Bone Conduction Hearing Implants

for patients with conductive or mixed hearing loss

Technology Guidance from the MOH Medical Technology Advisory Committee (MTAC)

Guidance Recommendations

The Ministry of Health's MTAC has recommended subsidy for:

a. Unilateral bone conduction hearing implant (BCHI) system in patients if they are:
   - Diagnosed with moderate-to-severe conductive hearing loss (CHL) or mixed hearing loss (MHL) in one or both ears; AND
   - Assessed by the attending healthcare professional to be:
     - Ineligible, or did not sufficiently benefit from surgery, conservative treatment, or conventional hearing aid; AND
     - Showing stable bone conduction thresholds (≤15 dB deterioration in more than two frequencies over at least a six-month period).

b. Unilateral bone conduction wearables (i.e. bone conduction sound processor with soft-band or headband) in children younger than five years old or without adequate mastoid thickness to support an implant if they are:
   - Diagnosed with moderate-to-severe CHL or MHL in one or both ears; AND
   - Assessed by the attending healthcare professional to be:
     - Ineligible, or did not sufficiently benefit from surgery, conservative treatment, or conventional hearing aid; AND
     - Showing stable bone conduction thresholds (≤15 dB deterioration in more than two frequencies over at least a six-month period), unless there are special clinical conditions deemed appropriate by the attending healthcare professional to warrant immediate fitting of the bone conduction wearables (e.g. children born with microtia or congenital aural atresia).

c. Patients with moderate-to-severe CHL or MHL in one or both ears who had previously received subsidised bone conduction wearables can be eligible for subsidy of unilateral BCHI system if deemed by the attending healthcare professional to be clinically suitable and likely to receive sufficient benefit from BCHI system.

d. Children (<18 years old) with moderate-to-severe CHL or MHL in one or both ears who are using BCHI system or bone conduction wearables can be eligible for subsidy for the replacement of BCHI sound processors (including replacement with or without upgrade

where an upgrade refers to a change to a later model than currently used by the individual) if the following criteria are met:

- The child is deemed by the attending healthcare professional to be receiving sufficient benefits from BCHI, and demonstrating continued need for BCHI; AND
- The existing BCHI sound processor has been used for at least five years, and its deterioration in performance is deemed by the attending healthcare professional to warrant replacement for achieving optimal hearing.

Subsidy status

BCHI and bone conduction wearables are recommended for inclusion on the MOH Medical Technology Subsidy List (MTSL). Listed models are recommended for subsidy when used in line with the abovementioned recommendations.

Subsidies will not apply to devices and accessories that are not included in the standard or replacement packages of BCHI devices, including replacement of, or upgrades to, internal implants.

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Factors considered to inform the recommendations for subsidy

Technology evaluation

1.1 The MOH MTAC ("the Committee") considered evidence presented for the technology evaluation of (i) BCHI for patients with moderate-to-severe CHL or MHL; and (ii) bone conduction wearables (i.e. bone conduction sound processor with soft-band or headband) for children (<18 years old) with moderate-to-severe CHL or MHL. The evaluation was conducted in consultation with clinical experts from the public healthcare institutions. Available clinical and economic evidence for BCHI and bone conduction wearables was considered in line with the registered indication.

1.2 The evidence was used to inform the Committee's deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Overall benefit of the technology to the patient and/or the system;
- Cost-effectiveness (value for money), which covers the incremental benefit and cost of the technology compared to existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology;
- Organisational feasibility, which covers the potential impact of adopting technology, especially barriers for diffusion.

1.3 Additional considerations, such as ethical or social issues related to adoption of the technology, may also inform the Committee's deliberations.

Clinical need

2.1 Hearing loss can be classified as CHL, MHL or sensorineural hearing loss (SNHL) depending on whether it is affected by either conductive or sensorineural hearing pathways, or both. Individuals with CHL or MHL can be at risk of poor language development in children, and social isolation. In Singapore, local studies estimated 422,000 elderly with hearing loss in 2017, and 3,000 individuals with congenital hearing loss aged 19 years and below in 2005.

2.2 Patients with moderate-to-severe CHL or MHL may be managed by receiving corrective surgery, medical therapy, or conventional hearing aids. In those who are medically unsuitable or unable to derive sufficient benefit from these

modalities, BCHI can be an alternative in patients with moderate-to-severe CHL or MHL.

2.3 BCHI comprises an implant and an external sound processor. The transmitter is surgically implanted in the mastoid bone behind the ear to transmit sound vibrations through the bone to the cochlear. To transfer sounds to the transmitter, the external sound processor either transmits sound directly to the transmitter via an abutment or magnetically without an abutment. Sound vibrations can then directly stimulate the bone, or pass through the skin before reaching the bone.

2.4 Bone conduction wearable comprises the external sound processor from a BCHI system attached to a soft-band or headband. It works by transmitting sound vibrations through the skin. As a precursor to the full BCHI system, bone conduction wearables are used in patients with CHL or MHL who are younger than five years old or have insufficient mastoid bone thickness to support an implant. In local clinical practice, bone conduction wearables are mainly used in children younger than five years old until their mastoid bones are thick enough to support the implant component of BCHI.

2.5 BCHI and bone conduction wearables can be offered to patients with moderate-to-severe CHL or MHL who are contraindicated to or did not sufficiently benefit from appropriate surgery, medical therapy, or conventional hearing aids.

Clinical effectiveness and safety

3.1 The Committee agreed that for patients with moderate-to-severe CHL or MHL, the main comparator for BCHI or bone conduction wearables was no treatment.

3.2 The Committee noted that the evidence base on clinical effectiveness and safety comprised two health technology assessment (HTA) reports and five additional systematic reviews. The evidence mostly included studies without further sub-group analyses by age group (i.e. adults, children), and some were in mixed populations (CHL or MHL, single-sided deafness [SSD]). Most evidence was from case series, case report or registry, and any comparative evidence was based on before-and-after implantation data.

