

EuroQol-5D (EQ-5D)

The EQ-5D is one of the most widely used instruments to measure health utility. It contains a visual analogue scale indicating general health state (scale 0–100) and questions on five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The result is a single index value for health status between -0.33 and 1.

Table 67 – EQ-5D questionnaire

Domain	Response category
Mobility	1. I have no problems in walking about 2. I have slight problems in walking about 3. I have moderate problems in walking ab 4. I have severe problems in walking abou 5. I am unable to walk about
Self-care	1. I have no problems washing or dressing 2. I have slight problems washing or dressing myself 3. I have moderate problems washing or dressing myself 4. I have severe problems washing or dressing myself 5. I am unable to wash or dress myself
Usual activities (e.g. work, study, housework, family or leisure activities)	1. I have no problems doing my usual acti 2. I have slight problems doing my usual a 3. I have moderate problems doing my usu 4. I have severe problems doing my usual 5. I am unable to do my usual activities
Pain or Discomfort	1. I have no pain or discomfort 2. I have slight pain or discomfort 3. I have moderate pain or discomfort 4. I have severe pain or discomfort 5. I have extreme pain or discomfort
Anxiety or Depression	1. I am not anxious or depressed 2. I am slightly anxious or depressed 3. I am moderately anxious or depressed 4. I am severely anxious or depressed 5. I am extremely anxious or depressed

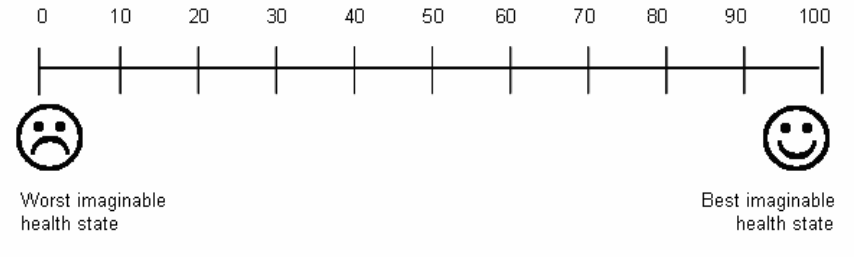
Visual Analog Scale (VAS) for general QoL

Participants are asked to rate their general QoL on a 0 to 1 scale.

Visual Analog Scale (VAS) for hearing

Participants are asked to rate their overall hearing on a 0 to 1 scale.

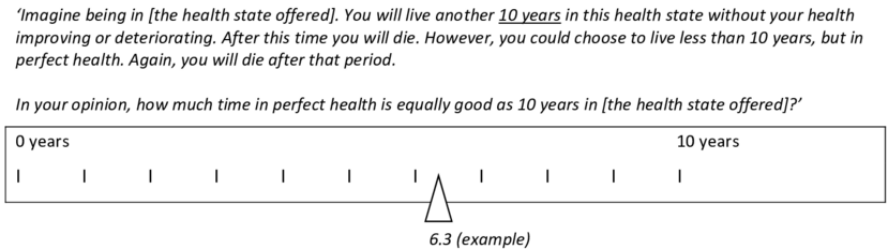
Figure 30 – Visual analogue scale (example)



Time tradeoff (TTO)

Participants are asked how many life years they are willing to give up to live the rest of their lives with perfect hearing. Based on the answer, a utility score between 0 and 1 can be calculated.

Figure 31 – Time trade-off question (example)



Health Utilities Index 3 (HUI-3)

This standardized self-reporting questionnaire measures eight elements of health status: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain. Each dimension has up to six levels. From the answers, a multi-attribute health status can be calculated, which is a utility score between 0.36 and 1. Although a generic instrument, it includes assessment of hearing and speech, particularly of relevance for evaluations of CI.

Table 68 – HUI-3 questionnaire

Attribute	Level and description
VISION	1 Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses. 2 Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses. 3 Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses. 4 Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses. 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses. 6 Unable to see at all.
HEARING	1 Able to hear what is said in a group conversation with at least three other people, without a hearing aid. 2 Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people. 3 Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid. 4 Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid. 5 Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid. 6 Unable to hear at all.
SPEECH	1 Able to be understood completely when speaking with strangers or friends. 2 Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well. 3 Able to be understood partially when speaking with strangers or people who know me well. 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well. 5 Unable to be understood when speaking to other people (or unable to speak at all).

AMBULATION	Able to walk around the neighbourhood without difficulty, and without walking equipment. 2 Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person. 3 Able to walk around the neighbourhood with walking equipment, but without the help of another person. 4 Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood. 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood. 6 Cannot walk at all.
DEXTERITY	1 Full use of two hands and ten fingers. 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person. 3 Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person). 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools). 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools). 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).
EMOTION	1 Happy and interested in life. 2 Somewhat happy. 3 Somewhat unhappy. 4 Very unhappy. 5 So unhappy that life is not worthwhile.
COGNITION	1 Able to remember most things, think clearly and solve day to day problems. 2 Able to remember most things, but have a little difficulty when trying to think and solve day to day problems. 3 Somewhat forgetful, but able to think clearly and solve day to day problems. 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems. 5 Very forgetful, and have great difficulty when trying to think or solve day to day problems. 6 Unable to remember anything at all, and unable to think or solve day to day problems.
PAIN	1 Free of pain and discomfort. 2 Mild to moderate pain that prevents no activities. 3 Moderate pain that prevents a few activities. 4 Moderate to severe pain that prevents some activities. 5 Severe pain that prevents most activities.

