OXFORD ALPHA FUND

24 Feb 2019

MedTech Industry Report

Introduction to Continuous Glucose Monitoring (CGM)

Diabetic patients are **increasingly favoring Continuous Glucose Monitoring (CGM) systems over traditional methods of Self Monitoring of Blood Glucose (SMBG) methods**, such as finger stick tests. Effective monitoring is critical to diabetes management as it enables diabetic patients to intervene as necessary to ensure healthy blood glucose levels and prevent periods of hyperglycemia and hypoglycemia. Without the ability to do so, patients will suffer from a variety of complications, which may even lead to hospitalization at a significant financial cost..

We believe that CGM achieves just that. CGM offers superior data gathering potential, providing hundreds of data points daily, to better enable patients to monitor their diet, activities and insulin injections. Ongoing technological progress will continue to expand CGM's advantages over established methods of SMBG. Yet, **CGM is currently underpenetrated in the market**. Incremental technological progress as well as increasing medical coverage and improved data analytics will accelerate this shift.

In addition to incremental improvements to CGMs that continue to reduce barriers to uptake that have contributed to the under penetration at present, the steps towards the development of an "Artificial Pancreas" are crucial to the potential of the CGM industry. **The "Artificial Pancreas" will constitute an integrated system containing an insulin delivery system and a CGM device**. Following the same physiological process present in a non-diabetic individual, the "Artificial Pancreas" will **automate the blood glucose management** of diabetic patients to enable better glycemic control and quality of life than any existing products (or combinations thereof) currently do. Whilst further development will be needed before this technology can be brought to market on a broad scale and achieve the coverage necessary to be competitive, we believe this is an inevitability that will redefine the competitive landscape. The result of a successful rollout will drastically increase the advantages of CGM and drive further penetration.

In addition to having a positive outlook for the performance of CGM among Type 1 and Type 2 insulin intensive patients, we also believe in the **expansion into the pre-diabetes segment of the population**. The pre-diabetic population has been on the rise globally, standing at 33 million in the US alone. Without the ability to manage blood glucose levels effectively, most of these pre-diabetics will eventually become Type 2 diabetics. As Type 2 diabetes is not reversable, the consequences are severe. Yet, recent findings have show that pre-diabetics using CGMs are more likely to make positive lifestyle adjustments. Subsequently, CGM producers have begun to realize this potential. To sum, we have a positive outlook for the CGM industry going forward as the large and growing market is almost entirely overlooked.

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Introduction to Diabetes

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Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize the hormone insulin, preventing the body from adequately regulating blood glucose levels. In people with diabetes, blood glucose levels fluctuate between very high levels (hyperglycemia) and very low levels (hypoglycemia). Both of these conditions can lead to serious short-term and long term consequences.

Type 1 Diabetes is an autoimmune disorder that is characterized by an absence of insulin, resulting from destruction of the insulin producing cells of the pancreas. Individuals must rely on frequent insulin injections in order to regulate and maintain blood glucose levels.

Type 2 Diabetes is a metabolic disorder which results when the body is unable to produce sufficient amounts of insulin or becomes insulin resistant, accounting for 90-95% of people with diabetes. Depending on the severity, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels. The ADA recommends initiating insulin therapy in Type 2 patients who are symptomatic and/or have A1C $\geq$ 10% (86 mmol/mol) and/or blood glucose levels $\geq$ 300 mg/dL (16.7 mmol/L).

