Active middle ear implants

for patients with hearing loss

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

Guidance Recommendations

The Ministry of Health's MTAC has recommended subsidy for active middle ear implants (AMEI) for:

- ✓ Patients with moderate-to-severe conductive hearing loss (CHL) or mixed hearing loss (MHL) who fulfil the following criteria and cannot achieve success or adequate benefit from traditional therapy and external hearing aids:
  - Bilateral stable hearing loss in each ear of ≥40dB HL;
  - Normal (free of infection or tympanic retraction) middle ear;
  - Normal tympanometry;
  - No inner ear disorders;
  - An air-bone gap of ≥30 dB HL across all frequencies OR at least involving the frequencies of 500, 1000 & 2000 Hz in cases of preceding reconstructive middle ear surgery with elimination of pathology; and
  - Having contraindications or medically valid reasons for not using bone conduction hearing implants (BCHI).

- ✓ Patients with moderate-to-severe sensorineural hearing loss (SNHL) who fulfil the following criteria and cannot achieve success or adequate benefit from traditional therapy and external hearing aids:
  - A pure tone average (PTA4) <80 dB HL;
  - Bilateral symmetrical SNHL with PTA thresholds in both ears within 20 dB HL of each other;
  - Speech perception discrimination ≥65%;
  - Normal (free of infection or tympanic retraction) middle ear;
  - Normal tympanometry;
  - No inner ear disorders; and
  - An air-bone gap of <10 dB HL across all frequencies.

Subsidy status

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

Only unilateral AMEI will be subsidised. No subsidy will be accorded for the contralateral ear in cases of bilateral implantation or to devices and accessories that are not included in the standard packages of AMEI devices.

Subsidies will not apply to devices and accessories that are not included in the standard packages of AMEI 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 AMEI for patients with hearing loss. The evaluation was conducted in consultation with clinical experts from the public healthcare institutions. Available clinical and economic evidence for AMEI were considered in line with the registered indication for patients with mild-to-severe hearing loss who did not achieve adequate benefit with traditional therapy.

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 SNHL depending on whether it is affected by either the conductive or sensorineural hearing pathways, or both. Hearing loss can adversely affect communications and physical wellbeing. 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 mild-to-severe CHL, MHL, or SNHL may be managed by receiving conventional hearing aids or traditional reconstructive middle ear surgery. In those who are medically unsuitable or unable to derive sufficient benefit from these modalities, both BCHI and AMEI are treatment options. Although cochlear implant can be used in mild-to-severe MHL or SNHL, it is rarely used in practice and considered only as a last resort where the patients' indications precluded all other treatment options.

2.3 AMEI are electronic hearing implant systems used to correct hearing loss by stimulating the ossicular chain. The external audio processor transmits sound signals to the internal implant component which stimulates the ossicular chain to enhance hearing.

Clinical effectiveness and safety

3.1 The Committee agreed that the appropriate main comparator(s) for AMEI were no treatment or BCHI in patients with CHL or MHL, and no treatment in patients with SNHL. Clinical effectiveness and safety evidence for CHL or MHL, and SNHL were based on a 2020 Health Quality Ontario (HQO) report and the 2016 Medical Services Advisory Committee (MSAC) public summary document (PSD) respectively.

3.2 The Committee acknowledged the additional risk for surgery and general anaesthesia associated with surgically implanting AMEI which could not be quantified. However, the Committee also noted that both reports concluded that AMEI were generally safe for patients with CHL, MHL, or SNHL with low rates of adverse events and technical complications. Severe adverse events and complications were rare.

3.3 In patients with SNHL, the Committee agreed that AMEI were generally more effective than no treatment for improving hearing, with the evidence reporting clinically relevant gains in functional hearing of 10 dB HL or more.

3.4 In patients with CHL or MHL, the Committee agreed that AMEI reported favourable and clinically meaningful improvements in functional gain in hearing of between 21 and 49 dB HL and speech recognition when compared to no treatment (55% to 98% vs 0 to 72%; $p<0.05$). Subjective benefits of hearing and improvements in hearing-related quality of life were also reported, when compared to no treatment.

3.5 The Committee noted that no evidence comparing AMEI to BCHI was identified. Key limitations in the clinical evidence included small study sizes, short follow-up periods, overlap between studies, potential for selection and reporting bias, and substantial heterogeneity in study design.

Cost-effectiveness

4.1 The Committee noted that no local cost-effectiveness analysis was performed. The Committee considered the cost-effectiveness of AMEI in patients with SNHL based on a published cost-effectiveness analyses from Medical Services Advisory Committee (MSAC, Australia) in 2016 comparing AMEI with no treatment. No published economic evidence was found for AMEI in patients with CHL or MHL.

4.2 The Committee noted that the published base case incremental cost-effectiveness ratio (ICER) was around AUD$38K per quality adjusted life-year (QALY) in patients with SNHL who cannot use or derive benefit from other treatments including external hearing aids. Sensitivity analyses showed that the ICER was sensitive to time horizon and cost of AMEI system.

4.3 The Committee further noted that the reduced price was comparable to overseas jurisdictions and the price used in MSAC's cost-effectiveness analyses, suggesting that AMEI would likely be cost-effective in the local setting.

Estimated annual technology cost

5.1 Based on the projection of fewer than 10 patients in Singapore who would benefit from Government subsidy for AMEI annually, the Committee estimated that the annual cost of providing AMEI was <$1 million.

Additional considerations

6.1 According to local clinician experts, AMEI is used mainly in adults locally. Furthermore, patients with mild hearing loss are unlikely to seek implantation treatment options. No organisational feasibility issues were identified.

Recommendation

7.1 Based on the evidence of acceptable safety, clinical and cost-effectiveness, the Committee recommends subsidy for AMEI for:

- ✓ Patients with moderate-to-severe CHL or MHL who fulfil the following criteria and cannot achieve success or adequate benefit from traditional therapy and external hearing aids:
  - Bilateral stable hearing loss in each ear of ≥40dB HL;
  - Normal (free of infection or tympanic retraction) middle ear;
  - Normal tympanometry;
  - No inner ear disorders;

- An air-bone gap of ≥30 dB HL across all frequencies OR at least involving the frequencies of 500, 1000 & 2000 Hz in cases of preceding reconstructive middle ear surgery with elimination of pathology; and
- Having contraindication or medically valid reasons for not using BCHI.

✓ Patients with moderate-to-severe SNHL who fulfil the following criteria and cannot achieve success or adequate benefit from traditional therapy and external hearing aids:

- A PTA4 <80 dB HL;
- Bilateral symmetrical SNHL with PTA thresholds in both ears within 20 dB HL of each other;
- Speech perception discrimination ≥65%;
- Normal (free of infection or tympanic retraction) middle ear;
- Normal tympanometry;
- No inner ear disorders; and
- An air-bone gap of <10 dB HL across all frequencies.

7.2 AMEI is recommended for inclusion on the MOH MTSL. Listed models are recommended for subsidy when used in line with the abovementioned recommendations. Only unilateral AMEI will be subsidised. No subsidy will be accorded for the contralateral ear in cases of bilateral implantation. Subsidies will not apply to devices and accessories that are not included in the standard packages of AMEI 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.

Publication of guidance

Date of Publication	2 May 2022

Revision to guidance and 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 17 March 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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