MARKET REPORT

Continuous Glucose Monitoring

U.S. market sizing, competition, regulation & reimbursement

A sourced, decision-grade analysis of the U.S. continuous glucose monitoring (CGM) market: how large each segment really is, who controls the category and why, the regulatory route a new sensor must travel, how it gets paid for, and a scored read on where the opportunity and the risk actually sit.

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SECTION 1

Executive Summary

A large, double-digit-growth market that is consolidating around two players just as it cracks open to consumers.

CGM has crossed from a diabetes sub-category into one of the most strategically important segments in medical devices. The headline opportunity is real, but the structure of the market makes *how* you enter matter far more than *whether* the market is growing. Six findings frame the rest of this report:

1. **The market is large and compounding fast.** The global CGM market is estimated at roughly $15.8 billion in 2025 and projected to approach $50 billion by 2033 (~15% CAGR); North America is ~57% of that revenue (Grand View Research).
2. **It is effectively a duopoly.** Abbott (~57%) and Dexcom (~35%) together hold ~92% of 2024 CGM revenue; Medtronic (~7%) and Senseonics hold defined niches.
3. **The real growth is non-insulin Type 2 and wellness.** Type 1 (~2M) and insulin-using patients are already well-penetrated; the ~21M non-insulin Type 2 population and 100M+ prediabetes/ wellness pool are where unit growth comes from.
4. **OTC clearance changed the game.** Four FDA over-the-counter clearances since 2024 (Stelo, Lingo, Libre Rio, Eversense 365) created a cash-pay consumer channel that did not exist two years ago.
5. **The regulatory path is navigable but exacting.** The iCGM special-controls framework lets credible sensors clear via 510(k) rather than PMA — faster, but with a demanding accuracy bar.
6. **Reimbursement is widening and shifting channels.** Medicare's 2023 expansion added ~1.5M eligible beneficiaries, and coverage is migrating from the DME channel to the pharmacy benefit.

> **Bottom line:** the winning entry strategy is differentiation, not imitation — a defined population, a distinct form factor, an OTC/consumer brand, or a software layer riding on existing sensors. The scored assessment in Section 6 quantifies these paths.

SECTION 2

Market Sizing & Segmentation

The category is big; the addressable opportunity depends entirely on which segment you target.

Estimates of CGM market size vary widely by research firm and by what each counts (devices only vs. sensors plus software, U.S. vs. North America). We present the figures with attribution rather than a single number. Grand View Research estimates the global CGM market at ~$15.8B in 2025 (up from ~$13.7B in 2024), reaching ~$49.9B by 2033 at a 15.4% CAGR, with North America at ~56.8% of revenue. For the U.S. specifically, GlobalMarketInsights estimates ~$5.7B in 2025 growing in the mid-teens; other firms place the U.S. lower depending on segmentation. The consistent signal across all sources is sustained double-digit growth.

~$15.8B	~$49.9B	15.4%	~57%
GLOBAL MARKET, 2025	PROJECTED 2033	CAGR TO 2033	NORTH AMERICA SHARE

TAM / SAM by segment (U.S.)

The U.S. opportunity is best understood through the diabetes population itself. Of ~40.1M Americans with diabetes (29.1M diagnosed), roughly 2M have Type 1 and ~8.4M use insulin. The segments differ enormously in both penetration today and headroom tomorrow:

~2M

TYPE 1 DIABETES

Near-saturated. High clinical need, AID-integrated, already on CGM. Replacement/ upgrade market, not growth.

~6.4M

TYPE 2, INSULIN-USING

Strong, reimbursed adoption underway. The core growth engine of the prescription market through the late 2020s.

~21M

TYPE 2, NON-INSULIN

Large, low-penetration, newly reimbursable in cases. The single biggest medical growth segment.

100M+

PREDIABETES / WELLNESS

Cash-pay, OTC-driven. Vast TAM but low conversion and price-sensitive; brand and experience decide winners.