Short Form – 36 (SF-36)

To measure health related quality of life. The instrument contains scales for physical functioning, social functioning, role limitation (physical, emotional), methal health, energy, pain and general health. A high score complies with a better quality of life and health.

Table 69 – SF-36 domains and items

Domain	Items
Physical functioning	Vigorous activities Moderate activities Lift, carry groceries Climb several flights Climb one flight Bend, kneel Walk mile Walk several blocks Walk one block Bathe, dress
Role-physical	Cut down time Accomplished less Limited in kind Had difficulty Pain-magnitude Pain-interfere
Bodily pain	Pain-magnitude Pain-interfere
General health	General health rating Excellent As healthy as anyone Sick easier Health worse
Vitality	Pep/life Energy Worn out Tired
Social functioning	Social-extent Social-time
Role-emotional	Cut down time Accomplished less Not careful
Mental health	Nervous Down in dumps Peaceful Blue/sad Happy
Health transition	Change in health last year

APPENDIX 5. APPENDIX TO THE DATA ANALYSIS

Appendix 5.1. RIZIV/INAMI REIMBURSEMENT CODES AND FEES

Table 70 – Nomenclature list of hearing aids and bone anchored devices (non-implantable part).

dB hearing loss	Description	Speech audiometry possible?	Before 2019		From 2019		
			< 18y old	≥ 18y old	< 18y old	18y – 64y old	≥ 65y old
≥ 40 dB	Monophonic device	Yes	679151 679162	679136 679140	679151 679162	705515 705526	705530 705541
		No	679276 679280	679254 679265	679276 679280	705773 705784	705795 705806
	Stereophonic device	Yes	679195 679206	679173 679184	679195 679206	705552 705563	705574 705585
		No	679313 679324	679291 679302	679313 679324	705810 705821	705832 705843
	Contralateral compared to previous device in order to change towards stereophonic device	Yes	679232 679243	679210 679221	679232 679243	705596 705600	705611 705622
		No	679350 679361	679335 679346	679350 679361	705854 705865	705876 705880
	Additional fee per ear with bone anchored device	Yes	679070 679081				
		No	679372 679383				
	Additional fee for the first bone anchored device	Yes			705655 705666	705670 705681	705692 705703
		No			705913 705924	705935 705946	705950 705961
	Additional fee for renewal of the bone anchored device	Yes			705714 705725	705736 705740	705751 705762
		No			705972 705983	706510 706521	706532 706543
	Additional fee per ear with bone conduction without bone anchored device	Yes				705633 705644	
		No				705891 705902	
	Additional fee for the microphone (wired or wireless) for a CROS/BICROS adjustment	Yes	679416 679420			679416 679420	
		No	679431 679442			679431 679442	
< 40 dB	Monophonic device	Yes	679652 679663	679630 679641	679652 679663	706554 706565	706576 706580
		No	679792 679803	679770 679781	679792 679803	706812 706823	706834 706845

	Stereophonic device	Yes	679696 679700	679674 679685	679696 679700	706591 706602	706613 706624
		No	679836 679840	679814 679825	679836 679840	706856 706860	706871 706882
	Contralateral compared to previous device in order to change towards stereophonic device	Yes	679733 679744	679711 679722	679733 679744	706635 706646	706650 706661
		No	679873 679884	679851 679862	679873 679884	706893 706904	706915 706926
	Additional fee per ear with bone anchored device	Yes	679755 679766				
		No	679895 679906				
	Additional fee for the first bone anchored device	Yes			706694 706705	706716 706720	706731 706742
		No			706952 706963	706974 706985	707512 707523
	Additional fee for renewal of the bone anchored device	Yes			706753 706764	706775 706786	706790 706801
		No			707534 707545	707556 707560	707571 707582
	Additional fee per ear with bone conduction without bone anchored device	Yes				706672 706683	
		No				706930 706941	
	Additional fee for the microphone (wired or wireless) for a CROS/BICROS adjustment	Yes				679954 679965	
		No				679976 679980	
Fee for the material costs made by the audicien in case the device is not purchased by the patient after the initial tests	≥ 40 dB				679615 679626		
	< 40 dB				679910 679921		

Source: RIZIV/INAMI (nomensoft: https://www.inami.fgov.be/fr/programmes-web/Pages/NomenSoft.aspx). Last consultation on the 01.09.2020.

Table 71 – Nomenclature fees for conventional hearing aids and bone anchored devices (non-implantable part) from 01.01.2020

Age (y)	Description	Nomenclature fee	Reimbursement	Co-payment
< 18	Monophonic	€1 203.66	Full	€0
	Stereophonic	€2 382.99	Full	€0
	Contralateral	€1 179.93	Full	€0
	Additional fee first BCD with bone anchoring	€1 658.61	Full	€0
	Additional fee renewal BCD with bone anchoring	€1 092.69	Full	€0
18-64	Monophonic	€779.34	€733.16	€46.18
	Stereophonic	€1 543.69	€1 451.26	€92.43
	Contralateral	€764.35	€718.17	€46.18
	Additional fee first BCD with bone anchoring	€740.32	Full	€0
	Additional fee renewal BCD with bone anchoring	€443.13	Full	€0
≥ 65	Monophonic	€740.32	€694.14	€46.18
	Stereophonic	€1 466.41	€1 373.98	€92.43
	Contralateral	€726.08	€679.90	€46.18
	Additional fee first BCD	€740.32	Full	€0
	Additional fee renewal BCD	€443.13	Full	€0
	Additional fee per ear with bone conduction without bone anchored device (softband or with magnet)	€99.66	Full	€0
	Additional fee for the microphone (wired or wireless) for a CROS/BICROS adjustment	€129.91	Full	€0

Source: RIZIV/INAMI (nomensoft: https://www.inami.fgov.be/fr/programmes-web/Pages/NomenSoft.aspx). Last consultation on the 01.09.2020.

