MARKET BRIEF

Continuous Glucose Monitoring

U.S. market landscape & entry signals

A fast, factual orientation to the U.S. continuous glucose monitoring (CGM) market — who leads it, how the regulatory picture is shifting toward over-the-counter access, and where a new entrant should look first.

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DATE **June 2026**

TIER **Market Brief**

MARKET AT A GLANCE

A large, fast-growing category.

And one in the middle of a structural shift from prescription-only to consumer access.

Continuous glucose monitoring has moved from a niche tool for insulin-dependent diabetes to one of the fastest-growing categories in medical devices. Grand View Research estimates the global CGM market at roughly **$15.8 billion in 2025**, up from about $13.7 billion in 2024, and projects it to reach nearly $50 billion by 2033 at a low-teens-to-mid-teens CAGR. North America alone accounts for an estimated 56.8% of global revenue. Estimates vary meaningfully by firm and segmentation, but every major source points the same direction: sustained double-digit growth.

~$15.8B	~15%	~92%	4
GLOBAL CGM MARKET, 2025	PROJECTED CAGR TO 2033	REVENUE HELD BY TOP 2 FIRMS	OTC CLEARANCES SINCE 2024

What is driving growth

- **Type 2 expansion.** Adoption is spreading well beyond Type 1 and insulin-using patients into the much larger non-insulin Type 2 population.
- **Over-the-counter access.** The first FDA-cleared OTC sensors (2024) opened a cash-pay wellness and metabolic-health buyer base that did not exist before.
- **Broader reimbursement.** Medicare's 2023 coverage expansion extended CGM eligibility to non-insulin patients with a history of problematic hypoglycemia — an estimated 1.5 million additional beneficiaries.

COMPETITIVE SNAPSHOT

Two firms dominate revenue.

Two more hold defensible niches.

The category is effectively a duopoly: Abbott and Dexcom together control roughly 92% of CGM revenue (Abbott ~57%, Dexcom ~35% of 2024 revenue per Grand View Research), with Medtronic at ~7% and Senseonics holding a small but distinct implantable position.

Company	Flagship product(s)	Wear time	Key differentiator
Dexcom	G7 & G7 15-Day (Rx); Stelo (OTC)	10.5–15.5 days	Best published accuracy (G7 MARD ~8.2%), 30-min warm-up; Stelo is the first OTC sensor for non-insulin adults
Abbott	FreeStyle Libre 3 Plus (Rx); Lingo & Libre Rio (OTC)	up to 14–15 days	Revenue and volume leader; lowest-cost scale; broadest OTC lineup (wellness + non-insulin T2D)
Medtronic	Guardian 4 / Simplera	~7 days	Tightly integrated with Medtronic's MiniMed automated insulin delivery ecosystem
Senseonics	Eversense 365	365 days (implantable)	Only implantable CGM; year-long sensor with in-office insertion, for Type 1 and Type 2

MARD = Mean Absolute Relative Difference, the standard accuracy measure; lower is better. Specifications reflect manufacturer-published and FDA-cleared figures as of mid-2026.

REGULATORY SNAPSHOT

A maturing pathway.

And a recent opening toward consumer access.

CGMs are regulated by the FDA as Class II devices. The integrated CGM (iCGM) category was established through a De Novo authorization (Dexcom G6, 2018) with special controls, which now lets subsequent sensors clear via the 510(k) pathway against iCGM predicates rather than starting from scratch — a meaningful accelerant for credible entrants. The defining recent development is the wave of over-the-counter clearances:

- **Dexcom Stelo** — first OTC CGM cleared (March 2024; launched August 2024, ~$89 for a two-sensor pack), for adults not using insulin.
- **Abbott Lingo & Libre Rio** — cleared June 2024; Lingo as a general wellness tool, Libre Rio for non-insulin Type 2 diabetes.
- **Senseonics Eversense 365** — cleared September 2024 as the first one-year implantable sensor.

What this signals: regulators have now validated a non-prescription, non-insulin "metabolic health" use case. That expands the addressable buyer pool far beyond insulin-dependent diabetes and changes the competitive question from "who has the best clinical sensor" to "who owns the consumer relationship."

ONE-PAGE TAKEAWAY

Where the opportunity is.

And where the hard parts are.

Three opportunities

- **OTC / cash-pay wellness.** Now FDA-sanctioned and largely greenfield beyond insulin users.
- **Non-insulin Type 2.** A large, under-penetrated, increasingly reimbursed population thanks to the 2023 Medicare expansion.
- **Software & integration.** Coaching, data, and AID integration layers offer room to differentiate above a commoditizing sensor.

Three risks

- **Duopoly scale.** Abbott + Dexcom hold ~92% of revenue; their cost, distribution, and payer relationships are hard to match.
- **Price compression.** OTC is pushing per-sensor pricing down (Stelo ≈ $45/sensor), squeezing margins.
- **Regulatory & accuracy bar.** iCGM special controls and MARD expectations raise the cost and time to a credible product.

What this means for a market entrant

Competing head-on with the duopoly on a general-purpose prescription sensor is the hardest possible path. The viable wedges are differentiation, not imitation: a defensible niche (a specific population, or a distinct form factor such as implantable, extended-wear, or non-invasive), an OTC / cash-pay consumer brand and experience, or a software and coaching layer that rides on existing sensors. Partnering into an incumbent's ecosystem may de-risk entry faster than competing against it.

Selected sources: Grand View Research, Continuous Glucose Monitoring Devices Market Report; GlobalMarketInsights, U.S. CGM Market; U.S. FDA device clearance announcements (Stelo, Lingo, Libre Rio, Eversense 365); CMS / Medicare 2023 CGM coverage update; manufacturer product specifications (Dexcom, Abbott, Medtronic, Senseonics). Market-size figures vary by research firm and segmentation; ranges are presented with attribution. Figures current as of June 2026.