Segment counts are analytic estimates derived from CDC National Diabetes Statistics (2024) and ADA figures (8.4M insulin users; ~2M Type 1). Insulin-using Type 2 is approximated as total insulin users less Type 1; non-insulin Type 2 as diagnosed diabetes less Type 1 and insulin-using Type 2. Figures are directional, for segmentation, not precise census counts.

Growth drivers vs. headwinds

Drivers

- **Non-insulin Type 2 adoption** — clinical evidence and guideline momentum push CGM earlier in the care pathway.
- **OTC / consumer access** — FDA-cleared cash-pay sensors open a buyer pool unconstrained by prescriptions.
- **Reimbursement expansion** — Medicare 2023 broadening (~1.5M added) plus commercial follow-on.
- **GLP-1 tailwind** — the weight-loss / metabolic-health wave drives interest in glucose data among non-diabetics.
- **AID integration** — automated insulin delivery pairing makes sensors stickier.

Headwinds

- **Price compression** — OTC and competition push per-sensor pricing down, pressuring margins.
- **Reimbursement complexity** — DME documentation burden and payer variability slow prescription uptake.
- **Accuracy / regulatory bar** — iCGM special controls raise the cost of a credible product.
- **Clinical-value debate** — evidence for routine CGM in non-insulin/wellness users is still maturing.
- **Incumbent scale** — manufacturing cost curves favor the two leaders.

SECTION 3

Competitive Landscape

Two leaders set the terms; the others compete on a structural difference, not on price.

Abbott leads on revenue and volume (lowest-cost scale, broadest lineup), while Dexcom leads on published accuracy and AID partnerships. Medtronic's CGM lives inside its MiniMed automated-insulin ecosystem, and Senseonics owns the only implantable position. The table below compares the flagship systems on the dimensions that actually drive purchasing and integration decisions.

Company	Flagship	Sensor life	MARD	Calibration	Channel	Integration	Cash price (approx.)
Dexcom	G7 / G7 15-Day	10.5–15.5 d	~8.2%	Factory (none)	Rx	AID: Tandem, iLet, twiist	~$6,800 / yr
Dexcom	Stelo (OTC)	15 d	~ G7 class	Factory (none)	OTC	App only (non-insulin)	~$1,100 / yr
Abbott	FreeStyle Libre 3 Plus	15 d	~9.2%	Factory (none)	Rx	AID: select pumps	~$2,900 / yr
Abbott	Lingo / Libre Rio (OTC)	14–15 d	~ Libre class	Factory (none)	OTC	App only (wellness / non-insulin)	—
Medtronic	Guardian 4 / Simplera	~7 d	~10%	Guardian: yes / Simplera: factory	Rx	MiniMed 780G AID	—
Senseonics	Eversense 365	365 d (implant)	~9%	Periodic fingerstick	Rx	twiist AID; in-office insertion	—

List/cash prices are approximate U.S. retail without insurance and vary by pharmacy and program; "—" indicates not publicly standardized. MARD = Mean Absolute Relative Difference (accuracy; lower is better).

Market share (2024 CGM revenue)

Per Grand View Research, Abbott held ~56.7% of 2024 CGM revenue, Dexcom ~35.2%, and Medtronic ~6.9%, with Senseonics and others making up the remainder. The practical implication: the two leaders set price and feature expectations, so a new entrant must compete on a dimension they are structurally weak on — form factor, a specific population, the consumer experience, or software — rather than on a marginally better general-purpose sensor.

Recent strategic moves

- **Dexcom** — launched Stelo (first OTC CGM, Aug 2024) and extended wear to a 15-day G7, defending both the clinical and consumer flanks.
- **Abbott** — split its OTC lineup into Lingo (wellness) and Libre Rio (non-insulin Type 2), and continued FreeStyle Libre's global volume leadership.
- **Medtronic** — advanced Simplera, a smaller, disposable, calibration-free sensor to modernize its CGM against the leaders, anchored to its 780G AID system.