Table 72 – Nomenclature codes and fees for implantable part of bone conduction devices (years 2014-2020).

Nomenclature	Description	2014	2015	2016	2017	2018	2019	2020
258495 258506	Placement of a hearing prosthesis with bone anchor, in the temporal bone in one or two operations	304.80	304.80	304.80	307.33	311.94	311.94	315.84
153193 153204	Implants used to place a hearing prosthesis with bone anchor in the temporal bone, the first fixation point, including all attachments and jackhammer.	1 139.16	1 139.16	1 139.16	1 139.16	1 128.34	1 128.34	1 128.34
153215 153226	Implants used to place the hearing prosthesis with bone anchor in the temporal bone, the second (sleeping) fixation point, inclusive all attachments and jackhammer.	320.32	320.32	320.32	320.32	317.28	317.28	317.28
153230 153241	Replacement of the abutment for BCD	914.93	914.93	914.93	914.93	906.24	906.24	906.24

Source: RIZIV/INAMI (nomensoft: https://www.inami.fgov.be/fr/programmes-web/Pages/NomenSoft.aspx). Last consultation on the 01.09.2020.

Table 73 – Nomenclature codes and fees for the middle ear implant (years 2014-2020).

Nomenclature	Description	2014	2015	2016	2017	2018	2019	2020
255312 255323	Functional surgery of the ossicular chain or surgical intervention for fenestration	-	846.68	846.68	853.71	866.51	866.51	877.34
172336 172340	Kit containing a full hearing device (including the implantable as well as the non-implantable speech processor) to stimulate the perception of sound through inducing vibrations in an electromagnetic mass, attached to one of the ossicles, the oval or the round window	-	9 460.5	9 460.5	9 460.5	9 460.5	9 370.63	9 370.63
172351 172362	Replacement of the speech processor of the MEI	-	2 407.08	2 407.08	2 407.08	2 407.08	2 384.21	2 384.21
172373 172384	Replacement of the implantable part of the MEI to stimulate the perception of sound through inducing vibrations in an electromagnetical mass, attached to one of the ossicles, the oval window or the round window	-	5 914.80	5 914.80	5 914.80	5 858.61	5 858.61	5 858.61

Source: RIZIV/INAMI (nomensoft: https://www.inami.fgov.be/fr/programmes-web/Pages/NomenSoft.aspx). Last consultation on the 01.09.2020.

Table 74 – Nomenclature codes and fees for a cochlear implant (years 2014-2020).

Nomenclature	Description	2014	2015	2016	2017	2018	2019	2020*
258263 258252	Placement of a cochlear prosthesis	1 058.35	1 058.35	1 058.35	1 067.13	1 083.14	1 083.14	1 096.68
152935 152946	Kit containing a full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes for children < 8 years old.	20 152.29	20 152.29	20 152.29	20 152.29	19 960.84	19 960.84	15 983.84
152950 152961	Kit containing a full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes for children ≥ 8 years old.	20 539.97	20 539.97	20 539.97	20 539.97	20 344.84	20 344.84	15 983.84
153016 153020	Kit to replace the non-implantable part for children < 8 years old.	6 484.58	6 484.58	6 484.58	6 484.58	6 422.98	6 422.98	5 138.38
153031 153042	Kit to replace the non-implantable part for children ≥ 8 years old	6 872.26	6 872.26	6 872.26	6 872.26	6 806.97	6 806.97	5 138.38
153090 153101	Replacement of the implantable part of the cochlear implant for electrical intracochlear stimulation with multiple electrodes (without speech processor)	13 667.72	13 667.72	13 667.72	13 667.72	13 537.88	13 537.88	10 845.46
152972 152983	Kit containing a second full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes placed simultaneously or sequentially with the hearing device under 152935-152946 or 170811-170822 for children < 8 years old.	15 211.14	15 211.14	15 211.14	15 211.14	15 066.63	15 066.63	15 983.84
152994 153005	Kit containing a second full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes placed simultaneously or sequentially with the hearing device under 152935-152946, 152950-152961, 170811-170822, 170833-170844 for children 8 to 12 years old.	15 598.82	15 598.82	15 598.82	15 598.82	15 450.63	15 450.63	15 983.84
153053 153064	Kit containing the replacement of the non-implantable part of the contralateral ear for children < 8 years old.	4 960.36	4 960.36	4 960.36	4 960.36	4 913.24	4 913.24	5 138.38

