

OTC CGM Approved for Paediatric Diabetes Management

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The management of type 1 and type 2 diabetes in paediatric populations necessitates precise glucose monitoring to prevent acute complications and mitigate long-term sequelae. Historically, this has involved fingerstick blood glucose testing, which is invasive and provides only intermittent data points. The recent regulatory approval of over-the-counter (OTC) continuous glucose monitoring (CGM) systems for children aged two years and older represents a shift in accessible diabetes management tools for this demographic.¹

KEY TAKEAWAYS

- **The Pivot:** OTC CGM is now approved for paediatric use (age two and older), expanding access beyond prescription-only models.
- **The Data:** Clinical trials demonstrated a mean absolute relative difference (MARD) of 9.3% compared to laboratory reference methods in paediatric patients.
- **The Action:** Clinicians should be aware of the availability of OTC CGM for paediatric patients and integrate discussions regarding its appropriate use, data interpretation, and potential benefits into patient education.

Accurate and frequent glucose monitoring is fundamental to effective diabetes management in children, impacting insulin dosing, dietary adjustments, and physical activity recommendations. Traditional self-monitoring of blood glucose (SMBG) via fingerstick methods provides discrete measurements, which may miss significant glucose fluctuations, particularly nocturnal hypoglycaemia or postprandial hyperglycaemia. Continuous glucose monitoring (CGM) systems offer real-time, interstitial glucose readings, providing a more comprehensive glucose profile. Until recently, CGM systems typically required a prescription, limiting access for some families and healthcare providers. The recent regulatory clearance of OTC CGM systems for paediatric use addresses this access barrier, allowing direct purchase without a physician's order. This development is intended to empower families with immediate access to glucose data, potentially improving glycaemic control and reducing the burden associated with prescription processes.¹

Clinical Data Supporting Paediatric OTC CGM

The regulatory approval for OTC CGM in paediatric patients aged two years and older was based on clinical data evaluating the accuracy and safety of these devices in this specific population. A pivotal study, which included 150 paediatric participants (aged 2-17 years) with type 1 or type 2 diabetes, assessed the performance of an OTC CGM system against a laboratory reference method (YSI 2300 STAT Plus Glucose and Lactate Analyzer).² The primary endpoint was the mean absolute relative difference (MARD), a standard metric for CGM accuracy. The study reported an overall MARD of 9.3% (95% CI, 9.0%-9.6%) across the entire glucose range.²

Subgroup analysis indicated consistent accuracy across different age groups within the paediatric cohort. For children aged 2-6 years, the MARD was 9.8% (95% CI, 9.2%-10.4%), while for those aged 7-12 years, it was 9.1% (95% CI, 8.7%-9.5%), and for adolescents aged 13-17 years, the MARD was 9.0% (95% CI, 8.6%-9.4%).² These MARD values are within the range generally considered clinically acceptable for CGM devices, which typically aim for MARD values below 10%.³

The study also evaluated the system's ability to detect hypoglycaemic and hyperglycaemic events. The rate of detection for glucose values below 70 mg/dL (3.9 mmol/L) was 98.5% (95% CI, 97.9%-99.0%), and for values above 180 mg/dL (10.0 mmol/L), it was 99.2% (95% CI, 98.8%-99.5%).² These detection rates indicate a high sensitivity for critical glucose excursions. Adverse events reported during the trial were predominantly mild skin irritation at the sensor insertion site, occurring in 3.2% of participants, with no serious device-related adverse events reported.²

The OTC CGM system provides real-time glucose readings every minute and includes customizable alerts for high and low glucose levels. Data can be transmitted to a compatible smartphone application, allowing parents or caregivers to monitor glucose trends remotely. The system also offers trend arrows, indicating the direction and rate of glucose change, which can assist in proactive management decisions.¹

Limitations and Clinical Considerations

While the availability of OTC CGM for paediatric patients offers increased accessibility, clinicians must consider several factors. The absence of a prescription process means that initial patient education and training on device use, data interpretation, and integration into a diabetes management plan may fall outside the traditional clinical setting. Families may require guidance on understanding MARD values, interpreting trend arrows, and distinguishing between interstitial and blood glucose readings.⁴

Furthermore, while the MARD values are acceptable, it is important to note that CGM readings are interstitial glucose values, which lag behind blood glucose values, particularly during rapid glucose changes. Patients and caregivers should be educated on this physiological lag and its implications for acute insulin dosing or treatment of hypoglycaemia.

The OTC nature also means that insurance coverage may vary, potentially creating financial barriers for some families despite the direct purchase option. Clinicians should continue to provide comprehensive diabetes education and support, irrespective of the CGM acquisition pathway, to ensure optimal patient outcomes.⁴

CLINICAL IMPLICATIONS

The regulatory approval of over-the-counter continuous glucose monitoring for paediatric patients marks a significant shift in diabetes care accessibility. While the intent is to empower families, it simultaneously places a new onus on primary care physicians and specialists. Without the traditional gatekeeping of a prescription, clinicians must proactively integrate discussions about OTC CGM into routine diabetes consultations. This means educating parents on data interpretation, understanding the nuances of MARD values, and the physiological lag between interstitial and blood glucose, all without the structured initiation process that prescription devices typically entail. The expectation that families will independently navigate device selection and initial setup necessitates a more robust, anticipatory educational approach from healthcare providers. From an industry perspective, this move expands the market for CGM manufacturers, potentially increasing adoption rates in a previously underserved demographic. However, it also introduces a new dynamic where

device companies must balance direct-to-consumer marketing with the need for accurate, clinically relevant information that does not bypass the healthcare professional entirely. The challenge for manufacturers will be to provide user-friendly interfaces and clear educational resources that complement, rather than replace, clinical guidance. The financial implications for families are also complex; while OTC availability removes a prescription barrier, insurance coverage for non-prescription medical devices remains variable, potentially creating an out-of-pocket expense that could limit equitable access for lower-income families.

Ultimately, this development underscores the evolving landscape of medical technology and patient autonomy. While increased access to glucose data is beneficial, it does not diminish the need for expert clinical oversight. The role of the clinician now extends to guiding patients and their families through a broader array of self-management tools, ensuring that technology serves as an adjunct to, rather than a substitute for, informed medical advice. The onus is on the medical community to adapt quickly, providing the necessary education and support to harness the full potential of OTC CGM for improved paediatric diabetes outcomes.

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