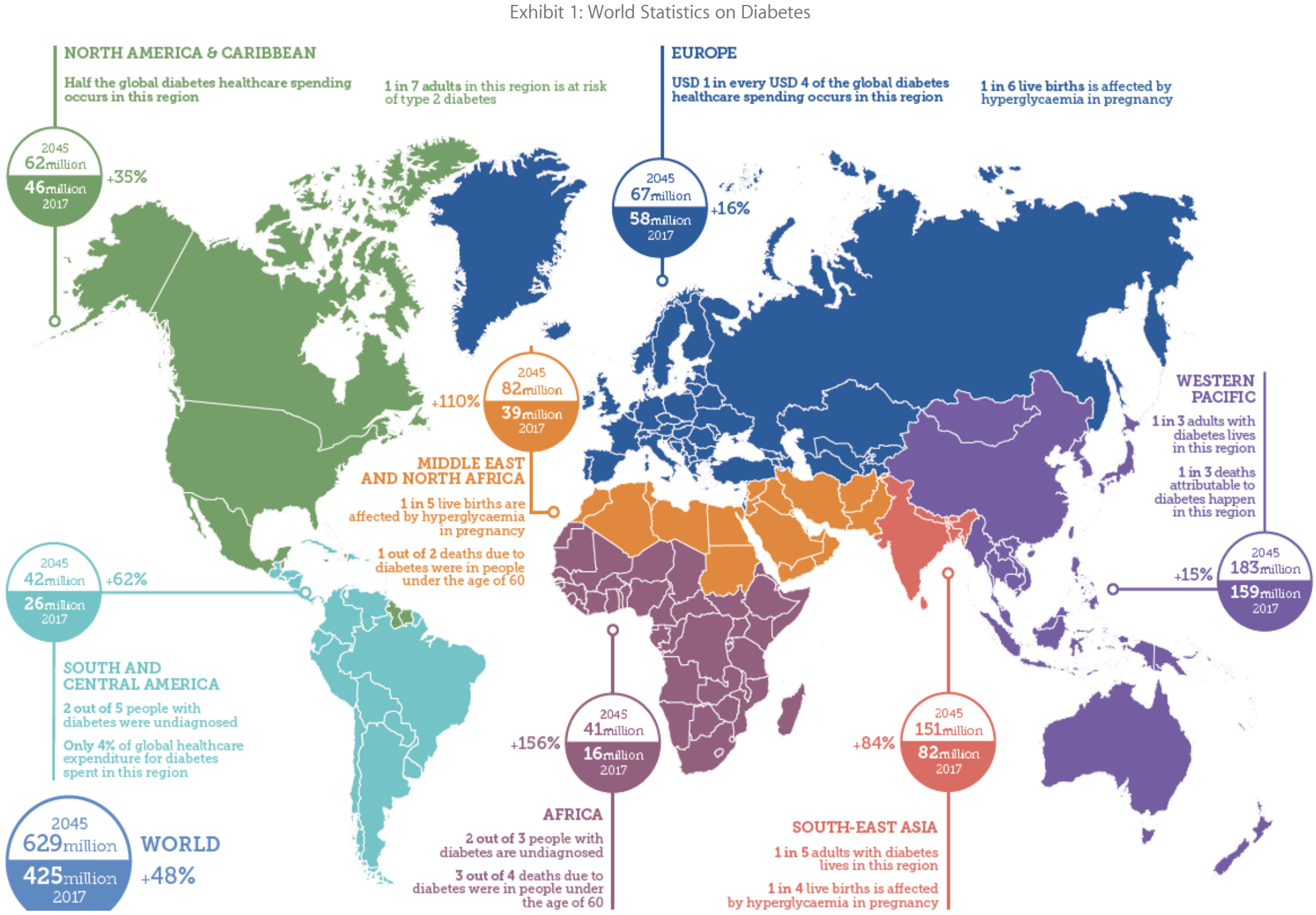
Gestational diabetes (GDM) is a form of diabetes consisting of high blood glucose levels during pregnancy. It develops in one in 25 pregnancies worldwide and is associated with complications to both mother and baby. GDM usually disappears after pregnancy but women with GDM and their children are at an increased risk of developing type 2 diabetes later in life. Approximately half of women with a history of GDM go on to develop type 2 diabetes within five to ten years after delivery.

Hypoglycemia, also known as low blood sugar, occurs when blood glucose levels fall below 4mmol/L Medication (often a too high dosage) is usually the main cause of hypoglycemia. Other causes include exercise, delayed meals and alcohol. Mild hypoglycemia can usually be treated by consuming 15-20g of fast acting carbohydrates. Severe hypoglycemia, on the other hand, requires immediate medical treatment and can potentially lead to coma or death.

Hyperglycemia, also known as high blood sugar, occurs when blood glucose levels rise above 7.0 mmol/L when fasting or 11.0mmol/L 2 hours after meals. This can be dangerous if blood glucose levels stay high for extended periods of time, leading to long term complications.

Undiagnosed Diabetes constitutes estimates of people who have diabetes but have not been diagnosed. The American Diabetes Association (ADA) estimates that more than 8 million people have undiagnosed diabetes in the US. In the UK, that figure is around half a million. Occurrence of undiagnosed diabetes is likely to be higher in developing countries

