Bilateral cochlear implants

for children with severe-to-profound sensorineural hearing loss in both ears

Technology Guidance from the MOH Medical Technology Advisory Committee

Guidance Recommendations

The Ministry of Health's Medical Technology Advisory Committee has recommended:

- ✓ Bilateral cochlear implants (BCI) for the management of children (<18 years old) with severe-to-profound sensorineural hearing loss in both ears who have:
  - A hearing threshold of >70 decibels hearing level (dB HL) without acoustic hearing aids (HA),
  - A hearing aid trial of 3 to 6 months, unless contraindicated or inappropriate, and
  - Parental support in the form of motivation and commitment to rehabilitation.

- ✓ Simultaneous BCI should be provided to the eligible child as early as clinically suitable.

- ✓ For children who have received unilateral cochlear implant (CI), the second CI in the contralateral ear should be provided only if this is judged to provide sufficient benefit by the clinician.
  - The second CI should be provided by 6 years of age unless there are special conditions to consider (e.g. large vestibular aqueduct syndrome (LVAS), meningitis, irradiated ears).

- ✓ Children will be eligible for subsidy for the replacement of CI sound processors, which include replacement with or without upgrade where an upgrade refers to a change to a later model than currently used by the individual, if all of the following criteria are met:
  - The child is deemed by the attending healthcare professional to be receiving sufficient benefits from the CI, and demonstrating continued need for CI; and
  - The existing CI sound processor has been used for at least 5 years, and its deterioration in performance is deemed by the attending healthcare professional to warrant replacement for achieving optimal hearing.

Subsidy status

CI is 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 CI 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 Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of bilateral cochlear implants (BCI) for children with severe-to-profound sensorineural hearing loss in both ears in 2017. A subsequent evaluation on replacement cochlear implant (CI) sound processors was presented to the Committee in 2019. The Agency for Care Effectiveness conducted the evaluation in consultation with an MOH expert working group comprising clinicians, audiologists, medical social workers, and educators.

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 technology, may also inform the Committee's deliberations.

Clinical need

2.1 The Committee noted that unilateral cochlear implant (UCI) is currently subsidised for children (<18 years old) with severe-to-profound sensorineural hearing loss in both ears. Children with UCI would normally use a hearing aid (HA) in the contralateral ear (UCI-HA).

2.2 The Committee further noted that the use of a HA in the contralateral ear may not confer adequate functional hearing benefits due to insufficient residual hearing in the non-implanted ear as the ability of the HA to filter out unintended sound signals depends on its sound processing algorithms.

2.3

The Committee acknowledged that routine wear and tear during the finite device lifespan of CI sound processors could lead to their functional decline.

Overall benefit of technology

3.1 In line with local clinical practice, the main comparator used in the evaluation was UCI-HA. The Committee noted that, compared to UCI-HA, BCI demonstrated similar short-term safety and that device failure rate was low. However, long-term safety data (>5 years) for BCI was currently lacking.

3.2 The Committee noted that a key limitation in studies on BCI for children was that there was no single measurement on functional outcomes as the assessment had to be appropriate for the age, developmental stage, and cognitive ability of the child. This contributed to the substantial heterogeneity in the studies included in the evaluation.

3.3 The Committee acknowledged that none of the studies looked at long term patient outcomes. However, compared to UCI-HA, BCI was associated with better sound localisation, similar or better speech perception and language development which may be acceptable surrogates for long term patient outcomes, such as academic performance and vocational placement.

3.4 The Committee also noted a number of published overseas position statements endorsed the use of BCI in clinically appropriate candidates, including a 2017 World Health Organization report which concluded that the benefits of BCI exceed its costs.

3.5 The Committee agreed that the benefits were greatest when CI was implanted as early as clinically suitable, and noted an age limit of 6 years old was applied in New Zealand to the funding of the second CI for children who had already received one CI. Taking into consideration the critical age of development of cortical auditory activity and inter-implant interval, the Committee agreed that the second CI should be provided by 6 years of age unless there are special conditions to consider (e.g. large vestibular aqueduct syndrome (LVAS), meningitis, irradiated ears).

