

# Investment Case for CGM Access for Children and Young Adults Living With Type 1 Diabetes under Kenya's Social Health Insurance Fund



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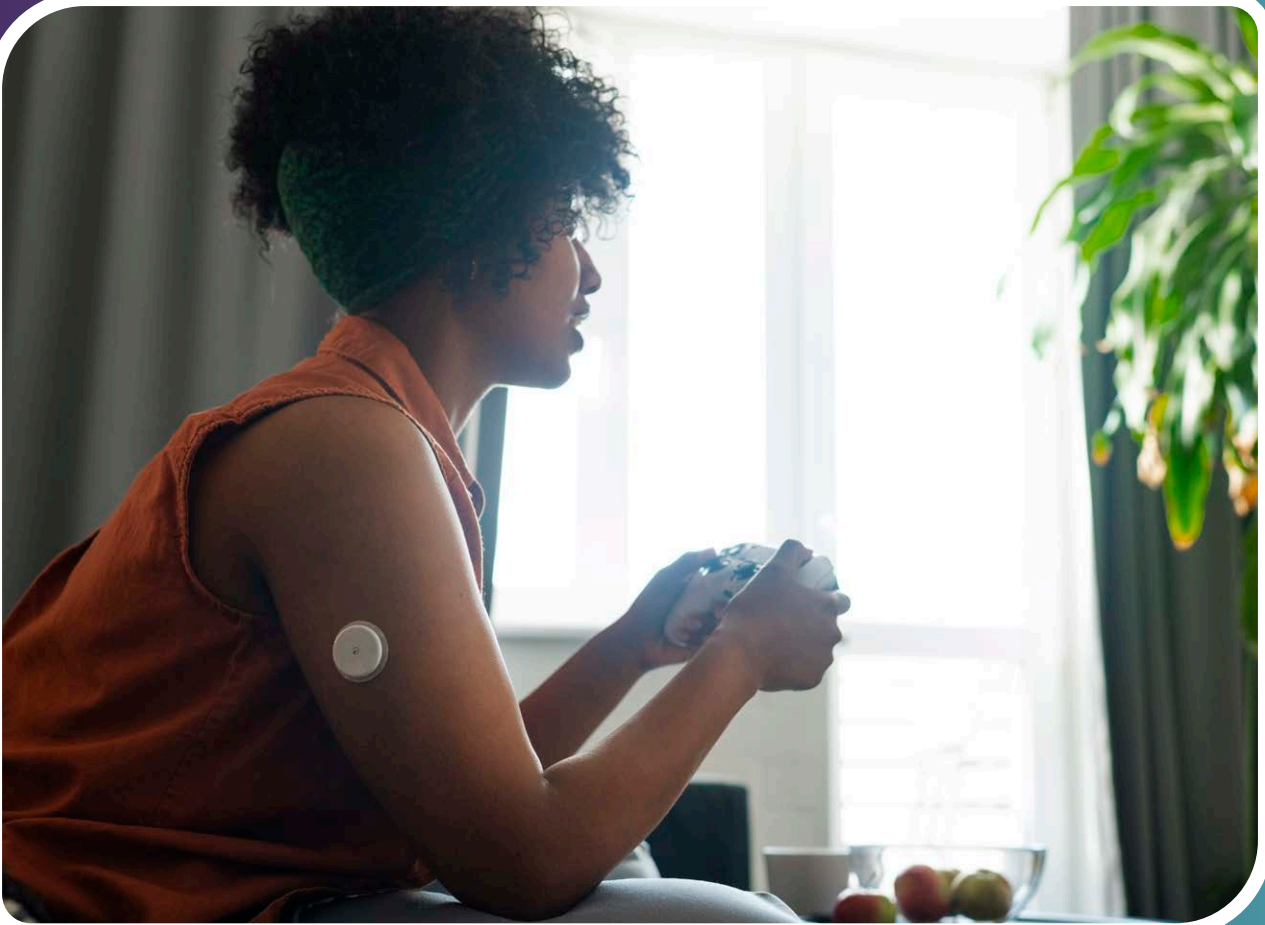
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# Abbreviations

ACCEDE	Access to CGMs for Equity in Diabetes Management
BIA	Budget Impact Analysis
CEA	Cost-Effectiveness Analysis
CGM	Continuous Glucose Monitoring
CI	Confidence Interval
CV	Coefficient of Variation
CVD	Cardiovascular Disease
DALY	Disability-Adjusted Life Year
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic Ketoacidosis
HbA1c	Glycated Haemoglobin
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
ISPAD	International Society for Pediatric and Adolescent Diabetes
isCGM	Intermittently Scanned Continuous Glucose Monitoring
ITT	Intention-To-Treat
JAMA	Journal of the American Medical Association
KEMSA	Kenyan Medical Supplies Authority
KES	Kenyan Shillings
LMIC	Low- and Middle-Income Country
MDI	Multiple Daily Injections
NCD	Non-Communicable Disease
NHI	National Health Insurance
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OOP	Out-of-pocket
PPB	Pharmacy and Poisons Board
PICOST	Population, Intervention, Comparator, Outcomes, Study Design, Time Horizon
QALY	Quality-Adjusted Life Year
RCT	Randomised Controlled Trial
ROI	Return on Investment
rtCGM	Real-Time Continuous Glucose Monitoring
SHIF	Social Health Insurance Fund
SHE	Severe Hypoglycaemic Episode
SMBG	Self-Monitoring of Blood Glucose
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
TAR	Time Above Range
TBR	Time Below Range
TIR	Time In Range
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization
WTP	Willingness-To-Pay

# 1. Executive Summary

1. **Strong demand, high engagement, and feasibility demonstrated:** Evidence from the ACCEDE studies in Kenya and South Africa shows that CGM is highly acceptable, feasible to implement in public-sector settings, and associated with meaningful improvements in patient experience. Participants in the Kenyan cohort demonstrated particularly high engagement, including high wear-time and frequent glucose checking behaviour.
2. **Clinical evidence supports CGM as a high-value intervention:** International evidence consistently demonstrates that CGM improves glycaemic management. Emerging African evidence, including the ACCEDE studies, suggests that CGM can achieve clinically meaningful improvements in glycaemic control in public-sector settings when accompanied by structured education and ongoing support.
3. **CGM is increasingly considered standard of care internationally:** CGM is now widely recommended for people living with Type 1 Diabetes (T1D) in many high-income settings and by international guidelines such as ISPAD. Although SMBG supplies themselves remain incompletely financed under government-funded diabetes care, this should not be interpreted as a reason to deprioritise CGM, but rather as part of the broader need to strengthen equitable access to effective glucose monitoring technologies.
4. **Current pricing is the primary barrier to scale:** End-user CGM prices in Kenya are substantially higher than estimated manufacturer (ex-works) prices and often higher than prices observed in comparable LMIC settings.
5. **Affordability constraints are confirmed across multiple analyses:** Budget impact and willingness-to-pay analyses consistently show that current CGM prices substantially exceed both health system affordability and what most users are willing or able to pay, reinforcing that price, rather than value or demand, is the binding constraint to scale-up.
6. **Substantial price reductions are required for broad public-sector adoption:** Economic modelling and threshold analyses suggest that continuous CGM would require sensor price reductions of approximately 86–93% to approach conventional cost-effectiveness thresholds in Kenya, while periodic CGM (2 weeks of CGM every 3 months) could become cost-effective at lower price reductions (45–61%).
7. **Periodic CGM offers a pragmatic and fiscally feasible entry point:** Lower-intensity periodic CGM strategies demonstrated clinically meaningful HbA1c improvements in the ACCEDE South Africa trial and substantially improved affordability in the Kenyan modelling. At a 50% discounted sensor price, introducing periodic CGM for children, adolescents, and young adults living with T1D would require an additional KES 132 million per year above the existing SMBG budget (a 111% increase).
8. **Strategic procurement and market shaping are critical enablers:** Achieving affordable CGM access will require coordinated procurement, active price negotiation, pooled purchasing, and supply-chain efficiencies to reduce cumulative mark-ups and avoid locking the Social Health Insurance Fund (SHIF) into inflated reimbursement prices.
9. **Implementation success depends on more than device provision alone:** The ACCEDE experience highlights that successful CGM scale-up requires integration into strengthened diabetes education pathways, healthcare worker training, routine clinical review, and ongoing patient support to ensure sustained engagement and effective use.
10. **Policy implication:** CGM should be considered a high-value but price-sensitive technology. A phased implementation strategy beginning with periodic CGM for children, adolescents, and young adults living with T1D represents a realistic and equitable pathway toward broader public-sector adoption as prices decline and procurement efficiencies improve.

## Recommendations

- **Prioritise children, adolescents, young adults, pregnant women, and individuals with T1D at high risk for early access to CGM technologies. Periodic CGM represents a fiscally lighter, high-benefit entry point that could rapidly improve diabetes management and quality of life for priority populations.**
- **Pursue coordinated national procurement and active price negotiation strategies, including pooled procurement, tiered LMIC pricing, and market-shaping approaches, to bring sensor prices closer to affordability and cost-effectiveness thresholds identified in the economic analyses.**
- **Strengthen supply-chain efficiency to reduce cumulative mark-ups across importation, distribution, and retail channels, ensuring that negotiated price reductions are realised at the point of service.**
- **Expand access to CGM progressively as procurement efficiencies, lower-cost technologies, market competition, donor support, and co-financing mechanisms mature over time.**
- **Build on the existing preference for CGM into Kenya's National Diabetes Guidelines and incorporate in future SHIF benefit-package planning for people living with T1D, with clear guidance on eligibility criteria, implementation pathways, education requirements, and follow-up.**
- **Invest in system readiness for CGM implementation, including specialist diabetes nurse educators, healthcare worker training, structured patient education, and practical implementation support for sensor application, troubleshooting, and interpretation of glucose data.**

## 2. Background

In Kenya, diabetes has become one of the leading causes of death and disability accounting for more than 10,645 deaths and 391,648 disability-adjusted life years (DALYs) in 2023<sup>1</sup>. Current estimates indicate that around 813,300 people are living with diabetes in Kenya<sup>2</sup>. Within this national context, people living with type 1 diabetes (T1D) remains a smaller but critical population: with an estimated 15,243 adults and 5,575 children and adolescents currently living with T1D<sup>2</sup>. Although this represents a relatively small proportion of the total population, people living with T1D use a disproportionately large share of health-care resources. Estimated annual health expenditure per person with diabetes in Kenya is approximately USD 410, which is substantially higher than the country's average health expenditure of around USD 85 per capita per year; costs for people with T1D are likely to be even higher than the USD 410 due to the need for lifelong insulin therapy, regular glucose monitoring, and more intensive clinical management compared to Type 2 (T2D) diabetes<sup>2,3</sup>.

The Kenyan National Clinical Guidelines on the Management of Diabetes Mellitus have defined glycaemic targets as maintaining HbA1c levels below 7%<sup>4</sup>. Kenya's National Strategic Plan for NCDs (2021/22–2025/26) identifies diabetes as a priority condition and sets a national target for 40% of people with diabetes to achieve glycaemic control (HbA1c <7%) by 2025, recognising that achieving adequate control among those on treatment is essential to preventing both acute and long-term complications<sup>5</sup>. While improving glycaemic control depends on a multipronged approach - including appropriate insulin therapy, structured education, dietary support, psychosocial care, and regular clinical follow-up - glucose monitoring remains a foundational tool within this package. It enables people living with T1D to understand their glucose patterns and make informed adjustments to diet, activity, and medication.

Self-monitoring of blood glucose (SMBG) via capillary fingerstick is standard practice to support safe and effective insulin management in Kenya<sup>4</sup>. National guidance recommends structured SMBG through either intensive 7-point profiles on selected days (equivalent to ~21 tests per week) or a staggered testing approach (~12 tests per week) where full profiling is not feasible<sup>4</sup>. However, SMBG via fingerstick in Kenya remains sub-optimal, with evidence indicating that only 28% of children and adolescents (<19 years) achieve recommended glycaemic targets, highlighting persistent gaps in effective glucose monitoring and diabetes management in routine care<sup>6</sup>.