Exhibit 1: World Statistics on Diabetes

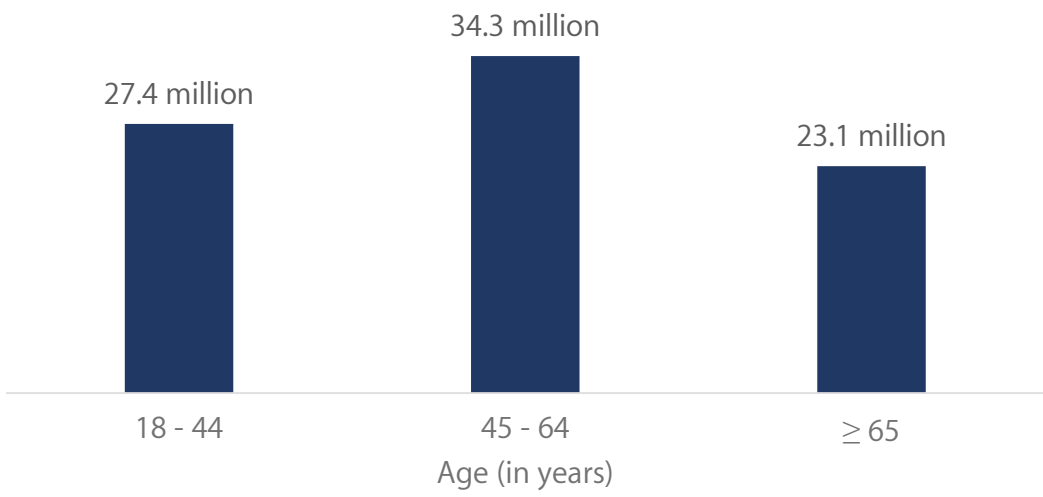


Source: IDF (2017)

Introduction to Diabetes

Prediabetes is a condition where a patient's glucose level is higher than it should be, but not in the diabetes range. Around 5-10% of people with prediabetes go on to develop Type 2 Diabetes in next 5 years. In the US, the ADA has set the level for prediabetes at a blood glucose measurement of HbA1C 5.7% (39mmol/mol). The CDC estimates that more than 84.1 million people in the US have prediabetes. In other countries, there is no defined criteria for prediabetes.

Exhibit 2: Estimate of Number of Adults with Prediabetes in the US (2015)



Source: 2011–2014 National Health and Nutrition Examination Survey and 2015 U.S. Census Bureau Data

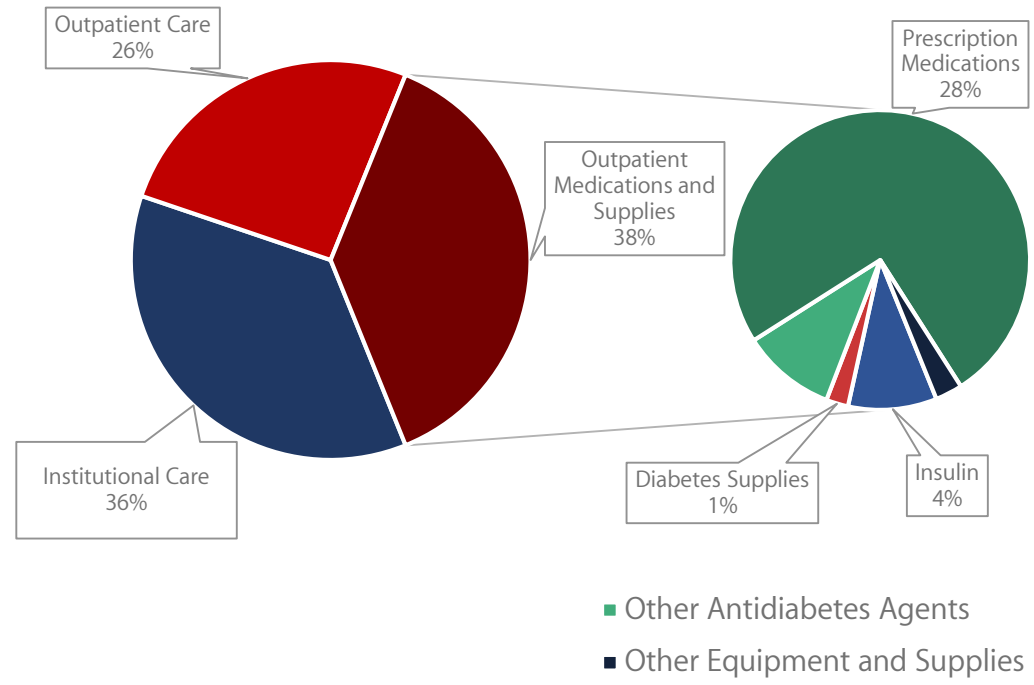
HbA1c refers to glycated haemoglobin, which identifies average plasma glucose concentration and gives an idea of average blood sugar levels over a period of weeks or months. HbA1c levels can be used as an indicator of diabetes control.

	HbA1c Levels
Normal	< 42 mmol/mol
Prediabetes	42 – 47 mmol/mol
Diabetes	> 48 mmol/mol

Time In Range (TIR) is the percentage of time that glucose levels stay between the 3.9 to 10 mmol/L range. In contrast with HbA1c, TIR gives an indication of the fluctuations in blood glucose levels.