- **Senseonics** — extended its implantable sensor to a full year (Eversense 365) and broadened AID integration (e.g., twiist) to expand beyond its niche.

Emerging entrants & non-invasive watch list

The next competitive wave is split between consumer-tech "no-needle" ambitions and lower-cost sensor challengers.

Player	Approach	Status & significance
Apple	Non-invasive optical (wearable)	Long-rumored, still years from a commercial, regulated product as of 2025–26. A breakthrough would reset the consumer segment overnight.
Samsung	Non-invasive optical (Galaxy Watch / Ring)	Publicly committed; accuracy and FDA clearance remain unsolved. Same disruptive potential as Apple if achieved.
Signos	CGM + AI coaching (weight management)	FDA-cleared OTC system pairing a sensor with an AI app — an example of the "software layer on a sensor" wedge.
SiBionics	Ultra-thin low-cost CGM	China-based; touts the "world's thinnest" sensor (~2.9mm), CE-marked, plus integrated insulin-patch partnerships. A cost/scale challenger.
Glucotrack	Implantable continuous blood glucose monitor	Multi-year implant measuring blood (not interstitial) glucose; early-stage (IDE expected). Differentiated form factor.

Read: a true non-invasive consumer device remains the category's biggest unknown — high impact, uncertain timing. The nearer-term competition is software-plus-sensor bundles and low-cost sensor challengers, both of which pressure incumbent margins without dislodging their installed base.

SECTION 4

Regulatory Pathway

Class II, iCGM special controls, and a 510(k) route — navigable, but the accuracy bar is the gate.

CGMs are regulated by the FDA as Class II devices. The pivotal structural change came in March 2018, when the FDA granted a De Novo request for the Dexcom G6 (DEN170088), creating the integrated CGM (iCGM) device category and a set of special controls defining accuracy, reliability, and clinical-relevance criteria. This was the unlock: once iCGM special controls existed, subsequent sensors no longer needed a PMA or their own De Novo — they could clear via the faster 510(k) pathway by demonstrating substantial equivalence to an iCGM predicate and meeting the special controls.

What a new entrant actually faces

- **Predicates exist.** Dexcom G6/G7 and Abbott FreeStyle Libre 2/3 serve as iCGM predicates, so a credible sensor has a defined comparison path.
- **The accuracy study is the real work.** Meeting iCGM special controls requires a clinical accuracy study against a reference method across glucose ranges — this, not the paperwork, is the gating cost and timeline.
- **Timeline.** FDA's 510(k) review target is ~90 days, but real-world clearance commonly runs several months to ~9 months after submission; the full development-plus-clinical cycle is typically measured in years.
- **OTC precedent.** Stelo (cleared March 2024) and Abbott's Lingo / Libre Rio (June 2024) established that non-prescription, non-insulin CGMs can clear — meaningfully widening the design space for new products aimed at consumers.

This section describes the general regulatory landscape and is not regulatory or legal advice. A specific product's pathway should be confirmed with qualified regulatory counsel and via FDA pre-submission (Q-Sub) feedback.

SECTION 5

Reimbursement Notes

Coverage is widening and moving channels — and a parallel cash-pay market now sets a price floor.

Medicare covers CGM under Part B as durable medical equipment (DME), generally paying 80% after the deductible. The defining recent change was the 2023 coverage expansion, which extended eligibility beyond intensive insulin users to include patients on any insulin and certain non-insulin patients with a history of problematic (level 2/3) hypoglycemia — an estimated ~1.5M additional beneficiaries. Covered systems include Dexcom, FreeStyle Libre, and Medtronic.

The DME-to-pharmacy channel shift

A structural trend worth underlining: coverage is migrating from the traditional DME channel to the pharmacy benefit. The DME route imposes heavy per-patient documentation and distributor logistics; the pharmacy benefit offers faster fulfillment, less paperwork, and broader access. Medicaid programs (e.g., Vermont) have led this shift, with commercial payers following more unevenly. For an entrant, pharmacy-benefit placement materially affects adoption friction and should shape distribution strategy.