153075 153086	Kit containing the replacement of the non-implantable part of the contralateral ear for children ≥ 8 years old.	5 348.04	5 348.04	5 348.04	5 348.04	5 297.23	5 297.23	5 138.38
153112 153123	Replacement of the implantable part of a contralateral cochlear implant for electrical intracochlear stimulation with multiple electrodes (without speech processor)	10 250.79	10 250.79	10 250.79	10 250.79	10 153.41	10 153.41	10 845.46
170811 170822	Kit containing a full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes for children < 8 years old with asymmetrical bilateral hearing loss.	20 152.29	20 152.29	20 152.29	20 152.29	19 960.84	19 960.84	15 983.84
170833 170844	Kit containing a full hearing device (implantable and non-implantable parts) for electrical intracochlear stimulation with multiple electrodes for children 8 to 12 years old with asymmetrical bilateral hearing loss.	20 539.97	20 539.97	20 539.97	20 539.97	20 344.84	20 344.84	15 983.84

Source: RIZIV/INAMI (nomensoft: https://www.inami.fgov.be/fr/programmes-web/Pages/NomenSoft.aspx). Last consultation on the 01.09.2020.

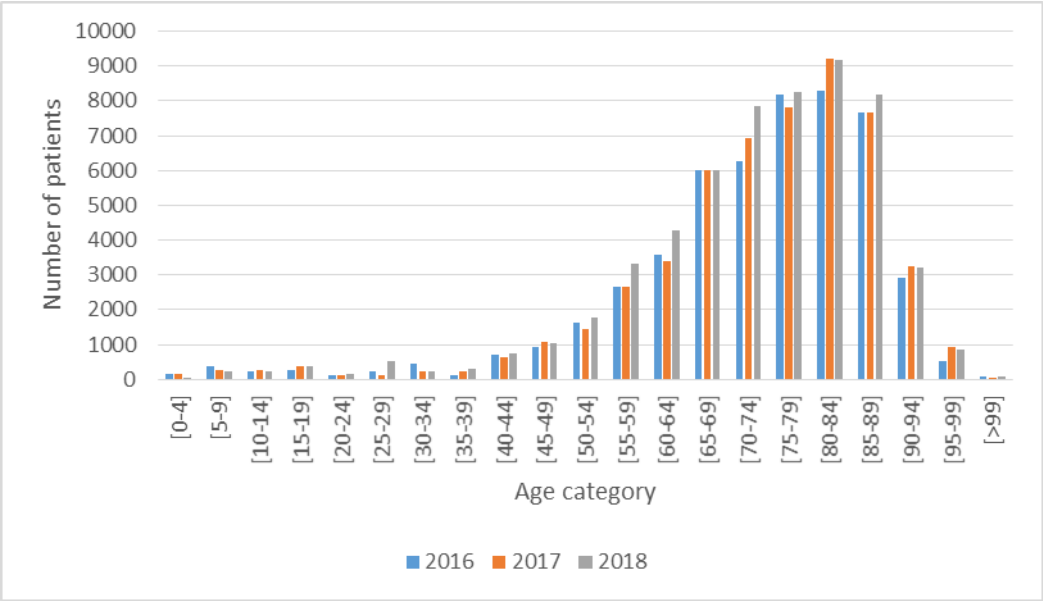
Appendix 5.2. Number of patients

Table 75 – Number of patients with hearing aids by year (in thousand)

	2016	2017	2018
Number of patients [95%CI]	51.4 [49.5;53.4]	52.8 [50.8;54.8]	56.9 [54.8;59.0]
Gender (% female)	49.1%	51.3%	52.6%

Source: extrapolation from EPS, CI: confidence interval

Figure 32 – Distribution of patients with conventional hearing aids by age category for the years 2014-2018