Treatment for diabetes depends on the type and severity, with the aim of controlling blood glucose levels. Managing diabetes usually includes a combination of medication, insulin therapy and blood glucose monitoring. The International Diabetes Federation (IDF) estimates that diabetes related health expenditure was at least USD727 billion in 2017. These costs include hospital inpatient care (largest percentage of expenditure), prescription medication for diabetes and complications of diabetes, outpatient care and diabetic supplies. In the US, people with diagnosed diabetes incur average medical expenditures of $16,752 per year, of which about $9,601 is attributed to diabetes.

Exhibit 3: Annual Per Capita Health Care Expenditure on Diabetes in the US (2017)

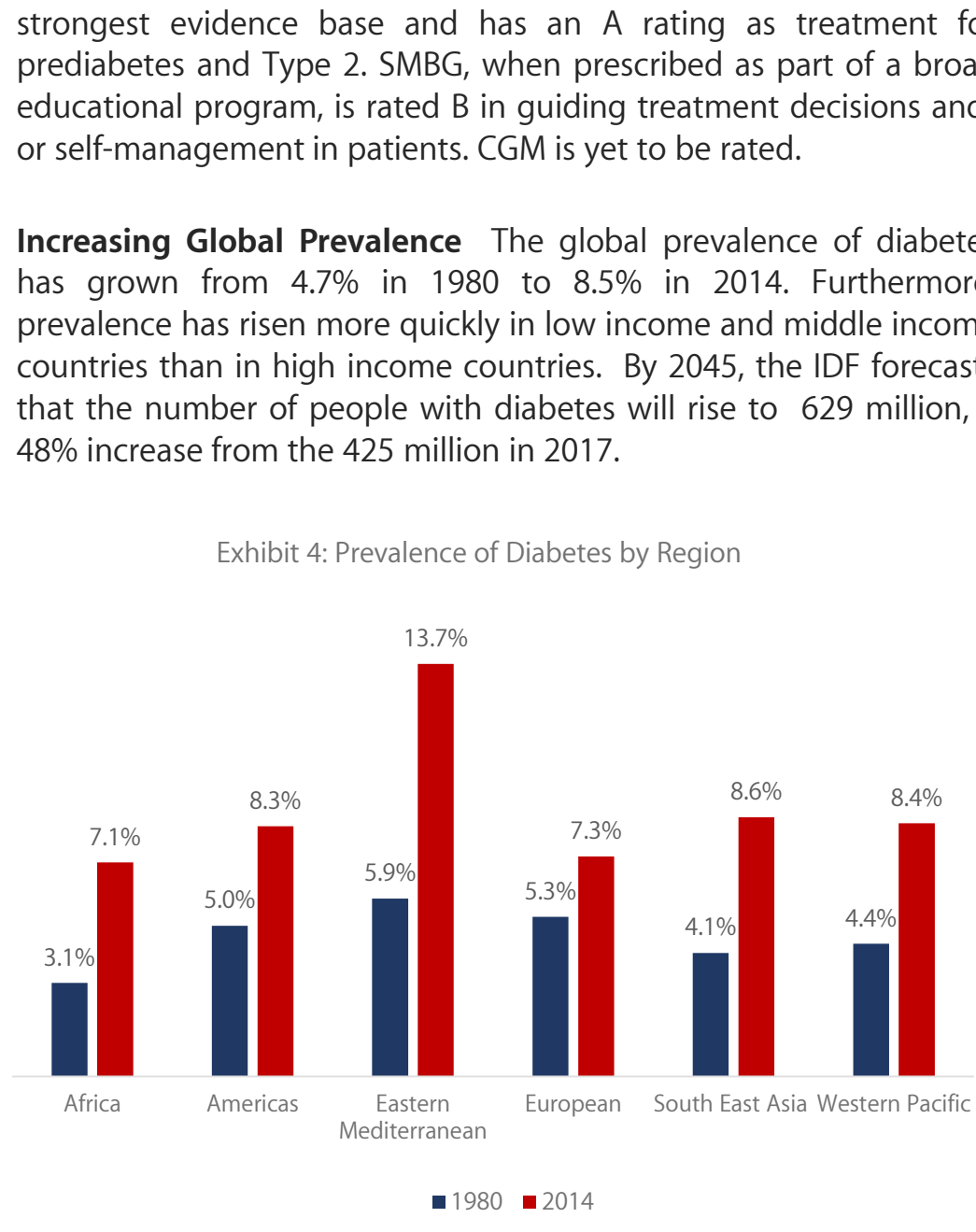


Source: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), Medicare 5% SAFs (2014), and U.S. Census Bureau (2017)

ADA Grading System was developed to grade the quality of scientific evidence supporting recommendations for treatment. Ratings from A to E are given depending on the level of evidence available. A ratings are given to treatments with clear evidence from randomised controlled trials and E ratings to treatments driven by expert consensus and clinical experience. Metformin has the strongest evidence base and has an A rating as treatment for prediabetes and Type 2. SMBG, when prescribed as part of a broad educational program, is rated B in guiding treatment decisions and/or self-management in patients. CGM is yet to be rated.

