Technology Guidance

Advanced hybrid closed loop system

for people with type 1 diabetes mellitus

Technology Guidance issued by the Agency for Care Effectiveness based on assessments made by the MOH Medical Technology Advisory Committee and recommendations of the Health Technology Advisory Council

Guidance Recommendations

Advanced hybrid closed loop (AHCL) system is not recommended for subsidy for people with type 1 diabetes mellitus. This is because, based on limited evidence available compared with the main comparator (multiple daily insulin injections + real-time continuous glucose monitoring), AHCL system has uncertain magnitude and durability of benefit, and unfavourable cost-effectiveness.

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Technology evaluation

1.1. At the March 2025 meeting, the MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of advanced hybrid closed loop (AHCL) system for people with type 1 diabetes mellitus (T1DM). This topic was later discussed in May 2025 by the Health Technology Advisory Council ("the Council"), an independent professional body that supports the MOH in determining if financial support for high-cost, high-impact health technologies is appropriate.

1.2. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions and patient experts from local patient and voluntary organisations. Clinical and economic evidence for AHCL system was considered in line with its registered indication.

1.3. The evidence was used to inform the deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – 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; and
- Organisational feasibility – the potential impact of adopting the technology, especially barriers for diffusion.

1.4. Additional factors, including social and value judgments, may also inform the funding considerations.

Assessments made by the MOH Medical Technology Advisory Committee

Clinical need

2.1. Effective diabetes management for people with T1DM requires a careful balance between insulin delivery and glucose monitoring systems. Technologies for managing hypo- and hyperglycaemia in diabetes include insulin delivery (multiple daily insulin injections [MDII] or continuous subcutaneous insulin infusion [CSII]), and glucose monitoring (self-monitoring of blood glucose [SMBG] or continuous glucose monitoring [CGM]). The Committee noted that MDII, CSII, and real-time CGM (rtCGM) are currently subsidised for people with T1DM in Singapore.

2.2. AHCL systems integrate CSII with rtCGM. Using software algorithms, AHCL systems create a closed loop that allow insulin doses to be automatically adjusted to prevent and manage hypo- and hyperglycaemia. However, these are not fully automated as people with T1DM still need to initiate meal-time boluses.

2.3. The Committee considered 103 patient testimonials from 68 individuals with T1DM and their carers, and a collated submission of 35 responses from a local patient support group. The Committee acknowledged that T1DM had a significant negative impact on patients' and their families' daily lives, affecting them mentally, emotionally and financially. They noted that 42 respondents were AHCL users, many of whom experienced improved diabetes care with the device. They also spent less time managing T1DM, which enabled them to have a more flexible lifestyle, and improved their quality of life compared to previous treatments. However, they reported concerns about cost and technical issues such as inaccurate readings, and algorithm and device failures. Nearly half of the patient experts who used AHCL experienced side effects such as skin irritation. The bulkiness of the device also affected sleep for many patients.

Clinical effectiveness and safety

3.1. The Committee noted that the main comparator for AHCL system was MDII + CGM (primarily rtCGM), in line with local clinical practice. The technology evaluation also compared AHCL with CSII + CGM, CSII + SMBG, MDII + SMBG, and compared different AHCL systems.

3.2. The evidence base included 15 publications. Seven publications from three randomised clinical trials (RCTs) were on adults with T1DM, including the pivotal ADAPT (Advanced Hybrid Closed Loop Study in Adult Population with Type 1 Diabetes) RCT, which compared AHCL with MDII + CGM. Eight publications comprising RCTs, observational studies and real-world evidence focused on children or mixed populations of adults and children.

3.3. The Committee noted that management using AHCL system was generally safe in adults and children with T1DM. Serious adverse events, diabetic ketoacidosis, severe hypoglycaemia and severe hyperglycaemia were uncommon for both AHCL and comparator technologies. Skin irritations and device technical issues were commonly reported in the AHCL arm.

3.4. In adults with T1DM, available evidence from the ADAPT trial comparing AHCL with the MDII + rtCGM cohort showed no statistically significant difference in HbA1c change. It was unclear however if this was due to the trial being underpowered, and possible confounding across treatment arms due to imbalances in baseline HbA1c levels.