Source: extrapolation from EPS

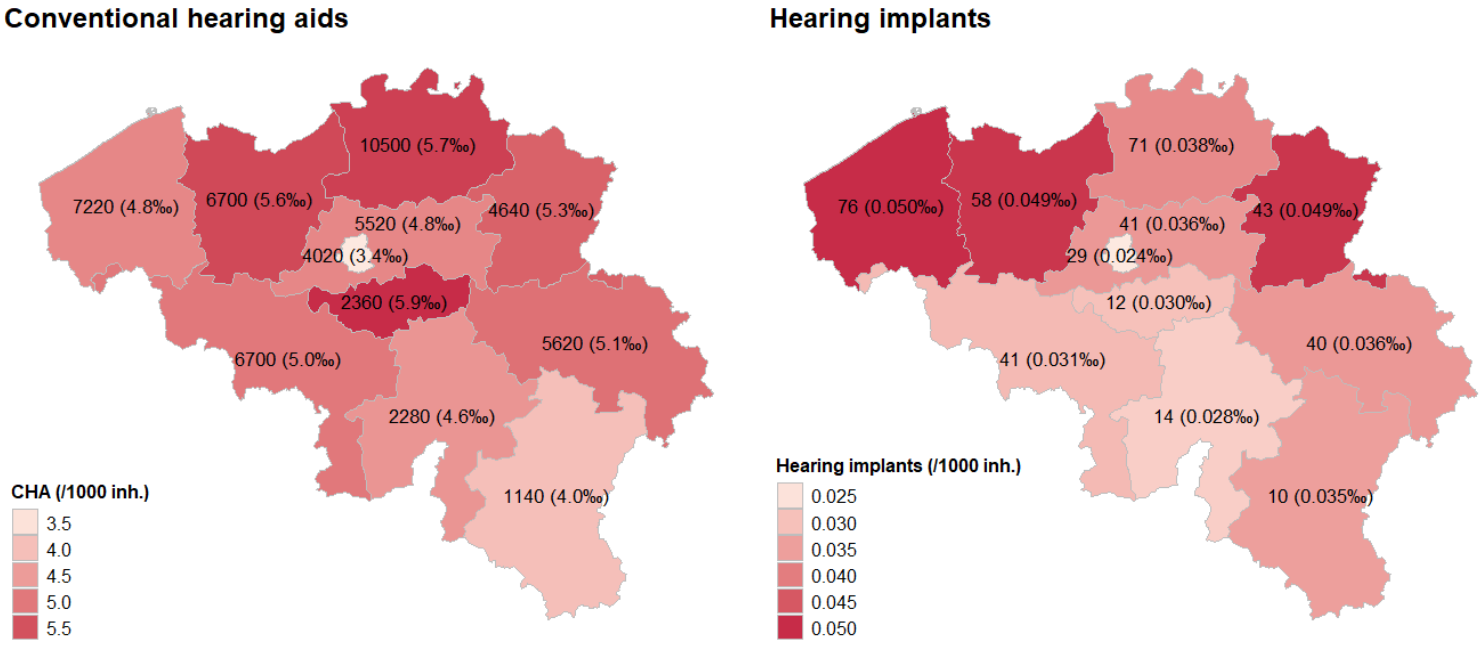
Appendix 5.3. Accessibility

Table 76 – Amount of patients with conventional hearing aids or hearing implants by number of inhabitants in Belgium and region.

Year		BELGIUM	REGION		
			BRUSSELS CAPITAL REGION	WALLONIA	FLANDERS
2016	Inhabitants	11 267 910	1 187 890	3 602 216	6 477 804
	CHA	51 360 (4.6‰)	3 760 (3.2‰)	16 460 (4.6‰)	31 140 (4.8‰)
	BCD	170 (0.015‰)	7 (0.006‰)	18 (0.005‰)	145 (0.022‰)
	CI	269 (0.024‰)	30 (0.025‰)	91 (0.025‰)	148 (0.023‰)
	MEI	26 (0.002‰)	1 (0.001‰)	12 (0.003‰)	13 (0.002‰)
2017	Inhabitants	11 322 088	1 191 604	3 614 473	6 516 011
	CHA	52 600 (4.6‰)	3 600 (3.0‰)	17 600 (4.9‰)	31 400 (4.8‰)
	BCD	143 (0.013‰)	4 (0.003‰)	26 (0.007‰)	113 (0.017‰)
	CI	302 (0.027‰)	32 (0.027‰)	98 (0.027‰)	172 (0.026‰)
	MEI	25 (0.002‰)	0 (0.0‰)	15 (0.004‰)	10 (0.002‰)
2018	Inhabitants	11 376 070	1 198 726	3 624 377	6 552 967
	CHA	56 700 (5.0‰)	4 020 (3.4‰)	18 100 (5.0‰)	34 580 (5.3‰)
	BCD	123 (0.011‰)	5 (0.004‰)	18 (0.005‰)	100 (0.015‰)
	CI	282 (0.025‰)	22 (0.018‰)	84 (0.023‰)	176 (0.027‰)
	MEI	30 (0.003‰)	2 (0.002‰)	15 (0.004‰)	13 (0.002‰)

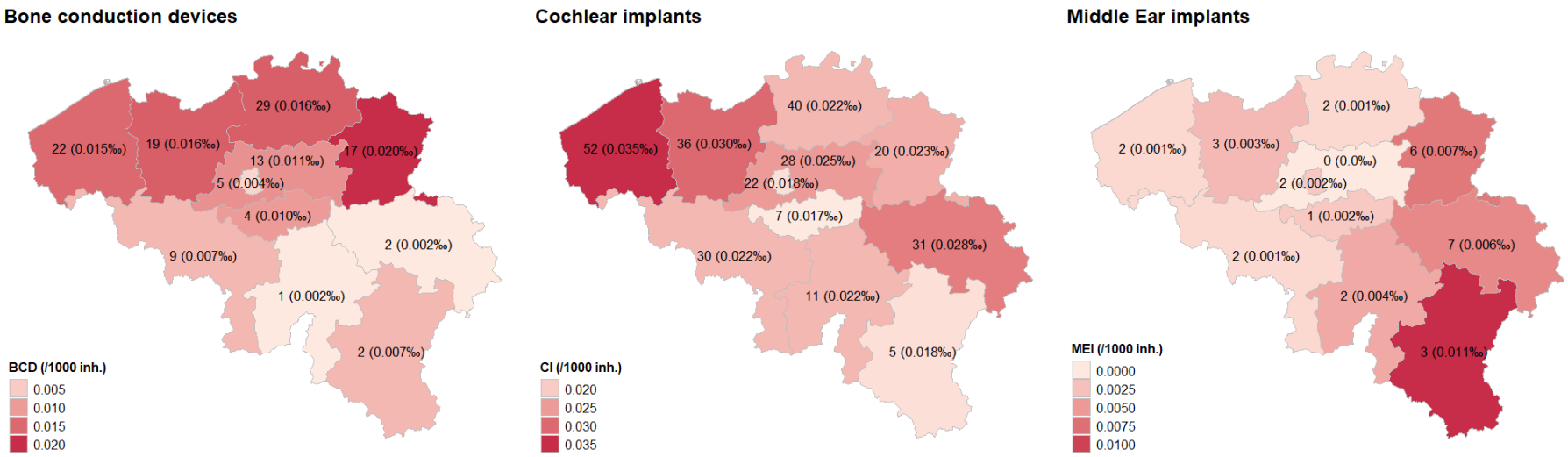
Source: EPS, TCT, Statbel. CHA: Conventional Hearing Aids, BCD: Bone Conduction Device, CI: Cochlear Implant, MEI: Middle Ear Implant.