In recent years, CGM technology has emerged as a transformative tool in diabetes care. CGMs offer real-time glucose readings, trend information, and alarms for hypo- or hyperglycemia, providing patients and healthcare providers with actionable insights into glycemic patterns. In addition to point glucose values, CGM enables a richer set of clinically relevant metrics beyond HbA1c, including time in range (TIR), time above range (TAR), time below range (TBR), and measures of glycaemic variability (GV), which together provide a more comprehensive picture of glucose control and short-term risk of hypo- and hyperglycaemia. Numerous studies have demonstrated that CGMs improve HbA1c, reduce the time spent in hypo- or hyperglycemia, and enhance quality of life by minimizing reliance on fingerstick testing and reducing the fear of hypoglycemia<sup>7,8</sup>. CGMs have shown particular benefit in people with insulin-treated T1D and T2D, both clinically and economically, with multiple evaluations supporting their cost-effectiveness<sup>9</sup>.

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In high-income countries, CGMs are now widely accessible and reimbursed, resulting in widespread uptake among people living with T1D<sup>10,11</sup>. However, in most low- and middle-income countries (LMICs), including Kenya, access to CGM remains severely limited with high sensor costs of CGMs remaining a major barrier to adoption, and with uptake further constrained by the scarcity of locally generated evidence to inform policy and reimbursement decisions<sup>12,13</sup>. Several CGMs are available



on the market in Kenya with some approved for use by the Pharmacy and Poisons Board (PPB). Although the Kenyan diabetes guidelines signal an emerging preference for CGM in high-level management frameworks, it is estimated that less than 6% of the 21,000 people living with T1D use CGMs at least occasionally<sup>4,14,15</sup>. Whilst this represents encouraging progress in the adoption of CGMs in Kenya, this is largely limited to those who were wealthier and more likely to have health insurance.

International efforts are increasingly focused on improving access to glucose monitoring and diabetes technologies. The WHO Global Diabetes Compact has set ambitious global targets, such as ensuring *100% of people with T1D have access to affordable insulin and blood-glucose self-monitoring*, and achieving *good glycaemic control in at least 80% of people with diagnosed diabetes*, to drive progress by 2030<sup>16</sup>. WHO guidance also recommends CGM use during pregnancy in women with diabetes to improve maternal and neonatal outcomes<sup>17</sup>. Complementing this, initiatives such as the T1D Community Fund highlight the urgent need to expand access to affordable, life-saving diabetes technologies, including CGM, for people living with T1D in LMICs<sup>18</sup>. The International Society for Paediatric and Adolescent Diabetes (ISPAD) recommends continuous use of CGM for all children, adolescents, and young adults living with T1DM<sup>19</sup>.

***The growing burden of diabetes and ongoing difficulties in managing blood sugar levels in Kenya highlight the urgent need to improve access to advanced glucose monitoring technologies.***

The growing burden of diabetes and ongoing difficulties in managing blood sugar levels in Kenya highlight the urgent need to improve access to advanced glucose monitoring technologies. Consequently, expanding access to affordable CGM in Kenya, beginning with priority groups, could significantly improve glucose monitoring and control, strengthen equity in care, reduce long-term complications, and lower healthcare costs. Such investments align directly with the country's national health priorities to manage NCDs and promote universal access to essential health technologies.

### 3. Policy Context and Decision-Making landscape

Kenya's healthcare financing system is characterised by a hybrid structure and is currently undergoing a transition to the Social Health Insurance Fund (SHIF) as the primary purchaser of health services for enrolled populations under Universal Health Coverage reforms<sup>20</sup>. While SHIF reimburses services based on centrally defined tariffs across accredited public and private providers, coverage remains incomplete (approximately 17%), particularly among informal sector populations, and the system continues to rely on government tax funding to support public service delivery and subsidise care for indigent groups<sup>21</sup>.

Under the current SHIF benefit package, chronic disease medicines, including insulin, are reimbursed through a pharmacy benefit capped at KES 5,000 per person per quarter, with a similar quarterly cap applied to diagnostic services for registered beneficiaries<sup>22</sup>. However, glucose monitoring consumables, including SMBG strips and CGM sensors, are not explicitly specified within the current tariff structure. In practice, SMBG consumables are likely to fall under the pharmacy or diagnostics benefit, but the existing reimbursement caps would be insufficient to cover both diabetes medicines and adequate glucose monitoring for people living with T1D, resulting in substantial out-of-pocket (OOP) expenditure. In addition, provider charges, especially in private facilities, may exceed SHIF reimbursement rates, resulting in additional OOP payments by patients to cover the difference. Furthermore, stock-outs and limitations in the current SHIF benefits package mean that many services and technologies, including advanced diabetes management tools such as CGM, are not routinely covered. As a result, Kenya's health financing landscape is characterised by a substantial reliance on OOP payments, which accounted for approximately 27% of total health expenditure in 2018<sup>23</sup>. High OOP spending burdens households and limits access to diabetes care, underscoring the need to consider affordability and financial risk protection. Incorporating glucose monitoring into the SHIF benefit package is therefore both a clinical and equity priority under Kenya's UHC agenda.

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From a system design perspective, SHIF functions primarily as a reimbursor rather than a direct procurer of commodities. Health facilities are responsible for procuring medicines and technologies through centralised mechanisms (e.g. KEMSA) or facility-level tenders, after which SHIF reimburses services based on defined tariffs<sup>20</sup>. This separation between procurement and reimbursement has important implications for pricing and affordability, as it can limit the ability of SHIF to directly influence input costs without coordinated purchasing strategies.

In addition, Kenya's devolved governance structure further shapes healthcare delivery and financing. County governments are responsible for service delivery, including the management of public health facilities, while national-level entities define policy and financing frameworks. This division of responsibilities can result in variation in service availability, procurement practices, and implementation capacity across counties, which has implications for the equitable rollout of new technologies such as CGM.

Take together, the introduction of new technologies such as CGM requires alignment across multiple system components, including benefit package design (SHIF), clinical guidelines (Ministry of Health), procurement mechanisms (KEMSA and facilities), and service delivery capacity at county level. Without such alignment, there is a risk that technologies may be formally covered but remain inaccessible in practice due to supply constraints, pricing inefficiencies, or limited implementation capacity.



Against this backdrop, Kenya has made important progress toward institutionalising Health Technology Assessments (HTA), driven by the need to define an explicit health benefits package under UHC and to improve the efficiency of resource allocation<sup>24,25</sup>. Rather than establishing a fully centralised HTA agency, the country has adopted a pragmatic,

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incremental approach, including the development of national-level structures, methodological guidance, and pilot initiatives such as hospital-based HTA at facilities like Kenyatta University Teaching Referral and Research Hospital, which aim to inform technology adoption decisions at the service delivery level<sup>26</sup>. Despite this progress, a fully institutionalised and publicly defined HTA process with a clear decision-making authority remains under development.

In this context, this report presents high-quality, locally relevant evidence in a structured format to inform policy dialogue and investment planning for the potential inclusion of CGM within the SHIF benefit package, rather than to substitute for formal HTA processes.

Within this broader financing landscape, private health insurance represents a relatively small share of total health expenditure (<7%) and primarily serves higher-income populations<sup>23</sup>. Privately insured individuals are excluded from this analysis, as coverage decisions, pricing, and reimbursement are determined through insurer-specific negotiation processes; nevertheless, the evidence generated in this report may provide relevant insights to inform adoption decisions within the private sector.

## 4. Objective and Scope

The objective of this investment case report is to provide a synthesis of locally generated evidence from the ACCEDE study, complemented by selected international findings, to inform immediate policy dialogue and investment planning for the potential inclusion of CGM in the SHIF benefit package for children, adolescents, young adults (youth), as well as others deemed high risk (pregnant) living with T1D in Kenya.

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To clearly define the scope of this investment case, we applied the Population, Intervention, Comparator, Outcomes, Study Design, and Time Horizon (PICOST) framework, consistent with international HTA best practice and aligned with Kenya's emerging methodological approaches. The table below summarises the key elements - population, intervention, comparators, outcomes, study designs, and time horizons - that structure the assessment of CGM versus SMBG in the Kenyan context. It provides an overview of the population, intervention, comparators, outcomes, and evidence sources considered, enabling transparent interpretation of the clinical, economic, and budget impact findings that follow. The PICOST table is not intended to specify all analyses conducted, but rather to clarify the parameters within which this assessment has been developed.

**Table 1: CGM within the PICOST framework**

CRITERIA	DETAILS
<b>Population</b>	<b>Primary population:</b> People living with T1D in Kenya who are not covered by private health insurance for glucose monitoring and insulin therapy. <b>Condition/severity:</b> people living with T1D requiring lifelong insulin. <b>Age groups:</b> All. <b>Sex:</b> All. <b>Comorbidities:</b> Any. <b>Clinical history:</b> may include individuals with suboptimal glycaemic control, recurrent diabetic ketoacidosis (DKA), frequent hypoglycaemia, or high variability in glucose control. <b>Subgroups for analysis:</b> Children, adolescents and young adults ( $\leq 25$ years) (youth); Individuals with persistent HbA1c $\geq 10\%$ ; Individuals with recurrent severe hypoglycaemia or DKA (high-risk); pregnant women; Populations with high expected clinical benefit; fully compliant populations in terms of CGM usage (both sensor wear time and scan adherence).
<b>Intervention</b>	<b>CGM devices used for real time or intermittently scanned glucose monitoring.</b> <b>Device and schedule:</b> Any CGM available in Kenya with sensor wear-time as stipulated by manufacturer (10-21 days). <b>Place in care pathway:</b> Adjunctive or non-adjunctive to existing SMBG. Intended to improve glycaemic control, reduce complications, and reduce burden on patients and providers. <b>Dosage/frequency:</b> Continuous use (sensor wear $\sim 100\%$ ) or periodic use (2 weeks every 3 months), or as defined. <b>Mode of delivery:</b> Self-applied sensor; readings accessed via reader or smartphone. Training by diabetes nurse educators required. <b>Setting:</b> Outpatient/primary or tertiary diabetes clinics. <b>Prescriber:</b> Medical officers, endocrinologists, nurse educators as per scope of practice. <b>Co-interventions:</b> Insulin therapy, diabetes education, acute care for hypoglycaemia or DKA.
<b>Comparator</b>	<b>Primary comparator:</b> Standard of care: SMBG using capillary fingerstick testing. <b>Components:</b> Glucometer + test strips + lancets; at Guideline recommended frequency. <b>Reason for selection:</b> SMBG is the existing, widely used and guideline-recommended method for monitoring glucose in Kenya. <b>Regulatory:</b> Only registered glucometers and strips included. <b>Place in care pathway:</b> Existing standard; CGM would partially or fully replace SMBG depending on policy scenario. <b>Additional comparators:</b> None relevant.

<b>Outcomes</b>	<p><b>Critical outcomes:</b>• HbA1c reduction (absolute and relative).• Frequency of severe hypoglycaemia.• Frequency of DKA episodes.• Time-in-range (TIR) 70–180 mg/dL.• Adverse events from device use. <b>Important outcomes:</b>• Glycaemic variability metrics (CV, time below range (TBR), time above range (TAR)).• Hospitalisations (diabetes-related).• Quality-adjusted life years (QALYs).• Utility change (EuroQol 5-Dimension Questionnaire (EQ-5D)).• Patient/caregiver burden and satisfaction.• Adherence and persistence with monitoring method. <b>Economic outcomes:</b>• Incremental cost-effectiveness ratios (ICER) (KES per QALY gained).• Direct medical costs (devices, insulin, strips, healthcare providers, hospitalisation, laboratory tests).• Indirect costs (productivity losses, caregiver time).• Long-term complication costs (retinopathy, nephropathy, neuropathy, cardio-vascular disease (CVD)).</p>
<b>Study designs / data sources</b>	<p><b>Clinical efficacy:</b>• Randomised controlled trials (ACCEDE trial; international RCTs).• Systematic reviews and meta-analyses of CGM vs SMBG.• Observational studies for real-world adherence and complication rates. <b>Economic / implementation evidence:</b>• Within-trial cost and QALY analyses (partial societal perspective).• Model-based economic evaluations (lifetime cost-utility).• Costing studies.• Qualitative evidence (acceptability, feasibility in public sector).• International HTAs, clinical guidelines (SEMDSA, ISPAD, NICE).</p>
<b>Time horizon</b>	<p><b>Clinical time horizon:</b> Short-term: &lt;12 months. <b>Economic time horizon:</b> Lifetime horizon preferred (sufficient to capture long-term complication avoidance and cost savings). <b>Budget Impact time horizon:</b>• 1-year and 5-year scenarios. Rationale: Diabetes complications evolve over decades; short-term analyses underestimate benefit.</p>

*Note: This investment report focuses on a relatively small but important population – people living with T1D. CGMs could equally be beneficial for the insulin-using T2D population.*

## 5. Technology, Pricing and Market Dynamics

### A. Overview of CGM technologies in Kenya

CGM technologies provide real-time information on glucose levels, offering a substantial advancement over conventional SMBG. Two main modalities are available: intermittently scanned CGM (isCGM), which requires the user to scan the sensor to obtain readings, and real-time CGM (rtCGM), which continuously transmits glucose data and can provide alerts for hypo- and hyperglycaemia.