3.6 By end of 2019, the Committee supported the subsidy of replacement of CI sound processors in children to optimise their growth and learning potential. This includes replacement with or without upgrade where an upgrade refers to a change to a later model than currently used by the individual. The replacement frequency should be

no earlier than 5 years to align with prevailing warranty periods. The deterioration in the sound processor performance should also be deemed by the attending healthcare professional to warrant replacement for achieving optimal hearing.

Cost effectiveness

4.1 The local cost-effectiveness model compared BCI with UCI-HA over a lifetime period. The Committee noted that the incremental cost-effectiveness ratios (ICERs) for BCI were high and was most sensitive to utility increment and the selling price of the CI device.

4.2 Following value-based pricing (VBP) discussions with the manufacturers, the Committee noted the ICERs for BCI were in the range of $15,000 to <$45,000 per QALY gained compared with UCI-HA, and agreed that BCI for children would likely be considered an acceptable use of healthcare resources. VBP prices for replacement CI sound processors also apply.

Estimated annual technology cost

5.1 Based on the projection of approximately 33 new cases a year who would benefit from government subsidy for BCI, the Committee noted that the annual cost of providing BCI was estimated to be less than $1 million.

5.2 In addition, the Committee recognised that there was an existing pool of children under 6 years of age currently with one CI who would potentially benefit from subsidy for BCI. If subsidy for the second CI is provided for them, the additional one-off cost was estimated to range from $1 million to <$3 million.

5.3 The estimated average annual cost of subsidising replacement CI sound processors in children, based on a 5-year replacement frequency, was less than $1 million. The Committee noted that it may be higher in the initial post-implementation period.

Organisational feasibility

6.1 According to local experts, there was sufficient expertise and infrastructure to manage the potential increase in clinical load, and no significant concerns over increased staff need was identified.

Additional considerations

7.1 The Committee noted that current UCI subsidies apply only to the initial CI, and there were no subsidies for replacements with or without upgrades of CI and its accessories.

Recommendation

8.1 On the basis of the evidence presented, in 2017, the Committee recommended subsidy for listed BCI (standard packages) in children (<18 years old) with severe-to-profound sensorineural hearing loss in both ears who have:

- A hearing threshold of >70 decibels hearing level (dB HL) without acoustic HAs;
- A hearing aid trial of 3 to 6 months unless contraindicated or inappropriate; and
- Parental support in the form of motivation and commitment to rehabilitation.

8.2 The Committee recommended the following criteria for subsidy of BCI in children:

- Simultaneous BCI should be provided to the eligible child as early as clinically suitable;
- For children who have received unilateral CI, the second CI in the contralateral ear should be provided only if this is judged to provide sufficient benefit by the clinician, and the second CI should be provided by age 6 years unless there are special conditions to consider (e.g. LVAS, meningitis, irradiated ears).

8.3 In late 2019, the Committee recommended subsidy for listed replacement CI sound processors (replacement packages) for children, which include replacement with or without upgrade where an upgrade refers to a change to a later model than currently used by the individual, if all of the following criteria are met:

- The child is deemed by the attending healthcare professional to be receiving sufficient benefits from the CI, and demonstrating continued need for CI; and
- The existing CI sound processor has been used for at least 5 years, and its deterioration in performance is deemed by the attending healthcare professional to warrant replacement for achieving optimal hearing.

The Committee agreed that the CI devices listed for subsidy should also be used for subsidy eligibility of UCI in adults with severe-to-profound sensorineural hearing loss in both ears.

8.4

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	1 Apr 2018
2.	**Amendment to Annex due to revision or addition of cochlear implant (CI) devices models (standard packages)**	
	Dates of Publication	2 Jul 2018 15 Apr 2019 1 Jul 2019
3.	**Amendment to incorporate subsidy recommendations and considerations for replacement CI sound processors, and amendment to Annex to incorporate replacement CI sound processors models (replacement packages)**	
	Date of Publication	12 Jun 2020
4.	**Amendment to Annex due to revision or addition of cochlear implant (CI) devices models (standard packages) or replacement CI sound processor models (replacement packages)**	
	Date of Publication	15 Oct 2020 26 Mar 2021 1 Jun 2021 19 Jul 2021
5	**Amendment to guidance to transit model listings from guidance annex to MTSL**	
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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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