Figure 33 – Amount of conventional hearing aids and hearing implants per 1000 inhabitants by province for the year 2018 in Belgium



Source: EPS, MZG-RHM

Figure 34 – Amount of BCD, CI and MEI implants per 1000 inhabitants by province for the year 2018 in Belgium



Source: MZG-RHM

Appendix 5.4. Pre and post-procedural costs

From the IMA-IAM data, all patients who had a cochlear or a bone conduction device implant between 2014 and 2018 were selected. For all these patients, the one-year pre- and the 5-years post-related reimbursed costs were categorized into 5 categories:

- ENT consultation: all reimbursed costs dispensed by ENT specialist. It includes consultations, examinations and treatments realized by ENT specialist (such as speech audiometry, pure-tone audiometry, tympanoscopy).
- ENT Prescriptions related costs: all reimbursed costs that were prescribed by ENT specialist. It includes imagery as MRI or CT-scanner, blood analysis, physiotherapy, conventional hearing aids ...
- Speech therapy: all reimbursed costs dispensed by a speech therapist
- Center for ambulatory reeducation: all reimbursed costs dispensed in ambulatory or specialized rehabilitation centres.
- Replacement of the non-implantable part: selection of the specific nomenclature codes (Appendix 5.1)

The hospitalisation costs (which consisted on selection of all reimbursed costs one day before, to 5 days after the intervention) were isolated but not detailed, because the analysis has already been described on the TCT data (6.6.1 Procedural phase). As well as the costs for the replacement of the implantable part were also not detailed because there were not enough patients (<2) in this case.

The rules applying to retrieve the data are presented in Table 77.

Table 77 – RIZIV/INAMI nomenclature for selection of costs components

Description	Nomenclature used
ENT specialist	*Health care qualification* corresponds to 410: Ear, Nose and Throat (ENT) Specialist *Health care qualification* corresponds to 41: Junior ENT specialist *Health care qualification* corresponds to 414: ENT specialist with a licence for functionnal and professional rehabilitation of persons with disabilities
ENT Prescriptions related costs	*Prescribers* corresponds to 410: Ear, Nose and Throat (ENT) Specialist *Prescribers* corresponds to 41: Junior ENT specialist *Prescribers* corresponds to 414: ENT specialist with a licence for functionnal and professional rehabilitation of persons with disabilities selected
Speech therapy	*nomen group n* = N84: Speech therapy
Center for ambulatory reeducation	*nomen group a* = 59: rehabilitation and re-education (6th state reform) *detailed nomen group a* = 59021 or 59046 or 59054: ENT or ENT-PSY or hearing impaired

Table 78 – Mean costs components of one year pre and global post hospitalisation for unilateral cochlear implant according to age and deafness (in euro).

		ENT costs		ENT prescriptions		Language therapy		Rehabilitation centres		Replc. Voice Processor	
	n	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.
Asymetric deafness – Age <8years											
1 year Pre-impl.	26	449	97	706	17	142	38	4 340	4	0	0
1 year Post-impl.	26	443	56	369	2	175	44	5 113	9	0	0
2 year Post-impl.	16	717	81	438	3	554	122	9 581	18	0	0
3 year Post-impl.	8	711	59	579	2	0	0	10 881	12	0	0
4 year Post-impl.	5	585	94	924	0	0	0	7 667	20	0	0
5 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Post-impl. (gobal)	26	577	71	547	3	504	104	8 325	12	0	0
Asymetric deafness – Age ≥8years											
1 year Pre-impl.	22	343	39	569	10	105	19	6 263	7	0	0
1 year Post-impl.	22	406	31	21	3	102	17	6 784	11	0	0
2 year Post-impl.	13	579	51	477	5	0	0	11 932	26	0	0
3 year Post-impl.	6	470	42	964	0	0	0	10 565	45	0	0
4 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
5 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Post-impl. (gobal)	22	467	37	337	3	139	28	8 717	16	0	0
Bilateral deafness, One implant – Age <8years											
1 year Pre-impl.	101	448	46	793	17	57	10	4324	6	0	0
1 year Post-impl.	101	421	23	278	8	80	11	6457	5	0	0
2 year Post-impl.	52	638	40	465	12	186	28	13892	14	0	0
3 year Post-impl.	73	725	44	507	16	318	52	21228	27	0	0
4 year Post-impl.	38	600	40	696	23	362	51	26896	36	4136	0
5 year Post-impl.	24	708	47	668	29	0	0	39209	30	4929	0
Post-impl. (gobal)	101	666	38	511	11	250	38	17310	19	1819	0
Bilateral deafness, One implant – Age ≥8years											
1 year Pre-impl.	835	391	65	425	33	10	2	524	1	0	0
1 year Post-impl.	835	384	58	144	23	107	20	3342	5	0	0
2 year Post-impl.	643	552	78	236	42	210	37	5239	9	0	0
3 year Post-impl.	475	696	93	282	52	280	47	6059	10	0	0
4 year Post-impl.	318	798	99	317	59	343	55	6478	11	0	0
5 year Post-impl.	155	867	96	386	77	394	64	7133	14	0	0
Post-impl. (gobal)	835	584	82	273	47	218	37	4991	9	0	0

Source: IMA – IAM. ENT: Ear Nose Throat.