The market is increasingly shifting toward rtCGM, with many newer devices incorporating real-time data transmission and alert functionality, meaning isCGM is likely to become less common over time.

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Several CGM devices are currently available in Kenya, including products registered with the PBB. These devices vary in features, including sensor wear-time (e.g. 10-14 days after which they need to be replaced), performance, price, age indications, and data access (smartphone versus dedicated reader). These device-specific characteristics are summarised in the table below. The remainder of this report adopts a technology-agnostic perspective, focusing on CGM as a class of intervention.

**Table 2: CGM devices available in Kenya**

Manufacturer	Sibionics	Sinocare	MicroTech	Yuwell	Abbott
Model name	GS1	iCan -i3	Linx	Yuwell Anytime CT-5 Sensor	Libre 2
Real-time or intermittently scanned	Real-time or intermittently	real-time	real-time	Real-time	Real-time
Age indication	18+	18+	18+	18+	4+ (2+)
Sensor duration	14 days	15 days	15 days	14 days	14 days
Sensor/transmitter configuration	integrated transmitter	separate transmitter	integrated transmitter	Compatible with CT3 rechargeable transmitter (2year lifespan)	integrated transmitter
Operating temperature	5-40°C	10-42°C	5-40°C	5-40°C	10-45°C
External reader/reading device	no	no	no	no	yes
Mobile phone application (Android/iOS)	yes	yes	yes	yes	yes
*Mean Absolute Relative Difference in %	8.83	8.83	8.66	6.9-9.07	8.2
Platform to consolidate results for healthcare provider and patient	yes	yes	yes	yes	yes
Regulatory approval	CE	CE	CE	CE	CE-IVDD, FDA 510k, Brazil ANVISA, Australia ARTG
Registered with the PBB	yes	yes	yes	yes	no
Alarms	yes	yes	yes	yes	yes
Price per sensor	KES 9,000-13,500	KES 9,000-13,500	KES 9,000-13,500	KES 9,000-13,500	KES 14,500-22,500

\*Mean Absolute Relative Difference (MARD) is the standard metric used to measure the accuracy of CGM devices

## B. Pricing landscape and supply chain

The cost of CGM in Kenya is driven primarily by recurring sensor use, with additional contributions from readers and ancillary supplies (such as plasters). Available evidence suggests that end-user prices in Kenya are substantially higher than ex-works manufacturer prices, reflecting cumulative costs across the supply chain. In practice, importation taxes alone can add approximately 33% to the base price, with additional mark-ups of at least 30% applied at successive stages

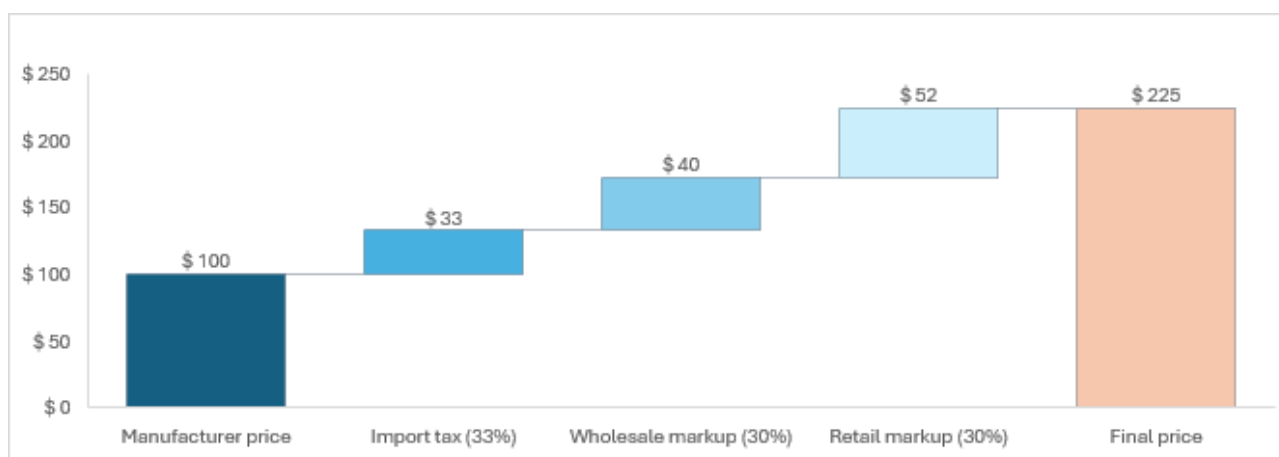
*These price differentials are consistent with evidence from LMIC markets, where mark-ups across distributors, importers, and retailers can increase prices by 50–200% above supplier prices<sup>12</sup>. Prices vary across procurement channels, including private retail markets, and donor-supported programmes, with limited transparency.*

of the supply chain (e.g. wholesale and retail), resulting in total price increases of over 125% relative to manufacturer prices (see Figure 1 for an illustrative example). These price differentials are consistent with evidence from LMIC markets, where mark-ups across distributors, importers, and retailers can increase prices by 50–200% above supplier prices<sup>12</sup>. Prices vary across procurement channels, including private retail markets, and donor-supported programmes, with limited transparency.

While some mark-ups, particularly at the retail level, may be justified, as retailers often bear the financial risk of sensor failure or replacement, and in some cases provide training and user support

to reduce sensor failure rates, the cumulative effect remains substantial. Under the current SHIF model, where facilities procure and SHIF reimburses, the cost of CGM will be determined as much by procurement efficiency as by manufacturer pricing. Without coordinated purchasing or price regulation, SHIF risks reimbursing inflated prices, limiting affordability and scalability.

**Figure 1: Illustrative price build-up for CGM across the supply chain, starting from a hypothetical manufacturer (ex-works) price of USD 100**



From a SHIF and government purchasing perspective, the price faced by SHIF and government reflects not only the underlying manufacturer cost, but the fully loaded price after passing through multiple layers of the supply chain. In Kenya, procurement is fragmented across central mechanisms (e.g. KEMSA with central tender where applicable) and facility-level tenders, while CGM is currently accessed predominantly through private distributors and OOP purchase. As a result, prices incorporate importation costs, distributor margins, and facility-level mark-ups. In addition, fragmented procurement channels limit price standardisation and negotiating power. Together, these factors lead to substantial divergence from international benchmark prices.



Market evidence from LMICs suggests that annual costs for glucose monitoring technologies vary widely, with SMBG typically ranging from approximately USD 98–1,300 per patient per year, and CGM from USD 1,300–2,600 per year, increasing to around USD 3,000 – USD 5,200 in high-income settings.<sup>12</sup> Using ACCEDE-aligned cost inputs for Kenya, SMBG costs are at the higher end of LMIC ranges, with strip prices of approximately USD 0.18 (KES 23) per strip, corresponding to an annual cost of around USD 279 (KES ~36,000), depending on testing frequency. However, CGM costs in Kenya are substantially higher - estimated at approximately USD 3,160 (KES 407,700) per user per year, including sensors (with plaster) and a reader (annualised). This places CGM costs in Kenya more in line with high-income country price levels than typical LMIC benchmarks. Notably, these costs are approximately double those observed in the South African ACCEDE trial (USD 1,602 per year). Sensor prices are a key driver of these costs. In the ACCEDE study, the unit price of the FreeStyle Libre 2 sensor was KES 15,000, while current retail prices in Kenya range from KES 14,500 to KES 22,500 per Libre sensor. Other CGM brands available in the Kenyan market (including Sinocare (iCAN-i3), Sibiomics (GS-1), Linx, and YuWell Anytime CT-5) are typically priced lower, ranging from approximately KES 9,000 to KES 13,500 per sensor, although prices can reach as high as KES 20,000 depending on the supplier and procurement channel. These variations highlight significant cross- and within-country price variation and suggest considerable scope for price reduction through procurement and market-shaping strategies.

*This places CGM costs in Kenya more in line with high-income country price levels than typical LMIC benchmarks.*

Without coordinated procurement, SHIF risks reimbursing inflated end-user prices, increasing budget impact and constraining scalability. Aligning reimbursement with centralised or negotiated procurement mechanisms will be critical to achieving affordable and sustainable CGM access.

### C. Opportunities for price reduction and market shaping

There are clear opportunities to improve CGM affordability in Kenya within existing procurement systems, including KEMSA and facility-level tenders. More strategic use of these mechanisms, such as coordinated or pooled procurement (potentially through SHIF or national structures (HTA)), direct price negotiations including tiered LMIC pricing, and efforts to streamline supply chains and limit intermediary mark-ups, could meaningfully reduce unit costs.

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Expanding public-sector uptake may further drive economies of scale and allow for meaning price discounts. These considerations have direct implications for policy and investment.

Strategic purchasing by SHIF, aligned with coordinated procurement and active price negotiation, has the potential to substantially reduce unit costs and enable equitable access at scale. Conversely, introducing reimbursement without addressing underlying price drivers' risks locking in high costs and limiting fiscal sustainability. As such, procurement strategy should be considered a central component of CGM adoption planning in Kenya.

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## 6. Patient, Caregiver and Community Perspectives

In addition to clinical, economic, and implementation evidence, the perspectives of people living with T1D, caregivers, clinicians, and community stakeholders are an important component of decision-making around CGM access and adoption in Kenya.

**The voices below reflect the everyday realities behind the data.**

*People living with diabetes in Kenya face a significant daily burden from fingerstick blood glucose monitoring. Patients are required to prick their fingers multiple times a day to guide insulin dosing and treatment decisions. This method is painful, disruptive, and difficult to sustain consistently, and also pegged with social stigmatisation.*

*The recurrent cost of test strips, lancets, and glucometers paid outofpocket leads many patients to ration testing or avoid it altogether. As a result, patients are frequently unable to meet recommended testing frequencies, increasing the risk of undetected hyperglycaemia and lifethreatening hypoglycemia.*

*Without continuous awareness of the blood sugar readings, the people living with T1D are at risk of developing diabetes complications. Managing diabetes without consistent blood glucose monitoring is similar to driving a car with zero visibility of the speedometer. Ultimately, investing in CGMs as early as during diagnosis saves premature deaths such as from nocturnal hypoglycemia and improves quality of life.*

*Evidence has shown improved life after CGM hence CGMs should be included as part of diabetes management and for a chronic and unpredictable condition such as T1D - CGMs are a necessary tool in management of T1D. Private health insurances are warming up to include CGMs as a benefit for T1D clients since it will be more economical to pursue this than end up with a kidney dialysis bill in the millions....In other words, CGMs are cheaper than a lost leg due to diabetes, lost sight due to diabetes and a youthful premature life lost.*

*Let's move from Fear in diabetes management to patient empowerment.  
The diabetes marathon...*

**Patient advocate and person living with T1D**

*I have been a Type 1 Diabetic for the past 15 years, and part of my treatment plan is to monitor my sugars constantly. I have been using the glucometer for glucose testing and have always hoped there is a better way to be able to do that. Testing with the glucometer has been hectic; to say the truth I had been missing tests often because of the many injections and the long process it took. Sometimes I would have to inject so many times before I got enough blood and sometimes it was painful. The needles leave marks on your fingers as a sign of your struggles. This had also been part of getting Diabetes fatigue and prayed for something better and less painful.*

*Last year, I decided to do some research on other ways to do the tests without as much pain. I had been really struggling and my sugars were very out of control. I saved up, bought myself one sensor, and tried it for two weeks. I felt like I had gotten a breath of fresh air. I got hope that things would be better and hoped to be able to get access to and afford such so that I can get better control of my sugars. The CGM (Continuous Glucose Monitor) was expensive hence could not afford another.*

*When I got the opportunity to participate in the study, I was so excited that the burden was getting easier. The CGM was free and had so many advantages that the glucometer did not have. I could get my graphs readily and get better treatment. The recording of sugars and meals was taken in the CGM hence no need to record in books.*

*It would alarm hypoglycemia and me if I was going low or high and would be able to mitigate the hyperglycemia before they could happen. The alarms also would wake me up or whoever was near me would be alarmed and take the necessary action to help me navigate.*

*The CGM was amazing and gave me hope that there was hope for the future. I had my HBA1C also estimated from the CGM and they helped me bring my sugars down. My nurses and doctors really supported us throughout the period and was able to be more open hence put correct measures in place. The CGM was convenient as it was easy to carry and you could get your glucose tested anywhere and at any time making more tests possible. It was also not painful to insert and only needed changing once every 2 weeks rather than the glucometers where you change strips every time and sometimes leave a mess as the strips may scatter.*