3.3 In patients with CHL or MHL, the Committee noted that BCHI was likely to be safe as the evidence reported infrequent major adverse events (≤5%) such as ischemia of the earlobe and mastoiditis.

3.4 For clinical effectiveness, when compared to no treatment, the Committee noted that BCHI consistently showed clinically important improvements in functional gain (a measure of hearing improvement between aided and un-aided under specific testing conditions). Although some evidence also showed that BCHI improved hearing-specific quality of life (QoL) and speech audiometry measures (e.g. speech perception in quiet environment), such evidence was rather sparse, inconsistent, or difficult to determine if the change was clinically important.

3.5 The Committee noted that a case series in 40 infants who received bone conduction wearables showed clinically meaningful improvements from baseline in audiology threshold, and audiology and speech development for the first three months, which approximated normal hearing levels for the remaining study follow-up period of 24 months. The Committee agreed that in patients with CHL and MHL, compared to no treatment, the benefits of improved hearing from BCHI were likely to outweigh its risks.

3.6 The Committee noted that key limitations of the clinical evidence as low level, small study size, and variable definitions or measurement tools used across studies. The inconsistent measurement tools and reporting also made it difficult to determine the clinical importance of changes. These contributed to the high level of heterogeneity observed in the evidence.

Cost-effectiveness

4.1 The Committee noted that the cost-effectiveness evidence was based on published literature, and no local cost-effectiveness analysis was conducted. One published cost-effective analysis comparing BCHI with continued conventional hearing aid reported an incremental cost-effectiveness ratio (ICER) of about £18K per quality-adjusted life year (QALY) gained in a mixed adult population with CHL or MHL (55%), SSD (44%) and bilateral SNHL (1%).

4.2 The Committee noted that another published study by Health Quality Ontario (Canada), comparing BCHI with no treatment in patients with CHL or MHL reported an ICER of CAD$88K per QALY gained in children and about CAD$74K per QALY gained in adults.

4.3 The Committee noted that published ICER was most sensitive to between-group difference in improvement in utilities from baseline. The Committee agreed that the published cost-effectiveness evidence was uncertain mainly because the utilities applied were based on two small studies (n= 50 to 89) in adults with

various types of hearing loss. No published studies investigated the cost-effectiveness of bone conduction wearables in children.

4.4 The Committee acknowledged that although the evidence base was moderate with some uncertainty on the cost-effectiveness of BCHI in the target population, most of the overseas jurisdictions reimburse BCHI for CHL and MHL. These included Australia, Canada (Ontario), UK, France, Germany, the Netherlands, and Spain. The Committee noted that some jurisdictions cited that there was a clinical need for BCHI. The Committee also noted that with sufficient price reductions, the prices of BCHI in Singapore were comparable to prices in overseas jurisdictions and agreed that the resultant annual technology cost in the eligible population was moderate.

Estimated annual technology cost

5.1 The Committee noted that based on the projection of approximately 108 patients with CHL or MHL a year who would benefit from government subsidy for BCHI and bone conduction wearables, the estimated annual cost to the government for subsidising them was $1 million to <$3 million when including sound processor replacements in children.

Organisational feasibility

6.1 No organisational feasibility issues were identified.

Additional considerations

7.1 The Committee considered that the subsidy criteria of replacement sound processor for BCHI and bone conduction wearables should be aligned with the prevailing subsidy policy for replacement sound processor for cochlear implants in children with severe-to-profound sensorineural hearing loss in both ears.

7.2 The Committee further considered that subsidy should be extended to unilateral BCHI in patients with CHL or MHL. Bilateral BCHI is rarely used in clinical practice.

Recommendation

8.1 Based on the evidence presented and other considerations, the Committee recommended subsidy for:

a. Unilateral BCHI system in patients if they are:
   - Diagnosed with moderate-to-severe CHL or MHL in one or both ears; AND
   - Assessed by the attending healthcare professional to be:
     - Ineligible, or did not sufficiently benefit from surgery, conservative treatment, or conventional hearing aid; AND
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8.2 The Committee agreed that patients with moderate-to-severe CHL or MHL in one or both ears who had previously received subsidised bone conduction wearables can be eligible for subsidy of unilateral BCHI system if deemed by the attending healthcare professional to be clinically suitable and likely to receive sufficient benefit from BCHI system.

8.3 The Committee agreed that children with moderate-to-severe CHL or MHL in one or both ears who are using BCHI system or bone conduction wearables can be eligible for subsidy for the replacement of BCHI sound processors (including replacement with or without upgrade where an upgrade refers to a change to a later model than currently used by the individual) if the following criteria are met:

- The child is deemed by the attending healthcare professional to be receiving sufficient benefits from BCHI, and demonstrating continued need for BCHI; AND

- The existing BCHI sound processor has been used for at least five years, and its deterioration in performance is deemed by the attending healthcare professional to warrant replacement for achieving optimal hearing.

8.4 BCHI and bone conduction wearables are recommended for inclusion on the MOH MTSL. Listed models are recommended for subsidy when used in line with the abovementioned recommendations. Subsidies will not apply to devices and accessories that are not included in the standard or replacement packages of BCHI devices, including replacement of, or upgrades to, internal implants.

VERSION HISTORY

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This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance**

   Date of Publication 2 May 2022

2. **Amendment to guidance to transit model listings from guidance annex to MTSL**

   Date of Publication 17 February 2023

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

As the national HTA agency, ACE conducts evaluations to inform government subsidy decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

This guidance is based on the evidence available to the MOH Medical Technology Advisory Committee as at 6 July 2021. It is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

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