Table 79 – Mean costs components of one year pre and global post hospitalisation for bilateral cochlear implant according to age and deafness (in euro).

		ENT costs		ENT prescriptions		Language therapy		Rehabilitation centres		Replc. Voice Processor	
	n	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.
Sequential bilateral cochlear implantation, age<8years											
1 year Pre-impl.	127	630	82	707	42	38	8	3323	1	0	0
Between both implants	127	317	34	132	6	83	16	4476	-12	0	0
1 year Post-impl.	127	468	33	38	5	207	28	7322	4	0	0
2 year Post-impl.	115	683	42	68	8	443	58	13182	7	392	0
3 year Post-impl.	90	797	49	94	11	652	86	17522	8	2141	0
4 year Post-impl.	56	867	43	137	13	999	115	22368	11	5681	0
5 year Post-impl.	27	775	55	110	16	944	132	26942	22	7705	0
Post-impl. (gobal)	127	740	47	81	10	556	71	14645	9	2505	0
Simultaneous bilateral cochlear implantation, age <8years											
1 year Pre-impl.	50	526	87	589	22	78	10	3354	6	0	0
1 year Post-impl.	50	287	27	25	3	156	15	7910	8	0	0
2 year Post-impl.	37	396	29	27	4	255	25	17847	18	0	0
3 year Post-impl.	26	454	31	39	5	429	42	28221	29	0	0
4 year Post-impl.	13	694	53	76	6	0	0	29033	6	7933	0

5 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Post-impl. (gobal)	50	436	36	34	5	387	36	20649	18	2063	0
Age ≥8years (include sequential and simultaneous bilateral cochlear implantation)											
1 year Pre-impl.	10	296	29	180	8	437	79	5043	5	0	0
Between both implants	7	294	24	0	0	0	0	3721	1	0	0
1 year Post-impl.	10	238	16	0	0	0	0	4708	1	0	1244
2 year Post-impl.	9	179	18	0	0	0	0	8811	1	0	1262
3 year Post-impl.	7	131	6	0	0	0	0	13654	0	0	1457
4 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
5 year Post-impl.	<3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Post-impl. (gobal)		242	16	0	0	0	0	9786	1	0	6304

Source: IMA – IAM. ENT: Ear Nose Throat.

Table 80 – Mean costs components of one year pre and global post hospitalisation for bone conduction devices (in euro).

		ENT costs		ENT prescriptions		Language therapy		Rehabilitation centres	
	n	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.	Reimb.	Copaym.
1 year Pre-implantation	687	281	65	232	30	28	7	160	0
Between both implants	40	12	5	28	13	0	0	0	0
1 year Post- implantation	687	175	60	684	274	27	8	98	0
Up to 5-year post- implantation	687	345	95	828	301	64	18	232	1

Source: IMA – IAM. ENT: Ear Nose Throat.

APPENDIX 6. APPENDIX TO THE INTERNATIONAL COMPARISON

Appendix 6.1. Swiss registry on cochlear implants: some examples of included results.

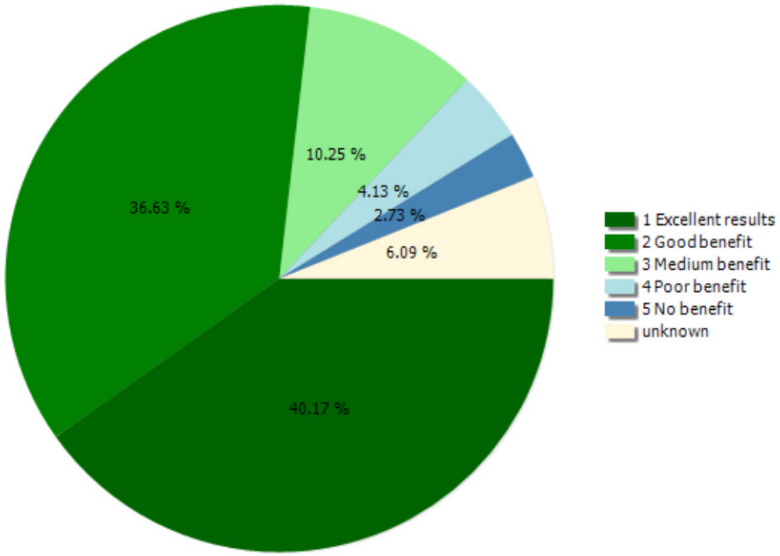
Table 81 – Number of bilateral cochlear implantations in Switzerland until 2018 (inclusive)