*The CGMs had a few disadvantages as they could be hit by someone or something or get off when asleep hence needing a sensor replacement which we would have to go for at the hospital. They also left a mark and get a bit itchy after removal.*

*I have since gone back to using the glucometer. It had taken a bit of time since I was not used to testing my fingers all the time. I have been able to try to test at least 4 times tests per day compared to the previous 9 or 10 per day. The marks on my fingers are back and I can only know my sugars by testing. If I am hypoglycemic or a hyperglycemic I no longer have alarms to remind me so I have to listen to my body. Even then, I have to test first to be sure. I can no longer use a CGM since I cannot afford it due to its high costs. I am also back to writing in my Diabetic Diary, which I tend to forget sometimes.*

*I was deeply motivated by the CGM use and would like to have them available for free or at a lower price so more of us can be able to use it and make Diabetes Management easier. This is so as to prevent extreme hypes and hypos leading to complications or early death. CGMs can really make the burden easier on us.*

#### **Person living with T1D**

*For us, N used the CGM for a month and she really loved it because there was no pricking anymore. As a caregiver the machine was good since I was able to monitor her sugar all the time so long as she was around the phone. The challenges were that her school never allowed her to go with the phone at school, so we had to take to her during lunch and also the sensor sticker required reinforcement as it 's glue was not strong enough.*

*Generally, CGM is the way to go because of the tap and go way of checking sugars and was comfortable for N.*

#### **Caregiver**

*My name is M, mother to a 13-year-old boy called CK with Type 1 diabetes.*

*Our experience using the CGM machine has been life changing. We got our first machine sometime in April '26. It really came in handy because 2 days later he experienced hypoglycemia and was unconscious for minutes. The machine was able to tell us how low the sugars had gone in seconds and how fast it was rising until he was conscious again.*

*It has also raised his confidence levels in that he can read his sugars without anyone noticing and enquiring what he is doing.*



*He recently travelled to Uganda for school activities, and we are able to monitor his sugars remotely. The alerts and continuous monitoring have also provided reassurance and helped him respond quickly whenever his levels change unexpectedly. Previous experiences with him travelling far have not been very pleasant, this really came at the right time.*

*Generally, I would say it has improved everybody's peace of mind and enabled better management.*

**Caregiver**

*Before CGM, my daughter was testing her blood sugar 4-6 times a day and still felt blindsided by highs and lows. Talking about pricking her finger that many times in a day was heartbreaking for both of us.*

*After getting the CGM, everything shifted. I could see in real time how food spiked her glucose, so we stopped guessing. On days when she wasn't in the mood to prick her finger, we still had the data we needed.*

*Honestly, the CGM gave me my peace of mind back. I'm not constantly wondering if she tested or not. And she feels less anxious about eating out – people don't keep asking her questions when she's not pulling out a glucometer in public.*

*It's changed our day-to-day more than I expected.*

*The only problem is that it's quite costly and sometimes with this economy it's a hassle.*

*So, I would really appreciate any help I can get to get the CGM.*

**Caregiver**

*Hello, Am Mama M and my daughter is 12 years old now...diagnosed with type 1 diabetes at 8 years of age. Four years of injections 8 or more times a day is not a joke, it takes God's grace.*

*Before CGM I had a hectic time with my daughter like:*

*\*Reminding her to regularly check her blood sugars*

*\*Sometimes the sugars are too high or too low maybe it's at night before you realize the child has become sick*

*\*The fact that you keep pricking the fingers some are left with bruises*

*\*She gets exhausted to keep now and then pricking, carrying the pricks, swabs, the waste around her...(It's dangerous especially to the young ones - they tend to forget and put the needles in the pockets or scatter them anyhowly).*

*THEN, recently, THE KENYATTA NATIONAL HOSPITAL, introduced us to CGM whereby it was the best thing that made our lives easier managing diabetes.*

- 1. CGM made our kids not to keep pricking themselves now and then...the pain that comes with pricking.*
- 2. It was safe and easy to use in terms of you just need to swipe the monitor and you get the readings anytime you need.*
- 3. It prevents hypoglycemia/hyperglycemia since the monitor shows you when the glucose levels start to go low or high and you correct at the right time.*

4. *One get to understand which kind of foods are favourable for managing diabetes... e.g. there are some foods once taken the sugars spike.*

5. *CGM keeps record over the longest time possible.*

*KINDLY, we request if there is a way we as the diabetic parents and children can benefit from CGM. We are going to be glad and much thankful again again....*

*May God bless you.*

**Caregiver**

*Hi, I am a beneficiary of the CGM and I would say it's a life saver, its helped alot because I could correct the sugars immediatly when they are high or low because of the alarm. It also helped on monitoring the sugars all day without missing any record. At night I didn't have to wake my son up and prick him just to know how he is and for the first time in years I saw my son's fingers without marks due to pricking. The list is endless, but it simply made our life with diabetes easier.*

**Caregiver**

*CGM was the best thing I ever encountered in this journey of diabetes type 1 management. It showed me the other side of managing this condition that I had overlooked. With it you don't have worries of how the child is faring on even in your absence.*

*And I thank your effort KNH for giving us an opportunity to experience CGM for those 3 months.*

*Thank you.*

**Caregiver**

*As of now you have to wake up in the middle of the night to test so she has to wake up so that's very uncomfortable, for CGM you just swipe.*

**Caregiver**

*Before trying CGM, I depended fully on finger-prick testing several times a day. The frequent pricking causes pain, discomfort, and leaves marks on her fingers. At times, especially in public places or school, testing became uncomfortable because people would stare or make assumptions without understanding what she was going through.*

*Another major concern was not being able to know immediatly when her sugars were going too high or too low. As a parent, this constant uncertainty creates fear, especially regarding hypoglycaemia and DKA. There was even a time when N experienced severe hypoglycaemia due to low blood sugar levels, which was very frightening for both her and us parents. Situations like this show how difficult it can be to manage Type 1 diabetes without continuous monitoring. CGM would make a huge difference for children. It offers convenience, privacy, and peace of mind. Being*

*able to monitor glucose readings remotely through a synchronized mobile phone, even while the child is in school, would greatly improve safety and reduce anxiety for caregivers. It would also reduce the physical and emotional burden of constant finger pricking. I truly believe wider access to CGM, regardless of status, would improve the quality of life and safety of many children and young adults living with Type 1 diabetes in Kenya.*

**Caregiver**

*My daughter is now one month into using the CGM machine. It is a life-saving machine, you stop worrying about the pain of pricking and wrong testing.*

**Caregiver**

*I would like to share my experience with using CGM that we were gladly offered by Kenyatta National Hospital. I'm a mother of a 10-year-old girl who is a warrior of type 1 diabetes since she was 6 years. And we have been using the strips, injecting and testing through the glucometer machine. Then this year, January 2026, we got a chance to be given the CGM machine which she was using until March 2026. And I can say that it was a game changer. CGM machine is very easy to use. For us, our daughter was really enjoying, imagining there are so many pricks she used to do that now she's not doing them. So, it was just scanning, and when she could scan and read, so she would know now the sugars are going up or down or they are okay.*

*I wish we can get or even afford to be getting the CGM sensors more often which we shall really appreciate. So, I think CGM machine is a lifesaver, it's a gamechanger to every person who has diabetes. And it saves time, it saves your energy, and it is easy to use. And you can carry it anywhere. You can swim with it. You can do your exercises while you have it on your body. So, thank you so much, KNH, for allowing us that opportunity to enjoy using the free CGM. I wish and I pray we can get that project ongoing forever.*

*Thank you, Mama N.*

**Caregiver**

*As a parent of an 8-year-old child living with Type 1 Diabetes, the introduction of CGM completely transformed our lives. Before using CGM, managing diabetes was emotionally and physically exhausting for both my daughter and our family. She had developed a strong fear of needles due to the many daily finger pricks required to monitor her blood sugar levels. Every glucose check became stressful, painful, and emotionally draining for her.*

*When we started using CGM, life became much easier and safer. The device provided real-time blood sugar readings throughout the day and night without constant finger pricks. This gave my daughter relief from the daily pain and anxiety she previously experienced. She became more comfortable, confident, and less fearful about diabetes management.*

*One of the greatest benefits for our family was nighttime monitoring. Before CGM, we constantly woke up at night to manually check her sugar levels because of the fear of hypoglycaemia. Sleep was interrupted, and we lived in constant worry. With CGM, we could rely on the alarm system to alert us whenever her sugar levels went too low or too high. This improved our sleep, reduced anxiety, and gave us peace of mind knowing that we would be warned early enough to take action.*

*CGM also helped us better understand how different meals, activities, and routines affected her glucose levels. We could clearly see patterns and trends after meals, during exercise, or while sleeping. This helped us identify which foods worked well for her body and which ones caused sudden spikes or drops in sugar levels. As a result, we were able to make better decisions regarding her diet, insulin dosing, and daily routine.*

*Most importantly, CGM improved my daughter's safety and overall quality of life. It reduced the risk of severe hypoglycaemia and diabetic emergencies such as DKA because we could respond quickly to changes in her glucose levels. It also allowed her to participate more freely in school activities, play, and daily childhood experiences without constant fear.*

*I strongly believe that every child living with Type 1 Diabetes should have access to CGM regardless of their socioeconomic status. CGM is not just a device; it is a lifesaving tool that reduces emotional stress, improves diabetes management, protects children from dangerous complications, and gives families hope and peace of mind. Increased access to CGM would greatly improve the lives of many children and caregivers living with Type 1 Diabetes in Kenya.*

**Caregiver**

*It is almost two years since our son was first diagnosed with Type 1 Diabetes, and not a single day has gone by without me remembering the fear, confusion, and heartbreak of that season. As I write this, I do so with deep gratitude for the nurses who stood beside us during one of the darkest moments of our lives.*

*Before the diagnosis, I honestly thought diabetes was mainly a lifestyle condition. I believed we were doing everything right as parents. I cooked with garlic and ginger, ensured there was fruit every day, and while we allowed the occasional snack or junk food, it was always in moderation – just the normal little treats children enjoy.*

*So, when my son started displaying symptoms of illness, diabetes never crossed my mind. He had just moved to a higher class in school, and because he is neurodivergent, I assumed the changes and increased workload were simply stressing him out. We took him to a nearby clinic, but they missed the diagnosis completely.*

*His breathing became heavier with time. He would come home with his bottle of water still full, so I even called his teacher and asked her to encourage him to drink more water at school. At night, he would wake up frequently. Still, I did not understand what was happening.*

*When his breathing did not improve, I decided to consult a pediatrician. I suspected pneumonia. The doctor requested a chest scan and also asked us to do an RBS test. I had never even heard of an RBS before.*

*At our local hospital, they started with the RBS. It read 26.*

*Immediately, I saw panic on the attendants' faces. People started running around, moving him into another room, setting things up urgently. I remember standing there confused, wondering, "What is happening? Why is everyone panicking?"*

*Then the questions began:*

*"Does your son have diabetes?"*

*"How long has he been like this?"*

*"Has he been drinking water excessively?"*

*"Has he been urinating frequently?"*



*It felt like an endless interrogation, and while I knew some answers, most of them I did not.*

*At the hospital, they put him on oxygen. That was the moment I completely lost it. I panicked. They started talking about needing an HbA1c test to determine how long he had been living with the condition.*

*Condition? What condition? From that instant, my nightmare began.*

*This was in June 2024. At some point, they could not bring his sugar levels down, and we had to rush him to another hospital that could accommodate him. That hospital did not have a pediatrician available, so we were referred again – this time transported in an ambulance, sirens blaring, my son hooked up to oxygen while the attendant kept saying they were trying to bring his sugar down.*

*When we finally arrived at the ER, it was another whirlwind of activity. There, a doctor finally explained to us what DKA was. Until then, I had never heard the words “Diabetic Ketoacidosis.”*

*All I could see was my son in pain. And all I kept asking myself was: “How could I have been so blind?”*

*The nurses at Kenyatta National Hospital held our hands through moments I thought I would never survive. They explained things and reassured us through this journey. Through them, I was introduced to Diabetes Management and Information Centre (DMI), and from that day to now, we have continued to receive tremendous support, education, and encouragement.*

*One thing that has greatly changed our journey is the use of a Continuous Glucose Monitor (CGM).*