3.5. Across all comparators, AHCL likely improved glycaemic control, although the magnitude of these benefits is uncertain. The Committee had concerns about how well the ADAPT trial results could be generalised to local patients. This was because the trial population enrolled patients with higher baseline HbA1c, which could overestimate the effectiveness of AHCL. Additionally, as the ADAPT trial only had one year of follow-up, it was unclear if AHCL could maintain its effectiveness in controlling HbA1c levels over a longer period.

3.6. In adults, AHCL showed statistically significant improvements in some domains of fear of hypoglycaemia (FoH) compared to MDII + intermittently-scanned CGM (isCGM) and CSII + CGM. However, no evidence was available comparing AHCL to MDII + rtCGM, so the comparative impact on FoH remains uncertain.

3.7. As the evidence for children with T1DM was limited, it was supplemented with evidence from a mixed population of adults and children with T1DM. The Committee noted that children tend to have greater difficulty with glycaemic control, and while the direction of effect was similar to the evidence for adults with T1DM, the magnitude of benefit for children was uncertain.

Cost effectiveness

4.1. An in-house cost-utility analysis (CUA) was conducted to compare AHCL system with the main comparator of MDII + CGM. The Committee noted that base case incremental cost-effectiveness ratios (ICERs) were high, between SG$165,000 and SG$205,000 per quality-adjusted life year (QALY) gained when using treatment effectiveness from MDII + isCGM cohort from ADAPT, and between SG$205,000 and SG$245,000 per QALY gained with the MDII + rtCGM cohort from ADAPT. The ICERs remained high across all sensitivity analyses.

4.2. The Committee also reviewed four published industry-sponsored CUAs in adults, comparing AHCL with MDII + isCGM (three studies) and AHCL with CSII + isCGM (one study). This included a local publication that reported an ICER of SG$33,797 per QALY gained for AHCL compared to MDII + isCGM. Comparison against MDII + rtCGM was not available. The Committee further considered that the difference in ICER between the local publication and in-house CUA was driven by including QALY gains due to reduction in FoH throughout the modelled time horizon, which was highly uncertain and likely optimistic. No published economic evidence was found for children.

4.3. The Committee noted that locally, at the company's proposed price, the AHCL system was substantially more expensive than all comparators. The average annual treatment cost of AHCL was more than twice that of MDII + rtCGM.

Estimated annual technology cost

5.1. The Committee noted that the cost impact to the public healthcare system was estimated to be between SG$1 million and SG$10 million per year in the first five years of Government subsidy for the AHCL system.

Organisational feasibility

6.1. AHCL system is provided in specialist outpatient clinics. As training to use AHCL systems is crucial, patient and caregiver training could include comprehensive education about device training, troubleshooting and ongoing educator support.

Additional considerations

7.1. Several clinical guidelines recommend the use of model-agnostic hybrid closed loop systems for T1DM. These guidelines support broad access across patient groups, while emphasising the importance of patient education, ongoing support, and individualised device selection based on patient needs and preferences.

7.2. The Committee also noted that only one AHCL model is currently available in the local market, despite the availability of multiple AHCL systems overseas.

Summary

8.1. Given AHCL system's limited clinical evidence against the main comparator, uncertain magnitude and durability of benefit, and unfavourable cost-effectiveness at the price proposed by the company, the Committee assessed that the AHCL system was not appropriate for subsidy listing.

Recommendations of the Health Technology Advisory Council

9.1. At the May 2025 meeting, the Council reviewed the evidence presented in ACE's evaluation of AHCL system and considered the assessment made by the MOH Medical Technology Advisory Committee.

9.2. The Council acknowledged that AHCL users would like AHCL systems for T1DM to be more affordable, allow them to reach a target HbA1c level and improve their time in target blood glucose range.

9.3. The Council noted that AHCL system was generally safe, and the most frequently reported issues were skin irritation and device technical issues.

9.4. The Council also noted that AHCL system showed no significant improvement in HbA1c levels compared to MDII + rtCGM, and acknowledged that whilst AHCL system was likely to improve glycaemic control across other comparators, the magnitude and durability of treatment benefits were uncertain.

9.5. The Council considered the results of the CUA, which showed high ICERs when compared with MDII + CGM. They noted that the ICERs remained high across all sensitivity analyses. While AHCL system may offer improved convenience, the technology comes at a substantial price premium. Nonetheless, people with T1DM currently have access to proven and effective technologies for managing hypo- and hyperglycaemia.

9.6. Overall, the Council concluded that the high cost of the AHCL system could not be justified by its benefits based on current available evidence. Therefore, the Council recommended not subsidising AHCL for people with T1DM.