Interval vs Age Group

Interval yrs	00 to 03	03 to 12	12 to 18	18 to 65	65 to 99	Total
0	192	47	3	25	2	269
1	29	38	2	62	3	134
2	1	32	6	33	6	78
3	0	25	4	27	10	66
4	0	17	4	27	4	52
5	0	19	4	13	3	39
6	0	15	2	10	2	29
7	0	8	4	13	0	25
8	0	4	4	14	0	22
9	0	1	4	2	4	11
10	0	0	5	8	0	13
11	0	0	3	6	0	9
12	0	0	2	6	1	9
13	0	0	0	6	1	7
14	0	0	0	1	2	3
15	0	0	0	4	0	4
16	0	0	0	1	0	1
17	0	0	0	2	0	2
18	0	0	0	5	0	5
19	0	0	0	2	1	3
20	0	0	0	1	0	1
21	0	0	0	1	0	1
22	0	0	0	1	0	1
23	0	0	0	1	0	1
24	0	0	0	1	0	1
Total	222	206	47	272	39	786

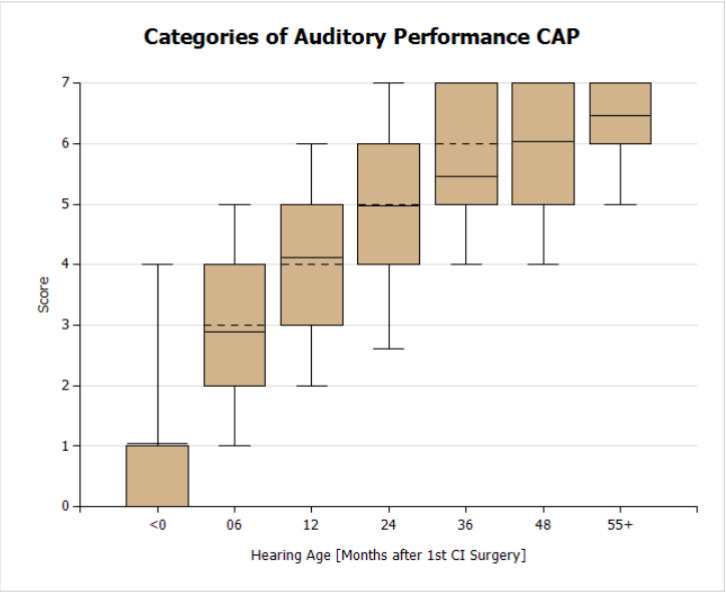
Source: https://www.orl-hno.ch/fileadmin/user_upload/Dokumente/Fuer_Patienten/Informationen_Links/CI-Richtlinien/CIREG2018.pdf

Figure 35 – Subjective evaluation of cochlear implantation success in the Swiss registry for CI (2018)



Source: https://www.orl-hno.ch/fileadmin/user_upload/Dokumente/Fuer_Patienten/Informationen_Links/CI-Richtlinien/CIREG2018.pdf

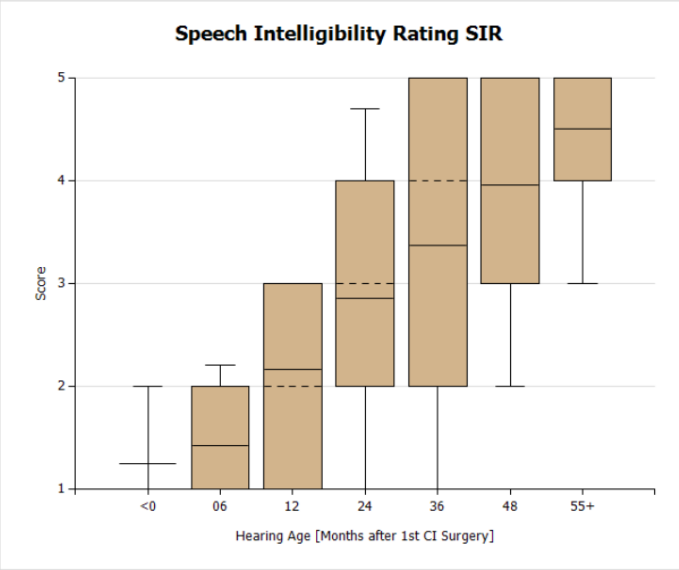
Figure 36 – Categories of Auditory Performance CAP results in the Swiss registry for CI (2018)



0 No awareness of environmental sound
1 Awareness of environmental sounds
2 Responds to speech sounds
3 Recognizes environmental sounds
4 Discriminates at least two speech sounds
5 Understands common phrases without lip reading
6 Understands conversation without lip reading with a familiar talker
7 Can use the telephone with a familiar talker

Source: https://www.orl-hno.ch/fileadmin/user_upload/Dokumente/Fuer_Patienten/Informationen_Links/CI-Richtlinien/CIREG2018.pdf

Figure 37 – Speech Intelligibility Rating (SIR) results in the Swiss registry for cochlear implants (2018)



1 Prerecognizable words in spoken language (the child's primary mode of everyday communication may be manual)
2 Connected speech is unintelligible; intelligible speech is developing in single words when context and lip reading cues are available
3 Connected speech is intelligible to a listener who concentrates and lip-reads within a known context
4 Connected speech is intelligible to a listener who has little experience of a deaf person's speech; the listener does not need to concentrate unduly
5 Connected speech is intelligible to all listeners; the child is understood easily in everyday contexts

Source: https://www.orl-hno.ch/fileadmin/user_upload/Dokumente/Fuer_Patienten/Informationen_Links/CI-Richtlinien/CIREG2018.pdf

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