*The CGM has been life-changing for our son and family.*

*It is more hygienic and reduces the risk of infection from constant finger pricks. It allows us to monitor glucose levels continuously without repeatedly causing pain and discomfort to our child. It gives real-time readings and alerts, helping us catch dangerous highs and lows before they become emergencies.*

*As a parent, it has also given me peace of mind, especially at night. Instead of waking him multiple times for finger-prick tests, we can monitor trends more comfortably and accurately. It has improved his quality of life, helped us manage school routines better, reduced anxiety, and allowed him to feel more like a normal child again.*

*Most importantly, the CGM has helped us make quicker, more informed decisions about insulin, meals, and activity levels. It has transformed diabetes management from constant fear into something more manageable and proactive.*

*To every nurse, caregiver, diabetes educator who works tirelessly managing, educating and caring for children with Type 1 Diabetes – thank you.*

*Thank you for your patience.*

*Thank you for your compassion.*

*Thank you for educating frightened parents.*

*Thank you for holding families together during terrifying moments.*

*Thank you for treating our children with kindness when they are at their most vulnerable.*

*You may not always realize it, but your words, calmness, reassurance, and care leave lifelong marks on families like ours.*

*Today, almost two years later, we are still learning, still adjusting, still fighting – but we are also stronger and more knowledgeable because of the support we received from nurses at KNH and the team at DMI.*

*A grateful mother*

**Caregiver**



*Using a CGM has honestly been life-changing for us. It is efficient, easy to use, and can be used anywhere, anytime. What I love most is that anyone can check the sugar levels even grandparents which brings so much peace of mind.*

*The reduced number of finger pricks has made such a huge difference. It truly feels like a lifesaver altogether.*

*And the best part? A child can still swim, shower, and live normally while wearing it - simply majestic.*

*Did I mention the alarms for high and low sugars? Those alerts instantly reduce the risks related to hypos and hypers. It gives comfort, confidence, and safety in a way that is hard to explain unless you have experienced it yourself.*

*I absolutely love it, and I genuinely wish every family that needs one could afford it. Maybe the government should step in and make CGMs more accessible because they are not just devices; they are lifesavers.*

**Caregiver**

## 7. Clinical Effectiveness of CGM in People Living with Type 1 Diabetes

This section synthesises the international clinical evidence on the effectiveness of CGM compared with SMBG and complements it with regionally generated evidence from the ACCEDE pragmatic randomised controlled trial (RCT) in South Africa and the usability study in Kenya. The purpose is to summarise high-quality existing evidence rather than perform a full systematic review, drawing on the strongest available trials and meta-analyses.

### A. International

The most robust synthesis of CGM effectiveness is the Maiorino et al. (2020) systematic review and meta-analysis, which pooled 18 randomised controlled comparisons of CGM versus SMBG use in T1D8. A key contribution of this review is its subgroup analysis separating real-time CGM (rtCGM) from intermittently scanned CGM (isCGM). Although both technologies improve glucose monitoring, they differ in functionality: rtCGM transmits glucose values automatically via Bluetooth, whereas isCGM requires users to actively scan the sensor to obtain readings. As mentioned in the Technology section, this distinction is no longer relevant as most new devices are rtCGM but it was relevant for the ACCEDE trial. The Maiorino subgroup findings show that the magnitude of the HbA1c benefit differs by device type:

- rtCGM: HbA1c reduction  $-0.23$  percentage points (95% CI  $-0.36$  to  $-0.10$ ),  $p < 0.001$
- isCGM: HbA1c effect  $0.00$  percentage points (95% CI  $-0.01$  to  $0.02$ ),  $p = 0.861$
- Overall pooled effect:  $-0.17$  percentage points ( $-0.29$  to  $-0.06$ ),  $p = 0.003$

These results are consistent with the more recent Diabetologia meta-analysis by Teo et al. (2022)<sup>7</sup>, which synthesised 22 RCTs ( $n \approx 2,100$ ) comparing CGM with SMBG in people living with T1D. Teo et al. reported an overall mean HbA1c reduction of  $-0.23$  percentage points with CGM versus SMBG, with larger benefits ( $\approx -0.4$  percentage points) among individuals with poorer baseline glucose levels (HbA1c  $> 8\%$ ), and no clear effect on DKA or severe hypoglycaemia events. A complementary meta-analysis of isCGM by Evans et al., which included predominantly real-world and short-term studies (rather than only RCTs), reported an HbA1c reduction of around  $0.5$  percentage points; this larger effect likely reflects differences in study design, higher baseline glycaemia, and shorter follow-up duration rather than a true divergence from RCT evidence<sup>27</sup>. Notably, the subsequent FLASH-UK RCT conducted within the UK National Health Service (NHS) by Leelarathna et al. also demonstrated a statistically significant HbA1c reduction of approximately  $0.5$  percentage points with isCGM compared with SMBG, alongside improvements in TIR and reduced hypoglycaemia, providing more recent RCT evidence that isCGM can achieve clinically meaningful glycaemic improvements in routine care settings<sup>28</sup>.

Table 3 below summarises the major RCTs since 2015 that directly compare CGM with SMBG and largely evaluate rtCGM systems. These trials, conducted primarily in Europe and the United States, reinforce the pattern observed in the Maiorino and Teo analysis (GOLD, DIAMOND, HypoDE are included in the Maiorino and Teo meta-analyses) and demonstrate:

- HbA1c reductions of approximately  $0.3$ – $0.6$  percentage points, with the strongest effects in adults with higher baseline HbA1c.
- Increases in TIR ( $70$ – $180$  mg/dL) of approximately  $1$ – $1.5$  hours per day, a clinically important improvement associated with fewer long-term complications.
- Substantial reductions in hypoglycaemia among high-risk individuals, particularly in trials focused on impaired awareness or recurrent severe hypoglycaemia (e.g., HypoDE).

**Table 3: Randomised Controlled Trials (2015–present) comparing CGM vs SMBG in people living with T1D**

Study (Year)	Population & Setting	Insulin Regimen	CGM Device	N	Duration	HbA1c Change (CGM – SMBG)	TIR/Hypo Change (CGM – SMBG)	Key Notes
<b>GOLD Trial</b> – Lind et al., 2017 (JAMA) <sup>29</sup>	Adults with T1D, Sweden	MDI only	Dexcom G4 rtCGM	161	2 × 6-month crossover	-0.43%		Crossover RCT; High adherence; strong evidence for MDI users.
<b>DIAMOND T1D</b> – Beck et al., 2017 (JAMA) <sup>30</sup>	Adults with T1D, US	MDI only	Dexcom G4 rtCGM	158	6 months	-0.6%	+1.0 h/day TIR	Better satisfaction; fewer hypoglycaemia episodes.
<b>HypoDE</b> – Heinemann et al., 2018 (Lancet) <sup>31</sup>	Adults with impaired hypoglycaemia awareness, Germany	MDI only	Dexcom G5 rtCGM	149	6 months	No significant HbA1c difference	↓ hypoglycaemic events by 72% (TIR ↑ mainly from reduced TBR)	Most relevant for high-risk patients.
<b>IMPACT Trial</b> – Bolinder et al., 2016 (Lancet) <sup>32</sup>	Adults with well-controlled T1D, Europe	MDI only	FreeStyle Libre (isCGM)	241	6 months	No significant HbA1c change	↓ time in hypoglycaemia by 38% (~1.0 h/day)	Key flash/isCGM RCT; improved satisfaction
Laffel et al., 2020 (JAMA) <sup>33</sup>	Adolescents & young adults (14–24 yrs), US	MDI & pumps	Dexcom G5 rtCGM	153	26 weeks	-0.37%	+1.7 h/day	Stronger benefits among adherent users.
Helmi et al., 2021 (Malaysia, paediatrics) ( <b>RoSEC</b> ) <sup>34</sup>	Children with T1D, Malaysia	Mixed	Medtronic CGM	22	3 months	No HbA1c difference	↓ hypoglycaemic events	LMIC evidence (small sample). Periodic use of CGM
<b>FLASH UK Trial</b> – Leelarithna et al., 2022 (N Engl J Med) <sup>28</sup>	Adults with T1D, UK (NHS setting)	MDI & pumps	FreeStyle Libre (isCGM)	156	6 months	-0.5%	↑ TIR (~+1h/day); ↓ time <3.9 mmol/L	Key isCGM RCT

*This table includes only the large RCTs published since 2015 where CGM was directly compared with SMBG, regardless of whether participants used Multiple Daily Injections (MDI) or pumps. Trials of sensor-augmented pumps or hybrid closed-loop systems are excluded because they reflect different technologies not under consideration in this investment case. MDI = multiple daily injections; TIR = Time in Range; TBR = Time*

While this evidence base is extensive, it is drawn predominantly from high-income countries. A recent scoping review by Bernabe-Ortiz et al.<sup>13</sup> (2023) mapped the use of CGMs in LMICs and found that empirical evidence is limited in both quantity and scope, with most studies being small, single-centre observational designs and very few RCTs. As a result, there is limited strong (trial-based) evidence from LMICs, and most robust RCT data on CGM effectiveness still comes from high-income settings. This evidence gap is particularly pronounced in sub-Saharan Africa, where published CGM studies remain few, generally involve small cohorts, and rarely include comparator SMBG arms.

*As a result, there is limited strong (trial-based) evidence from LMICs, and most robust RCT data on CGM effectiveness still comes from high-income settings. This evidence gap is particularly pronounced in sub-Saharan Africa, where published CGM studies remain few, generally involve small cohorts, and rarely include comparator SMBG arms.*



*As a result, robust trial evidence for periodic CGM use in T1D is extremely limited, and the ACCEDE trial represents one of the first randomised evaluations of a structured periodic-use regimen (2 weeks every 3 months).*

Further, there is no systematic review or meta-analysis specifically evaluating periodic CGM use in T1D. “Periodic use” refers to a structured regimen in which a CGM sensor is worn only for short, predefined intervals, such as 1–2 weeks every 1–3 months, while individuals rely on SMBG between these cycles. Existing syntheses focus almost entirely on continuous CGM wear, reflecting the structure of the underlying evidence base. Trials that involve periodic sensor use (such as blinded professional CGM worn for short diagnostic periods) are typically performed in T2D and for treatment adjustment, rather

than as an ongoing monitoring strategy. As a result, robust trial evidence for periodic CGM use in T1D is extremely limited, and the ACCEDE trial represents one of the first randomised evaluations of a structured periodic-use regimen (2 weeks every 3 months).

## **B. Local evidence**

Published evidence on CGM effectiveness in Kenya is extremely limited, with no large-scale trials or economic evaluations identified. One of the earliest CGM studies in East Africa was a pilot and feasibility study conducted in Kenya and Uganda by McClure Yauch et al. (2020), which assessed CGM use among children and young adults living with T1D but did not evaluate treatment effects versus SMBG or longitudinal HbA1c changes following CGM initiation<sup>35</sup>.

More recent observational evidence from the region nevertheless suggests that CGM may offer clinically meaningful glycaemic benefits in routine care settings. A recent study from Rwanda by Baker et al. (2025) reported large reductions in

*Similarly, early evidence from the Kenyan ACCEDE study (n=40) demonstrated a mean reduction in HbA1c from baseline of -1.38% [-2.07, -0.68] and an increase in TIR of 5.6% (from 32.4% to 38%) at 3 months following CGM initiation among participants aged 4-25 years.*

HbA1c among people living with T1D using CGM, with mean HbA1c decreasing by 2.8 percentage points at 6 months ( $P<0.001$ ) and 3.2 percentage points at 12 months ( $P<0.001$ ). However, the study did not include an SMBG comparator arm and therefore could not formally estimate treatment efficacy<sup>36</sup>. Similarly, early evidence from the Kenyan ACCEDE study (n=40) demonstrated a mean reduction in HbA1c from baseline of -1.38% [-2.07, -0.68] and an increase in TIR of 5.6% (from 32.4% to 38%) at 3 months following CGM initiation among participants aged 4-25 years. Although the study did not include a control arm and therefore could not formally establish

treatment efficacy, the magnitude of HbA1c improvement observed provides important preliminary evidence supporting the feasibility and potential effectiveness of CGM use in Kenya.

Further emerging evidence from sub-Saharan Africa includes the pilot RCT conducted by Gomber et al. (2024) evaluating rtCGM among individuals (n=45) with T1D in Malawi<sup>37</sup>. Although the study was not powered to detect statistically significant differences in HbA1c between the rtCGM and SMBG arms, the findings demonstrated the feasibility of rtCGM implementation in a low-resource setting and showed a promising downward trend in HbA1c among participants using rtCGM.