Increasing Global Prevalence The global prevalence of diabetes has grown from 4.7% in 1980 to 8.5% in 2014. Furthermore, prevalence has risen more quickly in low income and middle income countries than in high income countries. By 2045, the IDF forecasts that the number of people with diabetes will rise to 629 million, a 48% increase from the 425 million in 2017.

Exhibit 4: Prevalence of Diabetes by Region



Source: WHO

Artificial Pancreas

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The Basics

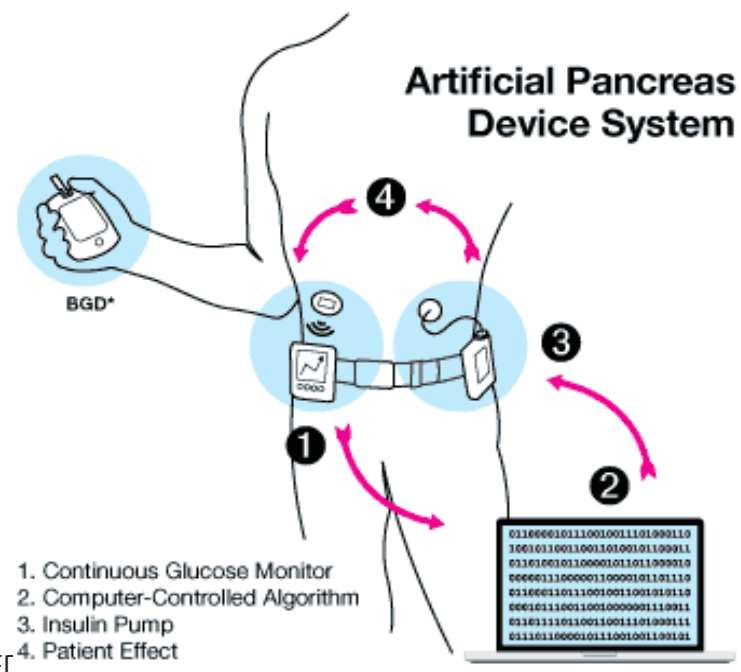
There are **three major functional components** of the modern artificial pancreas: a **continuous glucose-monitoring system**, an **insulin-infusion pump**, and a **control algorithm**. Together they form a **hybrid closed loop system** (HCL).

1. In a **CGM**, the glucose sensor is inserted through the skin and placed at a depth of 8-12 mm in the subcutaneous tissue. The sensor measures glucose as present in the interstitial fluid, rather than blood (which is what conventional SMBG devices measure). We will elaborate on CGMs in greater detail later in this report.

2. **Modern insulin pumps** are small electromechanical devices that are used to provide a programmed infusion of insulin into the subcutaneous tissue. Pumps consist of a refillable insulin cartridge, a pump mechanism, and a programmable user interface, which can be used by the patient to establish a basal infusion rate or to give a discrete bolus for coverage of a meal or for correction of hyperglycaemia.

3. **Control algorithms** are used to translate the readings from a CGM device into the appropriate amount of insulin required for a specific patient, accounting for multiple variables such as sleep, mealtimes and exercise. Control algorithms are relatively difficult to develop as the mechanism for translating interstitial glucose readings into an appropriate insulin delivery is not a linear, fixed equation – rather, such algorithms must retain the capacity to be predictive in responding to the unique habits of each patient. To this end, **control algorithms are the biggest barrier to entry in the development of a successful artificial pancreas**.

