Differential HTA Recommendations for Continuous Glucose Monitors (CGMs) - A Global Comparative Review of HTA focus, challenges and solutions

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BACKGROUND

- Diabetes is a chronic metabolic condition leading to high blood glucose levels (hyperglycemia) due to a malfunction in the body's ability to produce the hormone insulin. The most common forms of diabetes are type 1 diabetes (T1D), which arises due to deficient insulin production and type 2 diabetes (T2D), that results from the body's ineffective use of insulin.
- Continuous glucose monitor (CGM) devices are wearable devices that continuously monitor and automatically estimate blood glucose levels, rather than relying on finger-stick blood measurement. However, some CGMs require occasional calibration through self-monitoring (SMBG).
- CGMs have been evaluated by various HTA agencies worldwide, including NICE (UK), CDA (Canada), Medicare (US), and European bodies. Recommendations differ based on clinical effectiveness, cost-effectiveness thresholds, and reimbursement policies.

OBJECTIVE

- Compare HTA methodologies and outcomes across regions to identify key drivers of CGM adoption and propose methodological solutions for greater HTA acceptability.

METHODS

- A targeted review of technology reports from NICE (UK), CDA/AMC (CN), Medicare (US), IQWiG (DE), HAS (FR) and TLV (SE) agencies was conducted.
- Evaluations were categorized based on clinical effectiveness criteria, economic modeling approaches, and reimbursement decisions.
- Comparative analysis focused on quality-adjusted life years (QALYs), real-world evidence (RWE), budget impact analysis (BIA), and distributional cost-effectiveness analysis (DCEA).

RESULTS

Overall outcomes

- The clinical value of CGM is consistently recognized across all agencies with meaningful improvements. Reported benefits include:
  - Improved glycemic control (notable reductions in HbA1c)
  - Reduced hypoglycemia
  - Increased time in range and reduced glycemic variability
- Clinical evidence is strong and robust for T1D, with clinical trials and publications confirming clinical and QoL benefits, while evidence for T2D is moderate, and frequently non-specific to T2D and based on extrapolated data.

Key challenges identified

- Lack of validated surrogate endpoints linking wearable-generated data to long-term health outcomes
- Variability in patient adherence affecting intervention effectiveness
- Limitations of traditional Markov models in capturing dynamic monitoring effects
- Omission of indirect costs related to healthcare system integration
- Insufficient consideration of health inequalities in economic evaluations

HTA recommendations varied significantly

- NICE: Supports CGMs for T1D and for insulin-treated T2D meeting clinical criteria but highlights cost concerns for NHS funding.
- CDA/AMC: Endorses CGMs for T1D but selective use requiring strong cost-effectiveness justification for T2D.
- Medicare: Covers CGMs for frequent insulin users, with private insurers imposing HbA1c thresholds.
- IQWIG: Supports CGM for T1D based on clinical benefit and regulated condition of use.
- HAS & TLV: Fully reimburse CGMs for T1D and T2D, emphasizing preventive benefits.

Proposed solutions

- Bayesian validation methods for surrogate endpoints.
- Incorporation of real-world data from patient registries and insurance claims.
- Adoption of discrete event simulation (DES) and microsimulation models for dynamic interventions.
- Inclusion of budget impact analysis to assess system-wide costs
- Application of DCEA to evaluate equity impacts across socioeconomic groups.