*The larger ACCEDE RCT conducted in South Africa provides the first robust comparative evidence on the effectiveness of both continuous and periodic isCGM use for people living with T1D in public sector settings in South Africa*

The larger ACCEDE RCT conducted in South Africa provides the first robust comparative evidence on the effectiveness of both continuous and periodic isCGM use for people living with T1D in public sector settings in South Africa. Conducted across three major public sector hospitals in South Africa and enrolling 248 children, adolescents and adults with baseline HbA1c  $\geq 10\%$ , the trial compared continuous isCGM, periodic isCGM (2 weeks wear-time every 3 months), to standard SMBG-based care over a period of 9 months.

At 3 months, periodic isCGM already demonstrated statistically significant improvements in HbA1c compared with SMBG (-0.80%), while continuous isCGM showed a smaller, non-significant reduction (-0.43%) (Table 4). At 6 months in the intention-to-treat (ITT) population, only the periodic use CGM demonstrated statistically significant and clinically meaningful improvements in HbA1c (> 1 percentage point reductions) compared with SMBG. At month 9 (the trial endpoint), neither continuous nor periodic CGM showed statistically significant differences, where the effect sizes were smaller (ranging from -0.21% to -0.36%). Similarly, among children and adolescents in the ITT population, effect sizes were attenuated (approximately -0.12% to -0.24%) and did not reach statistical significance at the 9-month time point (periodic use was significant at the 6-month time point). These non-significant results likely reflect the complexity of the study population (including younger patients and those with a very high baseline HbA1c) as well as broader challenges to sustained engagement and scanning behaviour within a resource-constrained care ecosystem.

**Table 4: Adjusted between-arm differences in HbA1c (%) for CGM versus SMBG at 3, 6 and 9 months in the intention-to-treat population: ACCEDE trial, South Africa**

	Intention to treat population		
	3 months	6 months	9 months
Continuous isCGM vs SMBG	-0.43 [-1.18, 0.32]	-0.53 (SE 0.32, p=0.228)	-0.21 (SE 0.31, p=0.766)
Periodic isCGM vs SMBG	-0.80 [-1.54, -0.06]	-1.13 (SE 0.32, p=0.001)	-0.36 (SE 0.3, p=0.470)

Although the trial in South Africa was not powered to detect statistically significant differences in hospitalisation outcomes, a trend towards higher diabetes-related hospitalization rates was observed in the standard of care arm compared with the intervention arms. TIR outcomes were assessed only among CGM users; therefore, direct between-arm comparisons with standard care were not possible, although periodic CGM users generally demonstrated higher TIR than continuous CGM users (30-33% for periodic CGM users vs. 24-25% for continuous). Measures of glucose variability showed that the coefficient of variation of glucose concentrations was consistently lower among continuous CGM users than periodic CGM users across both ITT, reaching statistical significance at month 3 suggesting more stable glucose control with continuous use.

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### C. Interpretation and Implications

International meta-analyses typically report small but statistically significant CGM–SMBG differences, in the order of -0.17% to -0.23%. In contrast, the ACCEDE RCT in South Africa observed numerically larger HbA1c reductions (ranging from -0.2% to -1.13%) in a younger and more clinically complex real-world cohort. Unlike the more stable populations typically enrolled in high-income country trials, ACCEDE participants exhibited substantial glycaemic variability, with standard deviations higher than those reported internationally. This higher variability may have limited the ability to detect smaller effect sizes of the magnitude observed elsewhere.

In addition, the magnitudes of within-arm HbA1c reductions seen at 6 and 9 months in the ACCEDE trial, whilst not statistically significant, may still be of clinical interest. Even modest reductions in HbA1c ( $\approx 0.3$ – $0.5\%$ ) have been associated with reductions in microvascular risk, given the continuous relationship between glycaemia and complications demonstrated in the Diabetes Control and Complications Trial (DCCT)/ United Kingdom Prospective Diabetes Study (UKPDS), which may provide context for interpreting these findings<sup>38–40</sup>. Further, evidence from paediatric cohorts indicates a metabolic



memory effect, whereby glycaemic control in the first months after T1D diagnosis predicts long-term HbA1c trajectories and complication risk<sup>41–45</sup>. This suggests that CGM introduced early in the disease course could have longer-term implications, even where short-term trial effects (as observed in ACCEDE) in children and adolescents are not significant. This is consistent with ISPAD guidelines, which recommend intensive monitoring and individualized targets to support optimal long-term outcomes in children and adolescents with T1D<sup>46</sup>.

Across analyses, periodic CGM use appeared to perform similarly to, and in some cases better than, continuous use. At

*For a resource-constrained public health system, periodic use could therefore represent a potentially feasible early implementation strategy.*

6 months, the periodic arm achieved the largest observed HbA1c reduction. This suggests that periodic CGM may represent a lower-intensity approach to CGM use, delivering some glycaemic benefit even at lower levels of sensor utilisation. For a resource-constrained public health system, periodic use could therefore represent a potentially feasible early implementation strategy.

The HbA1c reductions observed in ACCEDE are particularly notable given that ACCEDE evaluated isCGM, not rtCGM, which has shown larger effects in high-income settings. With technological improvements, newer rtCGM devices such as the FreeStyle Libre 2 are now available at no additional cost relative to isCGM. This means that future implementation in Kenya and South Africa could potentially incorporate more advanced rtCGM technologies at the same price (or lower), although the extent of any additional benefit in this context remains uncertain.

In summary, international evidence strongly supports CGM effectiveness, while emerging evidence from Kenya and South Africa suggests that CGM can achieve clinically meaningful improvements in glycaemic control in public sector settings

*Collectively, these findings suggest that CGM impact in this setting may depend on sustained device engagement, structured education, and follow-up support.*

in sub-Saharan Africa. The Kenyan ACCEDE study demonstrated substantial HbA1c reductions over 3 months following CGM initiation, while the larger South African RCT showed significant HbA1c improvements with periodic CGM use at 3 and 6 months compared with SMBG. Collectively, these findings suggest that CGM impact in this setting may depend on sustained device engagement, structured education, and follow-up support.

## 8. Economic Evaluation – the ACCEDE Trial and Model

International economic evaluations consistently demonstrate that CGM is cost-effective for people living with T1D, particularly in high-income settings. A recent systematic review by Jiao et al. found that most published CGM evaluations report favourable incremental cost-effectiveness ratios (ICERs), often well below commonly used WTP thresholds<sup>9</sup>. In addition, the UK FLASH study, which evaluated isCGM in routine NHS care, found that isCGM was cost-effective and even cost-saving for the sub-group with high HbA1c (>9-11%)<sup>47</sup>. However, this evidence is almost exclusively based on high-income country cost structures, healthcare utilisation patterns, and reimbursement arrangements, which are not directly transferable to Kenya.

Given the large differences in health systems, device prices, service delivery costs, and baseline glycaemic control in Kenya, a de novo economic evaluation using local data was essential. We conducted a modelled lifetime cost-utility analysis to capture longer-term costs and health outcomes not observable within the study period. The device used in the study was the Abbott Freestyle Libre II priced at KES 25,000/reader and KES 15,000/sensor. Modelling report available upon request.

### Modelled lifetime cost-effectiveness analysis

A validated diabetes microsimulation model was used to project lifetime costs, life years, and QALYs associated with CGM compared with SMBG<sup>48</sup>. Given the absence of a Kenyan control arm, multiple effectiveness scenarios were explored to reflect uncertainty around the magnitude, durability, and generalisability of treatment effects across settings. Specifically, the analyses incorporated (Economic Modelling report available upon request):

- (i) the observed **3-month** HbA1c reduction from the *Kenyan ACCEDE cohort* for continuous CGM use,
- (ii) the **3-month** HbA1c effect observed in the *South African ACCEDE RCT* for continuous use, and
- (iii) the **9-month** HbA1c effect observed in the South African trial for continuous use, representing a more conservative estimate of sustained long-term treatment effect.

Across all scenarios, CGM used continuously or periodically was associated with improved glycaemic control, fewer acute diabetes events, increased life expectancy, and QALY gains relative to SMBG. However, the high acquisition cost of CGM devices substantially increased total lifetime costs.

The Kenyan ACCEDE cohort demonstrated the largest short-term treatment effect, with mean HbA1c decreasing by approximately 1.38 percentage points at 3 months from a high baseline HbA1c (~10.8%). Participants in the Kenyan cohort also demonstrated substantially higher CGM engagement than observed in the South African trial, with average scanning frequencies exceeding 10 scans per day compared with approximately 3–6 scans per day in South Africa, suggesting more consistent device use and potentially greater responsiveness to CGM-informed behavioural changes. However, as the Kenyan study included only a single-arm continuous CGM cohort, with no comparator or periodic CGM arm, these findings should be interpreted cautiously. When extrapolated over the lifetime horizon, the Kenyan effectiveness estimates resulted in an ICER of approximately KES 3 million per QALY gained for continuous CGM versus SMBG, substantially above commonly referenced Kenyan cost-effectiveness thresholds (Table 5)<sup>1</sup>.

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<sup>1</sup> As Kenya does not have an explicitly adopted cost-effectiveness threshold for decision-making, results were interpreted against published estimates of opportunity cost-based thresholds for the Kenyan health system. We used the estimate proposed by Pichon-Rivière et al., corresponding to approximately USD 682 per QALY (2024 USD equivalent), as the primary reference.<sup>49</sup>

Similarly, when South African ACCEDE treatment effects were applied, continuous CGM remained unlikely to be cost-effective at current Kenyan prices. Using the South African 3-month HbA1c effect resulted in an ICER of approximately KES 4.6 million per QALY gained, while using the more conservative 9-month treatment effect resulted in an ICER of approximately KES 4.7 million per QALY gained (Table 5). In all scenarios, acquisition costs of sensors and readers were the dominant cost driver and outweighed downstream savings from avoided complications and acute events.

These findings suggest that, at current retail pricing, continuous CGM is unlikely to represent good value for money for broad public-sector adoption in Kenya, despite potentially meaningful clinical benefits. However, the analyses also demonstrate that

*However, the analyses also demonstrate that cost-effectiveness is highly sensitive to device pricing.*

cost-effectiveness is highly sensitive to device pricing. Preliminary threshold analyses suggest that substantial price reductions (86%-93%) for both the reader and sensor would be required before continuous CGM approaches conventional cost-effectiveness thresholds<sup>1</sup> in Kenya (Table 5). These threshold ranges reflect the different treatment-effect scenarios explored, including both the more optimistic short-term effects observed at 3 months in Kenya and South Africa, and

the more conservative sustained 9-month treatment effect observed in the South African trial. This means that the price of the sensor needs to decrease from KES15,000 to approximately KES 1,125 – KES 2,100.

Although **periodic CGM use** was not directly evaluated in the Kenyan cohort, findings from the South African ACCEDE trial suggest that lower-intensity CGM strategies may offer a more feasible and potentially more cost-effective implementation pathway in resource-constrained settings. Because periodic CGM requires substantially fewer sensors per year, it markedly reduces acquisition costs while still delivering clinically meaningful improvements in glycaemic control. Because periodic CGM use was not directly evaluated in Kenya, exploratory threshold analyses incorporated both the 6-month periodic-use treatment effect observed in the South African ACCEDE RCT, representing the strongest observed periodic-use outcome in the trial, and an exploratory scenario applying the larger Kenyan 3-month continuous-use effect to periodic CGM. This assumption was informed by the South African findings, where periodic CGM achieved glycaemic improvements comparable to, and at some timepoints greater than, continuous use, together with the substantially higher CGM engagement observed in the Kenyan cohort. Preliminary scenario analyses suggest that periodic CGM could approach cost-effectiveness at lower price reduction thresholds (45-61%) than continuous CGM (Table 5). This means that the price of the sensor needs to decrease from KES15,000 to KES 5,850 – KES 8,250.

**Table 5: Summary of modelled cost-effectiveness results and estimated CGM price reductions required to approach cost-effectiveness thresholds in Kenya**

CGM strategy	Treatment-effect scenario	ICER (KES/QALY gained)	Price reduction required to approach cost-effectiveness	Approximate target sensor price
Continuous CGM	Kenya ACCEDE 3-month effect	~KES 3.0 million	86%	~KES 2,100
Continuous CGM	South Africa ACCEDE 3-month effect	~KES 4.6 million	90%	~KES 1,500
Continuous CGM	South Africa ACCEDE 9-month effect	~KES 4.7 million	93%	~KES 1,125
Periodic CGM	Kenya exploratory scenario*	~KES 558,000	45%	~KES 8,250
Periodic CGM	South Africa periodic 6-month effect	~KES 876,811	61%	~KES 5,850

\* Exploratory scenario applying the Kenyan 3-month continuous-use treatment effect to periodic CGM, informed by higher engagement observed in Kenya and comparable effectiveness of periodic and continuous CGM observed in the South African ACCEDE trial.