Exhibit 5: Artificial Pancreas Device System



Source: FD[illegible]

A Revolutionary Change

The artificial pancreas is an incredibly pivotal technology, due to the following:

1. **Improved glycemic controls**. (Weaver & Hirsch, 2017) demonstrated that achieving a well-controlled blood glucose level is essential for preventing complications in type 1 diabetic patients. The gold standard for determining a successful diabetes management system is the time a patient spends within a "safe" glucose range (3.9-10.0 mmol/L) relative to that spent within hypo/hyperglycemic ranges. (Weinzimer et al., 2008) showed for the first time that HCL insulin delivery could improve night glucose level where the patients time in range (TIR) improved from 58% to 85%. (Thabit et al., 2015) conducted a 12-week study of hybrid closed loop system(HCL) showing improved glucose control for HCL patients versus sensor-augmented pump patients, as such patients reported decreased incidence of hypoglycemia and a decreased level of HbA1c in adults. Clinical trials like those quoted above demonstrated that a HCL patient is able to have a higher percentage of TIR, particularly during vulnerable time periods (such as when one is sleeping) wherein a patient might not necessarily be immediately alerted to hypo/hyper glycaemia. As such, we can see that the introduction of an artificial pancreas will decisively improve the qualify of life of patients (in particular Type 1 and insulin-intensive Type 2s) who are at particular risk of hypo/ hyper glycaemia.

2. **Hospitalization Costs**. In 2017, FDA hosted a public workshop on reducing the risk of preventable adverse drug events associated with hypoglycemia. The workshop highlighted that insulin is the second most common drug associated with ER visits for adverse drug effects. (Lipska et al., 2014) showed that hypoglycemia was increasing the healthcare burden in US from 1999-2010 where rates of hospital admissions for hypoglycemia among Medicare beneficiaries increased by 22.3%. Severe hypoglycemia may result in coma, seizures and even death We believe that the ability for an artificial pancreas to better manage glucose levels and reduce the instances of hypoglycemic events will further reduce the cost of treatment borne by all parties. Hypoglycemic events, for instance, currently cost a hospital $2500 on an individual basis, thus leading to an annual cost of $750 million to US healthcare providers. In ADA's June 2018 conference, this message was further reiterated by FDA during their presentation. Since trials are showing that HCL systems increase the TIR range significantly, we believe that there will be increased avocation for HCL systems.

The Current Market

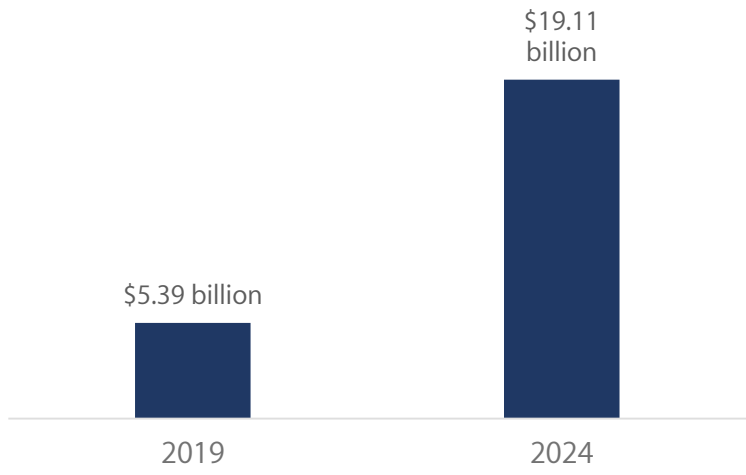
The current market for an artificial pancreas is **highly underpenetrated but rapidly developing**. In 2016, Medtronic's MiniMed 670G hybrid closed loop system was the first FDA approved automated insulin device for type 1 diabetes. In 2016, the FDA approved Dexcom's G6, the first system permitted to be used alongside other automatic insulin delivery systems such as insulin pens and pumps, giving patients the flexibility to switch and customise their diabetes management devices. With the approval of the G6, future interoperable CGMs (iCGM) can go through a more streamlined premarket review known as the 510(k) clearance.

Currently, the options available for a hybrid closed loop system are limited to MiniMed 670G and Dexcom G6 + Tandem t:slim X2 Insulin Pump with Basal-IQ Technology. However, other products are in the R&D pipeline or are undergoing clinical trials and awaiting FDA approval.

TAM

We estimate the total addressable market for CGM to be **$5.4 billion in 2019** and that it will grow to **$19.1 billion by 2024**, representing a 28.8% CAGR.

Exhibit 6: Global TAM



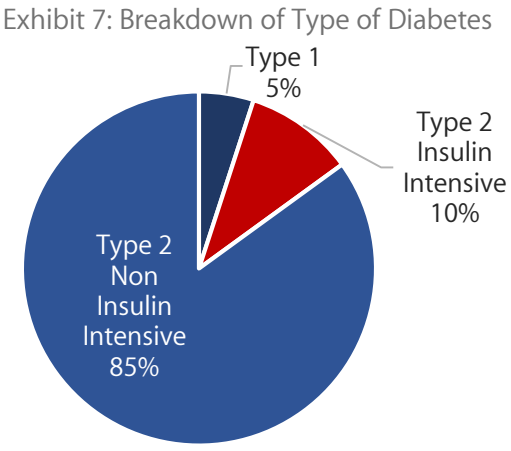
Our estimates are based on average cost per month and penetration rates in different regions. In the next five years, we believe TAM growth will be driven by increasing penetration rates and a growing diabetes population.

