

FDA clears Dexcom's Stelo as the first over-the-counter CGM for children aged two years and older – June 15, 2026

Pediatric clearance expands Stelo's reach as Dexcom targets growth beyond insulin-treated diabetes

The FDA [cleared](#) Dexcom's Stelo on Friday for children aged two years and older. The over-the-counter (OTC) CGM is designed for people not on insulin therapy. Stelo initially launched in the US for people aged 18 and older in [August 2024](#), becoming the first CGM available without a prescription at the time. Within its first twelve months of release for adult patients, Stelo revenue surpassed [\\$100 million](#). Stelo's positive reception this expanded indication as the first OTC CGM available for pediatric use reflects growing interest in CGM as a tool for improving glycemic awareness beyond insulin-treated diabetes. Given that nearly [one in three](#) adolescents in the US have prediabetes, the clearance could expand access to glucose data for children and families seeking to better understand the impact of meals, exercise, and other lifestyle factors on glycemic health. However, as [studies](#) have highlighted regarding barriers to CGM uptake in youth, Dexcom faces the important challenge of the device's visibility for users not familiar with diabetes technology.

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Stelo continues to expand access to CGM beyond insulin users

Stelo provides glucose readings every 15 minutes and displays values between 70 mg/dL and 250 mg/dL in the Stelo app. The Dexcom Clarity app can provide retrospective glucose data across a broader range of 40-400 mg/dL, but it is not meant to guide clinical decisions for glycemic data falling outside of 70-250 mg/dL. Each sensor is designed for up to 15-day wear and can transmit data to a compatible smartphone, including a parent's or caregiver's device. Stelo is indicated for people with diabetes who use oral medications as well as those without diabetes who wish to better understand how diet, exercise, and lifestyle changes affect glucose levels. Similar to its adult indication, Stelo is not intended for individuals who experience hypoglycemia because it does not provide predictive low-glucose alerts.

FDA clearance supported by clinical data and real-world evidence

According to the FDA, the clearance was supported by a combination of prior clinical study data and real-world evidence from current CGM users, allowing regulators to evaluate expected device performance in pediatric users throughout the full 15-day wear period. Participants in prior studies reported mild adverse events, including local infection, skin irritation, and pain or discomfort.

Recent data continue to support the growing role of CGM among people not using insulin. At ADA 2026, [Dexcom presented](#) real-world data from adults with self-reported T2D not using insulin (n=12,008), showing that Stelo users improved TIR by 2.8 hours/day over three months (from 43% to 55%). Separately, [studies](#) in adolescents with prediabetes have demonstrated that CGM use can reduce A1c levels by 0.2% and lower estimated daily carbohydrate consumption by 41%. Other research suggests that CGM metrics may help [identify](#) youth at risk for glycemic progression before the development of overt diabetes, supporting its use as a promising tool for early risk stratification.

Expanded pediatric indication further strengthens Dexcom's long-term strategy

The clearance comes as Dexcom continues to prioritize growth in non-insulin and consumer-focused CGM markets.

During Dexcom's [1Q26](#) earnings call, management noted that momentum was particularly strong in T2D, with non-insulin users emerging as one of the fastest-growth segments.

Earlier this month, the company also [unveiled](#) a redesigned Stelo app featuring AI-powered coaching, personalized metabolic summaries, and enhanced pattern-recognition capabilities, with a broader launch expected later this summer. Taken together, the pediatric expansion, expanding evidence base, and continued platform enhancements further position Stelo as a key component of Dexcom's strategy of extending CGM use beyond traditional insulin-treated populations.

Close Concerns' Questions

1. Will the new AI-powered coaching and metabolic summary features be tailored differently for pediatric users and caregivers?
2. How does Dexcom expect pediatric OTC CGM adoption to compare with uptake among adults following initial launch?
3. As Stelo expands into younger populations, how does Dexcom balance glycemic awareness and behavior change with concerns around data overload or anxiety among otherwise healthy users?

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