Taken together, these findings suggest that affordability, procurement strategy, and implementation approach are likely to be the key determinants of value for CGM in Kenya. While continuous CGM appears unlikely to be cost-effective at current market prices, targeted or periodic CGM strategies combined with substantial price reductions, pooled procurement, or co-financing arrangements may provide a more realistic pathway for phased public-sector adoption.

## 9. Local Evidence on Acceptability, Feasibility and Usability

There is a growing body of evidence assessing the feasibility, acceptability, and usability of CGM in low-resource settings, particularly in sub-Saharan Africa. Emerging evidence from East and Southern Africa suggests that CGM can be implemented successfully when accompanied by structured education, clinical support, and appropriate implementation planning. In Malawi, Gomber et al. conducted a RCT among 45 individuals aged 8–51 years with T1D and found rtCGM to be both feasible and acceptable in rural district hospital settings, although participants were unable to independently replace sensors initially, increasing reliance on clinic visits<sup>37</sup>. Participants wore sensors for approximately 64% of the intended study period, and no serious device-related adverse events were reported. Similarly, Thapa et al. found CGM to be acceptable and appropriate among both patients and healthcare providers in rural Malawian hospitals, particularly when accompanied by structured diabetes education<sup>50</sup>. In Rwanda, Baker et al.<sup>36</sup> reported high levels of engagement in a prospective feasibility study involving 50 adults with T1D, with participants wearing sensors for more than 80% of the intended monitoring period alongside significant improvements in HbA1c and TIR. McClure Yauch et al. also highlighted the importance of implementation support, patient education, and healthcare worker engagement to support sustained CGM uptake and effective use in African settings<sup>35</sup>.

Findings from both the Kenyan and South African ACCEDE studies further support the acceptability and feasibility of CGM use in public-sector African settings. In the Kenyan ACCEDE cohort, overall usability scores were extremely high, with a mean System Usability Scale score of 95.7/100 and 95% of participants categorised CGM as having “excellent” usability. General acceptability was also extremely high (~100%) with nearly all participants reporting that the CGM was easy to use (98%), that they felt confident using the device (~100%), and that using the CGM helped them improve their HbA1c (94%).

*Findings from both the Kenyan and South African ACCEDE studies further support the acceptability and feasibility of CGM use in public-sector African settings.*

The South African ACCEDE trial similarly demonstrated high levels of user satisfaction and acceptability. At 6 months, participants using CGM reported significantly higher glucose monitoring satisfaction scores compared with baseline and standard of care, indicating improved satisfaction with glucose monitoring and diabetes management. A complementary acceptability survey also demonstrated very high user acceptance (>99%) across both continuous and periodic CGM strategies. At 6 months, acceptability scores were slightly higher among periodic CGM users with more than 90% of participants in both arms reported that they felt confident using CGMs, more than 95% of participants in both arms liked using the CGM, and more than 65% of participants in both arms reported that they felt confident using the CGM.

Feasibility findings from Kenya were also encouraging. Mean CGM active time was 81%, with 80% of participants achieving the predefined  $\geq 70\%$  active-time threshold. Participants demonstrated high engagement with the technology, with 82% reporting that they checked their glucose readings very frequently ( $\geq 7$  times per day) and an observed median of  $\geq 8$  times per day, substantially higher than scanning frequencies observed in the South African ACCEDE trial (3-6 times per day). CGM use was also associated with reductions in diabetes-related distress (measured using the Diabetes Distress Scale) among caregivers and young adults, with improvements observed across several distress domains, including powerlessness, management distress, negative social perceptions, and family/friend distress. In South Africa, diabetes-related distress also declined over the course of the study, but across all arms (CGM and standard of care).

*Feasibility findings from Kenya were also encouraging.*



Several practical implementation considerations emerged from both the Kenyan and South African ACCEDE experiences. In Kenya, although most participants reported no major difficulties with device use, sensor-related issues were relatively

*Findings from ACCEDE highlighted the importance of proactively addressing practical challenges related to sensor use through structured patient and healthcare worker training, including education on sensor application, troubleshooting, and the routine use of medical-grade adhesive plasters over the sensor to reduce detachment, particularly in hot climates or during physical activity.*

common, including sensor failures (39%), device errors (24%), connectivity problems (16%), and inaccurate readings (16%). In Kenya, 16% of participants reported at least one episode of sensor detachment during the 3-month study period, often related to physical activity or school play. Similar sensor fixation challenges have also been reported in other LMIC studies, including India, where Kumar et al. observed sensor detachment or fixation issues in approximately 17% of children using CGM<sup>51</sup>Medtronic, USA. Findings from ACCEDE highlighted the importance of proactively addressing practical challenges related to sensor use through structured patient and healthcare worker training, including education on sensor application, troubleshooting, and the routine use of medical-grade adhesive plasters over the sensor to reduce detachment, particularly

in hot climates or during physical activity. Incorporating adhesive plasters into standard training and supply packs may help reduce device loss, improve wear time, minimise data gaps, and support sustained sensor engagement and benefit.

Training and education emerged as critical enablers of successful implementation. In the ACCEDE study, nurses received dedicated CGM training to support participant education, troubleshooting, and interpretation of glucose data. Building on these experiences, FIND, in collaboration with the International Diabetes Federation, local experts, and lived-experience representatives, has developed online CGM training courses for both healthcare professionals and people living with T1D. To date, more than 11,000 individuals have completed the online courses, alongside multiple in-person training workshops conducted in both South Africa and Kenya. These findings suggest that successful public-sector CGM implementation in Kenya will likely require not only device procurement, but also investment in ongoing patient education, healthcare worker training, and practical implementation support systems.

*Overall, ACCEDE underscores that successful scale-up requires a coordinated implementation strategy that couples device access with training, adequate staffing, and integration into routine care pathways to ensure sustainable and equitable CGM use in the public sector.*

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## 10. Financing and Sustainability

### A. Budget Impact Analysis

A budget impact analysis (BIA) was undertaken to estimate the financial implications for the SHIF in Kenya of introducing CGM technologies for people living with T1D into its reimbursed benefit package. The analysis complements the cost-effectiveness results by quantifying affordability and fiscal feasibility under budget constraints. The analysis reflects the direct costs associated with CGM reimbursement, together with potential cost offsets from avoided acute diabetes-related hospitalisations, including diabetic ketoacidosis (DKA) and severe hypoglycaemic episodes (SHE).

The BIA is conducted from the perspective of the SHIF, as the primary decision-maker for reimbursement. While SHIF currently reimburses components of diabetes-related care, including inpatient and emergency services, coverage of outpatient diabetes technologies and consumables remains incomplete, with many patients continuing to incur OOP costs for glucose monitoring and related supplies. This analysis therefore estimates the financial implications of a future scenario in which SHIF progressively expands reimbursement to include CGM technologies as part of a more comprehensive publicly financed diabetes package.

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### Intervention, comparator, and scope

The analysis compares three scenarios:

- **Status quo:** SMBG only, using strips, lancets and glucometers aligned with testing frequency as follows: 1.71 x per day for adults, 3 x per day for children.<sup>4</sup>
- **Periodic isCGM:** four sensors per year (one per quarter) used in combination with continued SMBG.
- **Continuous isCGM:** full-time wear, equivalent to 26 sensors per year (14-day sensors), also with reduced SMBG use.

The intervention package includes sensors, readers (annualised over two years), adhesive plasters, glucometers (three-year useful life), and training (per user per year). Prices were drawn from the ACCEDE trial procurement data, KEMSA, literature and SHIF tariffs (2025 KES), with alternative scenarios reflecting potential price reductions for CGM sensors through price negotiations.

### Eligible and user population

The total population of people living with T1D in Kenya was estimated at 23,388, of whom approximately 11,409 are children, adolescents and young adults (<25 years of age).<sup>52</sup> Currently, just under 20% of the population is covered by SHIF; however, for this analysis, the eligible population was conservatively doubled to reflect anticipated future expansion in SHIF enrolment and coverage over time<sup>21</sup>. This assumption reflects a forward-looking reimbursement scenario in which SHIF enrolment and diabetes benefit coverage expand progressively over time. To reflect uncertainty in programme rollout, uptake among eligible users varied between 80% and 100%, representing different implementation scenarios (Table 6).

The BIA considered two sequential phases for population coverage:

- **Phase 1:** paediatric, adolescent and young adult T1D population (“youth” < 25 years of age);
- **Phase 2:** full T1D population (youth and adults).

**Table 6: Input parameters**

Parameter	Parameter	Source/Note
Total T1D population	23,388	T1D Index (2026) <sup>52</sup>
Total YouthT1D population (<25)	11,409	T1D Index (2026) <sup>52</sup>
Share covered by SHIF	40%	Doubled estimated coverage (assumption) <sup>21</sup>
Uptake	80-100%	Assumption

## Time horizon

The BIA was conducted over one-year and five-year, undiscounted time horizons. Minimal variation was observed between the Year 1 and Year 5 budgets, as most cost components remain stable over time. The only elements expected to vary are replacement of glucometers and readers, which occur on a multi-year cycle. No population growth was assumed over the five-year analytic horizon.

## Costs and resource use

All direct health-sector expenditures were included:

- Pharmaceutical budget: sensors (KES 15,000), plasters, readers, and SMBG supplies (lancets, test strips and glucometers) for the SMBG scenario<sup>53</sup>.
- Event-related cost offsets: expected reductions in DKA and SHE, valued using micro-costing estimates (KES 85,180 per DKA; KES 8,920 per SHE). Event rates were drawn from the South African ACCEDE trial. These event-related offsets were included because acute diabetes-related admissions are reimbursed within the current SHIF tariff structure and therefore represent potential payer-side savings associated with improved glycaemic management.
- Training and education: A once-yearly CGM refresher session (1 hour of nurse educator time per CGM user) was included to reflect device onboarding, interpretation support, and ongoing updates on CGM use. Annual refresher training for nurse educators (4 hours per year) was also included. Routine diabetes education was not included as it should not be attributed specifically to CGM users, as any investment in diabetes education should be applied equitably across all people living with T1D, regardless of monitoring modality.

No discounting or productivity costs were applied, consistent with BIA conventions. All parameters and calculations are available in the BIA workbook (available upon request).

## Scenarios

The following budget impact scenarios were explored to reflect different potential procurement and reimbursement pathways for CGM implementation in Kenya:

1. **Base case scenario (current Kenyan market prices):** reflects the current fragmented procurement environment and prevailing retail market prices for CGM sensors and supplies in Kenya. This scenario assumes full SHIF reimbursement of CGM-related costs for eligible users.
2. **50% sensor price discount scenario:** reflects a negotiated procurement scenario in which CGM sensor prices are reduced by 50%, bringing prices closer to those observed in the South African ACCEDE trial. This scenario explores the potential impact of centralised procurement and price negotiations on fiscal feasibility.
3. **75% sensor price discount scenario (5-year horizon):** reflects a longer-term market-shaping scenario in which substantial reductions in CGM prices are achieved through pooled procurement, increased market competition, lower-cost technology entrants, or donor-supported access mechanisms. This scenario was modelled over a five-year period to assess the medium-term affordability of CGM under substantially reduced device costs.

## Results

At current prices, the total annual cost of introducing CGM across the SHIF-covered T1D population would vary substantially by user group and device schedule. **Periodic CGM** - where patients use one sensor every three months while continuing standard SMBG (requiring just four sensors per year) - represents the most financially feasible option for phased adoption. Among paediatric, adolescent and young adult T1D users, the additional annual cost is estimated at approximately KES 288 million above the current SMBG expenditure of KES 120 million, corresponding to a 241% increase in spending for this group. For all T1D users combined (youth and adults), total incremental expenditure rises to approximately KES 598 million above a baseline SMBG budget of KES 191 million, representing a 313% increase (Table 7).

*Periodic CGM - where patients use one sensor every three months while continuing standard SMBG (requiring just four sensors per year) - represents the most financially feasible option for phased adoption.*

In contrast, continuous CGM - where sensors are worn continuously (requiring 26 sensors per year) - would entail substantially higher annual expenditure and may only be feasible for targeted sub-groups. For children, adolescents and young adults, expenditure would increase by approximately KES 1.4 billion over the current KES 120 million SMBG budget (~1162% increase), while adoption across all T1D users (adult and youth) would require an additional KES 2.9 billion per year (~1517% increase) over the current KES 191 million SMBG budget. Even when accounting for modest cost offsets from reduced DKA and SHE admissions, continuous CGM remains a substantial fiscal commitment at current sensor prices.