Total Addressable Market = Penetration Rate of CGM × Diabetes Population × Average Annual Cost

Diabetes Population

For our estimations, we segmented the global market for CGM into the US, Europe and the rest of the world. In the US, the number of people with diabetes stands at 32 million. Using projections derived from the Institute of Alternative Futures' (IAF) diabetes model for 2030 and interpolating, this number is projected to grow to 35.7 million by 2024. In Europe and the rest of the world, estimations for population growth were obtained using projections by the International Diabetes Federation (IDF). These numbers are likely to be a conservative estimate as the IDF assumes no change in the prevalence of diabetes for each age group and no changes in obesity and other risk factors. We estimate Type 1 diabetes affects 5% of the people diagnosed with diabetes and 10% of the diabetes population are Type 2 Insulin Intensive (Type 2 II). For TAM calculations, we have assumed the proportions of patients with Type 1, Type 2 II and Type 2 Non-II diabetes are constant for US, Europe and RoW and will not change throughout the forecast period.

Exhibit 7: Breakdown of Type of Diabetes

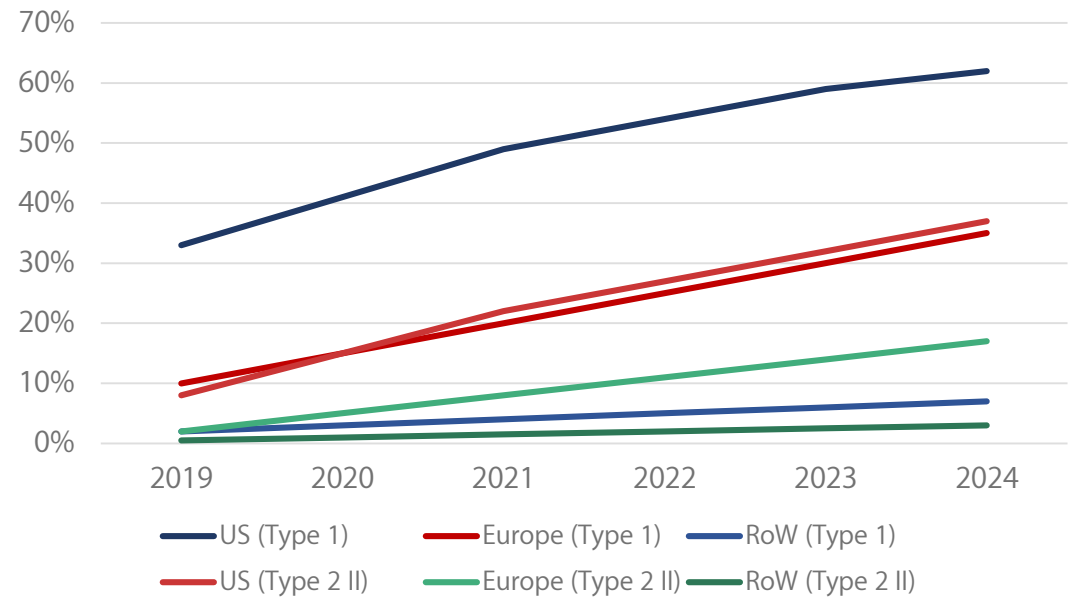


Penetration Rate of CGM

Currently, the penetration rates for CGM are at approximately 33% in the US for Type 1 and approximately 8% for Type 2 Insulin Intensive patients. The US is the leader in terms of adoption of CGM with the UK trailing behind at approximately 10% for Type 1 and 2% for Type 2 Insulin Intensive. In the rest of the world, penetration rates remain at low single digits, with Type 2 Insulin Intensive close to zero.

By 2024, we forecast US Type 1 penetration to be at 62% and Type 2 II to be at 37% . In Europe, Type 1 is expected to reach 35% while Type 2 II will be a 17%. In RoW, penetration rates remain low at 8% for Type 1 and 3.5% for Type 2 II.

Exhibit 8: Forecasted Penetration Rates in Each Region



Average Cost

Costs of using a CGM are comprised of an upfront cost of purchasing a receiver and recurring cots of purchasing transmitters and sensors. Some brands no longer require the purchase of a receiver, instead users can use their mobile phones as a receiver.

