Beyond Finger Pricks: A Review of Continuous Glucose Monitors and Barriers to Access

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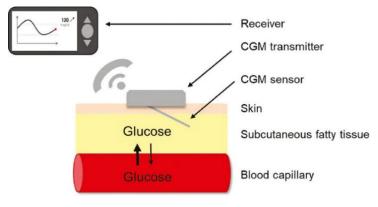
With diabetes on the rise in the United States and around the world, advancements in blood glucose monitoring – like continuous glucose monitors (CGMs) – have revolutionized at-home care for patients living with diabetes. This executive briefing describes the importance and uses of CGMs, a brief overview of the market trends, and global barriers to accessing CGMs.

CGMs are medical devices used to estimate blood glucose levels, or blood sugar, and are commonly used by people with diabetes – a disease growing in prevalence around the world. Globally, more than 500 million people live with diabetes, and some estimates indicate that nearly 800 million people will be living with the disease by 2045. Additionally, 3 in 4 people living with diabetes live in low- and middle-income countries, and half of the top 20 countries with the highest rates of diabetes are classified as low- and middle-income countries by the World Bank. Pakistan has the highest rate of diabetes in the world with an estimated 30.8 percent of their population living with the disease. In the United States, diabetes is on the rise with an estimated 38.4 million people (11.6 percent of the population) living with diabetes in 2021 – up from 34.1 million in 2018. The increasing prevalence of diabetes in the United States and around the world reinforces the importance of at-home diabetic care through technologies like CGMs.

What are CGMs?

CGM devices automatically estimate blood glucose levels throughout the day and night, while older glucose monitoring technology requires users to administer the test periodically. CGMs are recommended for people with type 1 or type 2 diabetes who rely on insulin to manage their disease. Advances in glucose monitor technology have made it easier for patients to monitor their blood glucose levels, reducing the

Figure 1: Components of a CGM System



Source: Journal of Laboratory Medicine, accessed December 2023

need to perform finger pricks while also providing information in real time so patients can better manage their disease.

There are two main types of personal CGM systems — real-time CGM and intermittently scanned CGM. Real-time CGMs are made up of three components: a sensor, a transmitter, and a receiver (a handheld device or a smartphone) (figure 1). Intermittently scanned CGMs use a combined sensor and transmitter to send data to a separate touch screen device providing new blood glucose levels every minute. CGMs cost between \$100 to \$400 a month (depending on brand and

country) covering the sensors and transmitter. Further, sensors need to be changed two-to-four times a month resulting in continuous fees for users.

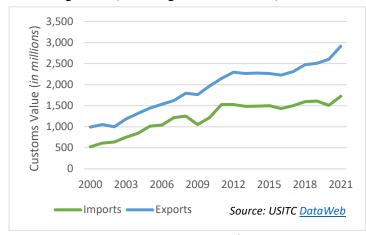
Recent advancements in CGM technologies include the ability to link CGMs with insulin pumps to create a hybrid closed-loop system, or so-called artificial pancreas. This system utilizes data from the CGM in combination with an algorithm to regulate insulin delivery.

¹ Diabetes is a health condition affecting the pancreas' production of insulin and the body's blood glucose levels.

² Other countries with high rates of diabetes include Kuwait (24.9 percent), French Polynesia (25.0 percent), Mauritius (22.6 percent), New Caledonia (23.0 percent), Marshall Islands (23.0 percent), Egypt (20.9 percent), and Qatar (19.5 percent).

³ Estimates of total diabetes cases includes both diagnosed and undiagnosed cases of type 1, type 2, and gestational diabetes. The views expressed solely represent the opinions and professional research of the individual authors. The content of the EBOT is not meant to represent the views of the U.S. International Trade Commission, any of its individual Commissioners, or the United States government.

Figure 2: U.S. Imports and Exports of Other Measuring and Testing Devices, Including Glucose Monitors, 2000–2021



Growing Global Demand

Trade flows of other measuring and testing devices, including glucose monitors, have steadily risen in recent years – between 2000 and 2021, U.S. exports increased by \$1.9 billion (193.7 percent) and U.S. imports increased by \$1.2 billion (229.5 percent) (figure 2).⁴ The top destination markets for U.S. exports include China, Germany, and Canada, while the top sources of U.S. imports include Germany, Japan, and Singapore.⁵ Current U.S. manufacturers of FDA-approved CGMs include Medtronic Diabetes, Dexcom Inc., Abbott Diabetes Care, and Senseonics Inc. The global CGM

market was valued at approximately \$4.5 billion in 2020 and is projected to grow at a compound annual growth rate of 13 percent. These trends speak to the growing prevalence of diabetes and the technological advances in CGMs, which have become a key tool in diabetes management.

Access to CGMs in the United States

Despite the growing demand for CGMs, there are still significant barriers to access for certain populations in the United States – namely insurance coverage and costs associated with the devices. A study conducted by the American Diabetes Association found that Medicaid enrollees living in the Southeast region of the United States, where many states have poverty rates higher than the national average, consistently have the lowest utilization rates of CGMs for individuals with diabetes. Results from the study also show that individuals with commercial insurance are 2.5 to 4.3 times more likely (depending on age) to get a CGM than those enrolled in Medicaid.

Access to CGMs in Low- and Middle-Income Countries

As the number of people with diabetes increases throughout the world, the World Health Organization has prioritized the need for reliable and affordable diabetic care in low- and middle-income countries. The Foundation for Innovative New Diagnostics (FIND) has partnered with Helmsley Charitable Trust to provide access to CGMs in Kenya and South Africa. Even so, according to a study involving researchers from FIND and academia, the availability of CGMs in lower middle-income countries (LMICs) is almost nonexistent, and results on impacts of CGMs in LMICs, while positive, are limited due to a lack of access leading to a smaller sample size. According to various sources, barriers to access in LMICs include a lack of public funding for CGMs and diabetes management, inconsistent regulatory oversight, and high prices in the private market.⁷

Sources: ADA, "Choosing a CGM," accessed 12/23; Bernabe-Ortiz et al., "Use of continuous," 3/16/23; CDC, "By the Numbers," 10/25/22; CDC, "National Diabetes Statistics," accessed 12/23; CDC, "What is Diabetes," 10/25/22; CHAI, "Market Report," 10/21; FIND, "FIND and the," 12/19/22; HHS, "Continuous Glucose Monitoring," 6/23; Garg et al., "Continuous Glucose Monitors," 4/27/23; Silva, "How Much Does a Continuous," 10/31/23; USITC DataWeb, accessed 10/23; WHO, "Diabetes," 4/5/23; Singh, "World Diabetes Day," 11/14/23; World Population Review, "Diabetes Rates by," accessed 12/23.

⁴ Import and export data were derived using HS subheading 9027.80, a basket category that includes glucose monitors and other measuring and testing devices. As of 2022, glucose monitors are imported under HS subheading 9027.89.

⁵ With the exception of China, the top 10 destination markets for exports from the United States are high-income countries.

⁶ Conversely, states in the Midwest and Northeast regions of the United States – where diabetes prevalence is among the lowest in the country – have some of the highest utilization rates of CGMs.

⁷ Most sales in LMICs occur in the private market where products experience markups ranging from 50 to 200 percent due to a combination of markups from distributors, retailers, import tariffs, and sales tax.

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