Table 1. Assessments of CGMs by HTA body

HTA body	HTA methods	Key outcomes	Highlighted challenges	Recommendations
NICE	• Cost-utility analysis (CUA) for HCL • Evidence from RCTs + meta-analyses	In T1D compared to standard care: • Effective glycemic control • ↑ Time in range • ↓ Hypoglycemia • Cost-effective at negotiated prices In T2D: • Modest benefit in hypoglycemia prevention or SMBG testing	• Uncertainty in economic model inputs; including long-term real-world adherence, effectiveness and resource use • Cost assumptions vary by device	• Broadly recommended in T1D patients • Limited to T2D patients meeting defined clinical criteria (e.g., recurrent severe hypoglycemia, impaired awareness, requiring multiple prick tests daily…) • Price agreements required
CDA/ AMC	Systematic reviews & Cost-utility analysis	In T1D compared to SMBG • ↓ HbA1C • ↑ Time in range • ↓ Severe hypoglycemia • Cost-effective on the long-term In T2D: • Modest ↓ HbA1C	• Models depend on assumptions of durability of benefit • Limited long-term trials • Limited quality evidence in T2D	• Strongly recommended for T1D patients • Recommended in T2D based on low-to high quality evidence (more selective use)
IQWIG	Clinical benefit assessment (patient relevant outcomes)	In T1D compared to SMBG: • ↓ HbA1C • ↓ Severe hypoglycemia • ↑ Time in range • ↓ Glycemic variability	• Limited long-term outcomes • Variable adherence • Economic evaluation not reported • Limited evidence in T2D	Recommended in T1D due to meaningful clinical benefit, while less certain benefit in T2D (restricted to insulin-treated/high-risk patients)
HAS	Clinical benefit assessment	In T1D & T2D: • ↓ HbA1C • ↓ Hypoglycemia	• Uncertainty in cost-effective use	Sufficient clinical benefit to justify reimbursement in T1D and insulin-treated T2D
TLV	Cost-utility analysis	Clinically relevant benefit in T1D • ↓ HbA1C • ↓ Hypoglycemia • ↑ Time in range • ↓ Glycemic variability	• Uncertainty in QoL improvement & CEA • Limited evidence specific to T2D (extrapolation) • Adherence based on assumptions	Recommended in T1D and insulin treated T2D patients

Table 2. Medicare coverage for CGMs in the United States

	Coverage
Medicare	• Part B durable medical equipment (DME) medical necessity (20% co-payment) • Recognized as essential for safe insulin management • Coverage dependent on diabetes and an insulin use or problematic hypoglycemia

Key findings

- There is consensus among reimbursement agencies on the clinical value of CGMs, particularly highlighting clinically meaningful improvements, especially in T1D patients. However, uncertainties remain regarding long-term durability of outcomes, comparative evidence, and adherence.
- Recent assessments show a shift towards universal access for CGM among T1D patients and expanding inclusion for T2D.
- Where economic modelling is reported, CGMs are mainly cost-effective based on QoL improvement.
- Real-world impact depends on real-world use, adherence, and device training, the latter being required by most reimbursement bodies.

Conclusion

HTA agencies recognize CGMs' clinical benefits in controlling blood glucose parameters, but CE and medical integration remain key barriers due to user adherence and disparity in access. NICE and CDA require stronger economic justification, while HAS and TLV emphasize preventive benefits. Future evaluations should prioritize validated surrogate endpoints, RWE, and adaptive economic modeling to enhance HTA acceptability.

References

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5. GBA[IQWGIG CGM monitoring ; IQWIG V24-11; IQWIG v22-05]
4. TLV [Free Style Libre ; SBU report; TLV Knowledge Base]
5. CDA [Guideline review; RC1442-000; RC1443-000]
6. MEDICARE [Policy article MEDICARE ; CGM MEDICARE]

Abbreviations: AMC: L'Agence des médicaments du Canada (Canada's Drug Agency); BIA: Budget Impact Analysis; CDA: Canada's Drug Agency; CE: Cost-Effectiveness; CGM: Continuous Glucose Monitor; CUA: Cost-Utility Analysis; DCEA: Distributional Cost-Effectiveness Analysis; DES: Discrete Event Simulation; DME: Durable Medical Equipment; HbA1c: Hemoglobin A1c; HAS: Haute Autorité de Santé; HTA: Health Technology Assessment; IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; NHS: National Health Service; NICE: National Institute for Health and Care Excellence; QALY: Quality-Adjusted Life Year; QoL: Quality of Life; RCT: Randomized Controlled Trial; RWE: Real-World Evidence; SMBG: Self-Monitoring of Blood Glucose; T1D: Type 1 Diabetes; T2D: Type 2 Diabetes; TLV: Tandvårds- och läkemedelsförmånsverket; US: United States

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