Commercial & cash-pay dynamics

Commercial coverage broadly tracks Medicare but varies by plan and increasingly favors pharmacy adjudication. Running alongside reimbursement is the new cash-pay / OTC market: Dexcom's Stelo at ~$89 for a two-sensor pack (~$45/sensor, roughly $1,100/year at continuous wear) effectively sets a consumer price floor that reframes expectations even for prescription products. Any entrant must position against both a reimbursed price and a transparent retail price.

SECTION 6

Opportunity & Risk Assessment

A scored read on the three best entry paths and the three biggest threats.

Factor	Type	Impact	Likelihood	Rationale
OTC / cash-pay wellness channel	OPP	High	High	FDA-sanctioned, largely greenfield, and amplified by the GLP-1 / metabolic-health wave. Lowest reimbursement dependency; brand and experience are the moat.
Non-insulin Type 2 penetration	OPP	High	Med	~21M people, low current penetration, expanding reimbursement. Large prize, but clinical-value evidence and payer pace gate the speed.
Software / data / coaching layer	OPP	Med	High	Rides on existing sensors (low hardware risk), differentiates above a commoditizing device, and fits the wellness buyer. Signos is an early proof point.
Duopoly scale (Abbott + Dexcom)	RISK	High	High	~92% combined revenue share, manufacturing cost advantage, and entrenched payer relationships make head-on competition the hardest path.
Price compression	RISK	High	Med	OTC pricing (~$45/sensor) and low-cost challengers (SiBionics) pressure margins; a new entrant needs a cost or value story, not parity.
Regulatory & accuracy bar	RISK	Med	High	iCGM special controls and a clinical accuracy study impose real time and capital cost; manageable but non-trivial, and a common stumbling point.

Strategic recommendation (summary)

The highest-conviction entry combines the two highest-scoring opportunities: an OTC / cash-pay consumer position aimed at the wellness and non-insulin Type 2 buyer, differentiated by a software / coaching layer rather than by sensor hardware alone. This minimizes reimbursement dependency and direct hardware competition with the duopoly while riding the strongest demand tailwind. A hardware-led play is only advisable with a genuinely distinct form factor (implantable, extended-wear, or non-invasive) or a partnership into an incumbent ecosystem. The full Strategy Package develops this into a sequenced go-to-market plan.

SECTION 7

Sources & Methodology

Approach. This report synthesizes public market-research estimates, FDA clearance records, CMS/Medicare coverage policy, manufacturer product specifications, and reputable trade reporting. Where market-size estimates diverge, ranges are presented with attribution rather than a single figure. Segment counts are analytic estimates derived from public population statistics (see Section 2 note) and are directional, intended for segmentation rather than precise forecasting.

Principal sources

Grand View Research, *Continuous Glucose Monitoring Devices Market Report* (market size, CAGR, 2024 revenue shares, North America share). · GlobalMarketInsights, *U.S. Continuous Glucose Monitoring Market* (U.S. sizing). · U.S. CDC, *National Diabetes Statistics Report 2024* (diabetes prevalence). · American Diabetes Association (insulin-user and Type 1 counts). · U.S. FDA — Dexcom G6 De Novo (DEN170088, 2018) and iCGM special controls; OTC clearances for Stelo (2024), Lingo & Libre Rio (2024), Eversense 365 (2024). · CMS / Medicare 2023 CGM coverage expansion. · Manufacturer specifications (Dexcom, Abbott, Medtronic, Senseonics). · SingleCare / GoodRx (U.S. cash-price ranges). · Drug Delivery Business, MedTech Dive, Medical Economics (strategic moves; emerging and non-invasive entrants). · Journal of Managed Care & Specialty Pharmacy (DME-to-pharmacy channel evidence).

Figures current as of June 2026. This sample contains no confidential or client-specific data.