*In contrast, continuous CGM - where sensors are worn continuously (requiring 26 sensors per year) - would entail substantially higher annual expenditure and may only be feasible for targeted sub-groups.*

At a 50% discounted sensor price, reflecting a negotiated procurement scenario and prices more aligned with those observed in the South African ACCEDE trial, the incremental budget impact of periodic CGM is substantially reduced, requiring an additional KES 132 million for youth (111% increase) and KES 280 million for all eligible people living with T1D (146% increase). Under this scenario, continuous CGM becomes more affordable but still requires an additional KES 631 million and KES 1.3 billion for youth and adult T1D users, respectively.

Under a longer-term market-shaping scenario, assuming a 75% reduction in sensor prices over five years, periodic CGM becomes substantially more affordable, requiring an additional KES 228 million for youth and an additional KES 510 million for all eligible T1D users over the five-year period. In contrast, continuous CGM would still require substantial additional expenditure, with incremental costs of approximately KES 1.2 billion and KES 2.8 billion for youth and adult T1D users, respectively.

Minimal variation was observed between the Year 1 and Year 5 budgets, as most cost components remain stable over time. The only elements expected to vary are replacement of readers (which are not necessarily required but are CGM brand dependent), which occur on a multi-year cycle. Importantly, large reductions in sensor prices substantially improve the fiscal feasibility of periodic CGM, highlighting the importance of procurement negotiations, market competition, and lower-cost technology entrants in supporting sustainable public-sector adoption.

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**Table 7: Budget Impact Analysis: One and five-year results**

	No. of users/ year	Status quo annual cost (KES)	Additional budget required (KES)	% increase	Additional budget required (KES)	% increase
<b>1 year BIA</b>						
<b>80% uptake, Baseline sensor price</b>			<b>Periodic CGM</b>		<b>Continuous CGM</b>	
T1D Youth	3,651	120m	+288m	241%	+1,389m	1162%
T1D All	7,484	191m	+598m	313%	+2,901m	1517%
<b>80% uptake, 50% sensor price discount</b>						
T1D Youth	3,651	120m	+132m	111%	+631m	527%
T1D All	7,484	191m	+280m	146%	+1,348m	740%
<b>5 year BIA</b>						
<b>80% uptake, 65% sensor price discount</b>			<b>Periodic CGM</b>		<b>Continuous CGM</b>	
T1D Youth	3,651	598m	+228m	38%	+1,217m	204%
T1D All	7,484	956m	+510m	53%	+2,764m	289%

While CGM may appear expensive on a per-user basis, the eligible T1D population in Kenya remains relatively small. At current prices, periodic CGM for all eligible T1D users would require an additional KES 598 million annually, equivalent to approximately 0.7% of the annual SHIF budget (KES 82.4 billion), while continuous CGM would require approximately KES 2.9 billion annually (~3.5% of the SHIF budget)<sup>54</sup>. Under a 50% discounted sensor price scenario, the incremental budget impact of periodic CGM falls to 0.3% of the annual SHIF budget.

## B. Willingness to Pay Findings

A willingness-to-pay (WTP) analysis conducted in 2023 among 314 respondents living with diabetes (both T1D and T2D) in Kenya provides important insights into perceived affordability and demand for CGM devices in this setting. Using the Van Westendorp Price Sensitivity Meter, the study estimated an acceptable monthly price range of approximately US\$17–32, with an optimal price point of US\$19 per month: substantially lower than the market prices at the time of around US\$120 per month<sup>14</sup>.

These findings indicate that current CGM prices exceed what most users in Kenya are willing or able to pay, even within a sample that was wealthier and more insured than the national average<sup>14</sup>. As such, true population-level affordability is likely to be even lower. WTP was higher among insulin users, individuals with higher OOP spending on diabetes care, and those who test glucose more frequently, suggesting that perceived value is closely linked to disease intensity and current management burden.

*Overall, the results suggest that while people living with diabetes in Kenya value CGMs and may be willing to contribute modest amounts toward their cost, affordability constraints are binding, reinforcing the need for significant price reductions, targeted subsidies, or pooled procurement mechanisms to enable access at scale.*

Price sensitivity appears high: while there is clear latent demand for CGMs, uptake is likely to remain limited unless prices fall substantially. Importantly, respondents expressed a preference for CGM pricing that is lower than their current spending on diabetes supplies, indicating both financial constraints and expectations of value for money. Overall, the results suggest that while people living with diabetes in Kenya value CGMs and may be willing to contribute modest amounts toward their cost, affordability constraints are binding, reinforcing the need for significant price reductions, targeted subsidies, or pooled procurement mechanisms to enable access at scale.

## C. Conclusion and Financing Pathway

This BIA suggests that periodic CGM could represent a fiscally feasible pathway for phased public-sector introduction in Kenya, particularly if meaningful reductions in sensor prices can be achieved. At current prices, periodic CGM for all eligible T1D users would require an additional approximately KES 598 million annually, equivalent to approximately 0.7% of the annual SHIF budget. Under a 50% discounted sensor price scenario - reflecting prices closer to those observed in the South African ACCEDE trial - this falls to 0.3% of the annual SHIF budget. In contrast, continuous CGM would require substantially larger budget increases and is unlikely to be affordable at current market prices without major price reductions.

These findings point to a clear and pragmatic pathway for CGM scale-up in Kenya. A phased implementation strategy beginning with children, adolescents and young adults with T1D appears to represent the most practical and affordable entry point for public-sector adoption. Periodic CGM offers a substantially lower-cost approach than continuous CGM while still providing clinically meaningful benefits. Expansion to broader adult populations or continuous CGM use would likely depend on achieving substantial reductions in sensor prices through procurement negotiations, pooled purchasing, and lower-cost market entrants.

Importantly, WTP findings from Kenya suggest strong latent demand for CGM, but substantial affordability constraints at current prices. These findings reinforce the importance of significant price reductions, pooled procurement mechanisms, and targeted public-sector subsidies to enable CGM access at scale.

These analyses represent a forward-looking reimbursement scenario in which SHIF progressively expands coverage of diabetes technologies and consumables over time. Currently, many diabetes-related supplies continue to be financed through OOP payments. As such, phased implementation, partial reimbursement, or co-payment mechanisms may represent realistic transitional approaches for improving CGM access while limiting the immediate fiscal burden on SHIF during early implementation phases. Periodic CGM may also represent a pragmatic publicly funded minimum package of CGM access, with some users potentially choosing to purchase additional sensors OOP if they wish to increase wear-time beyond the publicly reimbursed allocation. Donor or philanthropic support may also help facilitate initial rollout and market shaping while procurement prices continue to decline.

*Donor or philanthropic support may also help facilitate initial rollout and market shaping while procurement prices continue to decline.*

Importantly, these estimates are highly conservative: unlike a BIA in the UK by Blissett et al<sup>55</sup>, which incorporated longer-term savings from improved glycaemic levels, our analysis includes only the most certain, short-term cost offsets - reductions in DKA and SHE<sup>56</sup>. Overall, the relatively small eligible T1D population means that periodic CGM may become increasingly achievable within the broader SHIF financing envelope as CGM prices continue to fall.



## 11. Conclusion and Recommendations

Demand for CGM in Kenya is clear and compelling. In addition, evidence from the ACCEDE studies in Kenya and South Africa demonstrates that CGM is highly acceptable, feasible to implement in public-sector settings, and strongly valued by people living with T1D, caregivers, and healthcare providers. Importantly, this study has generated one of the first locally generated African

*Further, the Kenyan ACCEDE cohort demonstrated very high engagement with CGM technology, including high wear-time and frequent glucose checking behaviour, suggesting that people living with T1D in Kenya are both willing and able to use CGM effectively when devices and appropriate support are available.*

evidence bases for CGM, combining evidence on clinical effectiveness, usability, acceptability, implementation feasibility, and economic value within real-world public-sector settings. Participants consistently reported reduced anxiety, improved confidence in self-management, and meaningful improvements in quality of life. Further, the Kenyan ACCEDE cohort demonstrated very high engagement with CGM technology, including high wear-time and frequent glucose checking behaviour, suggesting that people living with T1D in Kenya are both willing and able to use CGM effectively when devices and appropriate support are available.

These findings are consistent with robust international evidence demonstrating that CGM improves glycaemic control, increases TIR, reduces hypoglycaemia, and improves quality of life. CGM is now considered standard of care for people living with T1D in many high-income settings and is recommended by international guidelines, including ISPAD. Although SMBG supplies themselves remain incompletely financed under SHIF and government-funded diabetes care, this should not be interpreted as a reason to deprioritise CGM. Rather, it highlights the broader need to strengthen access to effective glucose monitoring technologies across the diabetes care pathway as Kenya moves toward more equitable and modern diabetes care.

At the same time, this investment case demonstrates clearly that affordability remains the binding constraint to large-scale public-sector adoption. Continuous CGM is unlikely to be cost-effective at current Kenyan market prices, with ICERs ranging from approximately KES 3.0 - 4.7 million per QALY gained. Threshold analyses suggest that substantial sensor price reductions (approximately 86–93%) would be required before continuous CGM use approaches conventional cost-effectiveness thresholds in Kenya.

Importantly, lower-intensity periodic CGM strategies appear substantially more feasible from both an economic and fiscal perspective. The South African ACCEDE RCT demonstrated clinically meaningful HbA1c improvements with periodic CGM use, while exploratory Kenyan modelling suggests that periodic CGM could approach cost-effectiveness at substantially lower price reductions (approximately 45–61%) than continuous use. The BIA similarly suggests that periodic CGM represents a pragmatic and fiscally manageable entry point for phased adoption. At a 50% discounted sensor price, introducing periodic CGM for children, adolescents, and young adults living with T1D would require an additional approximately KES 132 million per year above the existing SMBG budget (a 111% increase).

The ACCEDE experience also highlights that device provision alone is insufficient to achieve sustained glycaemic improvement. Real-world effectiveness depends on integrating CGM into strengthened diabetes education pathways, routine clinical review, healthcare worker training, and ongoing support for interpretation and behavioural change.

*The findings provide a strong foundation for future HTA processes and for progressive inclusion of CGM within SHIF reimbursement pathways as procurement efficiencies improve and prices continue to decline.*

Taken together, the evidence supports a phased but decisive expansion of CGM access in Kenya grounded in affordability, equity, and health-system readiness. The findings provide a strong foundation for future HTA processes and for progressive inclusion of CGM within SHIF reimbursement pathways as procurement efficiencies improve and prices continue to decline.

## Recommendations

- **Prioritise children, adolescents, young adults, pregnant women, and individuals with T1D at high risk for early access to CGM technologies. Periodic CGM represents a fiscally lighter, high-benefit entry point that could rapidly improve diabetes management and quality of life for priority populations.**
- **Pursue coordinated national procurement and active price negotiation strategies, including pooled procurement, tiered LMIC pricing, and market-shaping approaches, to bring sensor prices closer to affordability and cost-effectiveness thresholds identified in the economic analyses.**
- **Strengthen supply-chain efficiency to reduce cumulative mark-ups across importation, distribution, and retail channels, ensuring that negotiated price reductions are realised at the point of service.**
- **Expand access to CGM progressively as procurement efficiencies, lower-cost technologies, market competition, donor support, and co-financing mechanisms mature over time.**
- **Build on the existing preference for CGM into Kenya's National Diabetes Guidelines and incorporate in future SHIF benefit-package planning for people living with T1D, with clear guidance on eligibility criteria, implementation pathways, education requirements, and follow-up.**
- **Invest in system readiness for CGM implementation, including specialist diabetes nurse educators, healthcare worker training, structured patient education, and practical implementation support for sensor application, troubleshooting, and interpretation of glucose data.**

## 12. Recommended Additional Reading

### 1. ACCEDE publications:

- [Willingness to pay Report](#)
- [Protocol paper](#)
- Please check the ACCEDE website for upcoming publications:

#### South Africa

- ▶ Qualitative acceptability
- ▶ Clinical outcomes
- ▶ Accessibility and feasibility
- ▶ Cost-effectiveness

#### Kenya

- ▶ Usability, Acceptability and Feasibility
  - ▶ Clinical outcomes
- 
- Kenyan Economic Modelling report – available upon request

### 2. CHAI market report on glucose monitoring

### 3. FIND CGM training:

- [People living with diabetes](#)
- [Healthcare professionals](#)

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