Average Cost = Receiver + Transmitter + Sensors

Prices of CGM vary across different brands. At the moment, the Abbott Freestyle Libre is the cheapest option. By weighting costs of using a CGM across Abbott, Dexcom and Medtronic according to their respective market share, the average cost per month is $268.71. We expect average costs across different brands to converge in the next few years, falling to $233 in 2024.

Dexcom G6	Price in USD
Sensors	349
Transmitters	83.33
Average Cost per Month	**432.33**

Abbott Freestyle Libre	Price in USD
Receiver	107.97
Sensors (Assuming useful life of 3 years)	23.33
Average Cost per Month	**131.30**

The Cool Stuff – The Technology Behind CGM

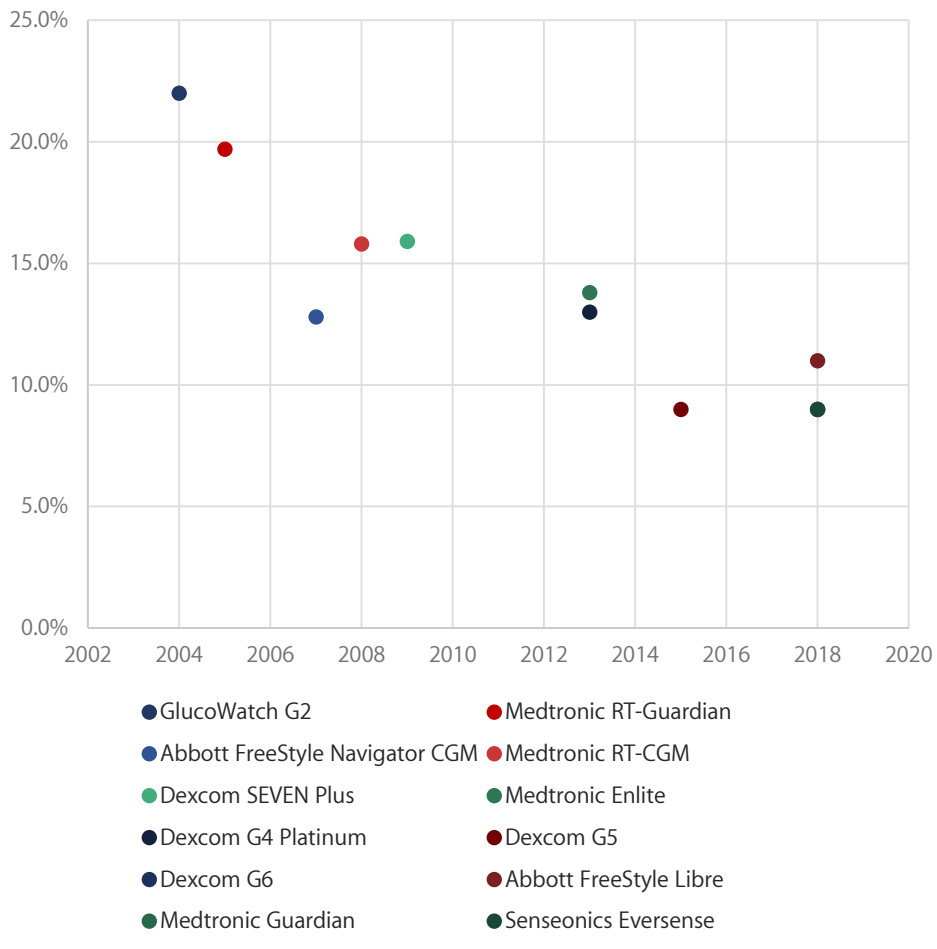
Technological Premise. CGMs primarily consist of three components:

1. The Sensor. The sensors utilized in CGMs tend to be enzyme based, and thus reliant on a chemical reaction between glucose and the enzyme glucose oxidase to form hydrogen peroxide, which in turn triggers a corresponding glucose reading. This, however, means that enzyme-based sensors are accurate in so far that they are able to sustain said chemical reaction continuously, which is currently between 7 – 10 days (depending on the sensor). Till date, only Senseonic's Eversense utilizes a Fluorescent Polymer approach, which is more durable (up to 90 days), yet requires a trained physician / doctor for replacement. All sensors utilized in CGMs are disposable, and thus require constant replacement.

2. The Transmitter. A transmitter is required for the transmission of data from a sensor to a receiver. Since CGMs are (by definition) "continuous" in their data monitoring and transmission, such transmitters also require constant replacement. However, not all "CGMs" consist of a transmitter – Abbott's FreeStyle Libre, for example, does not continuously transmit data to its receiver (a patient must "scan" their sensors to obtain a reading). As such, the FreeStyle Libre does not contain a transmitter (unlike its sister products on the market).

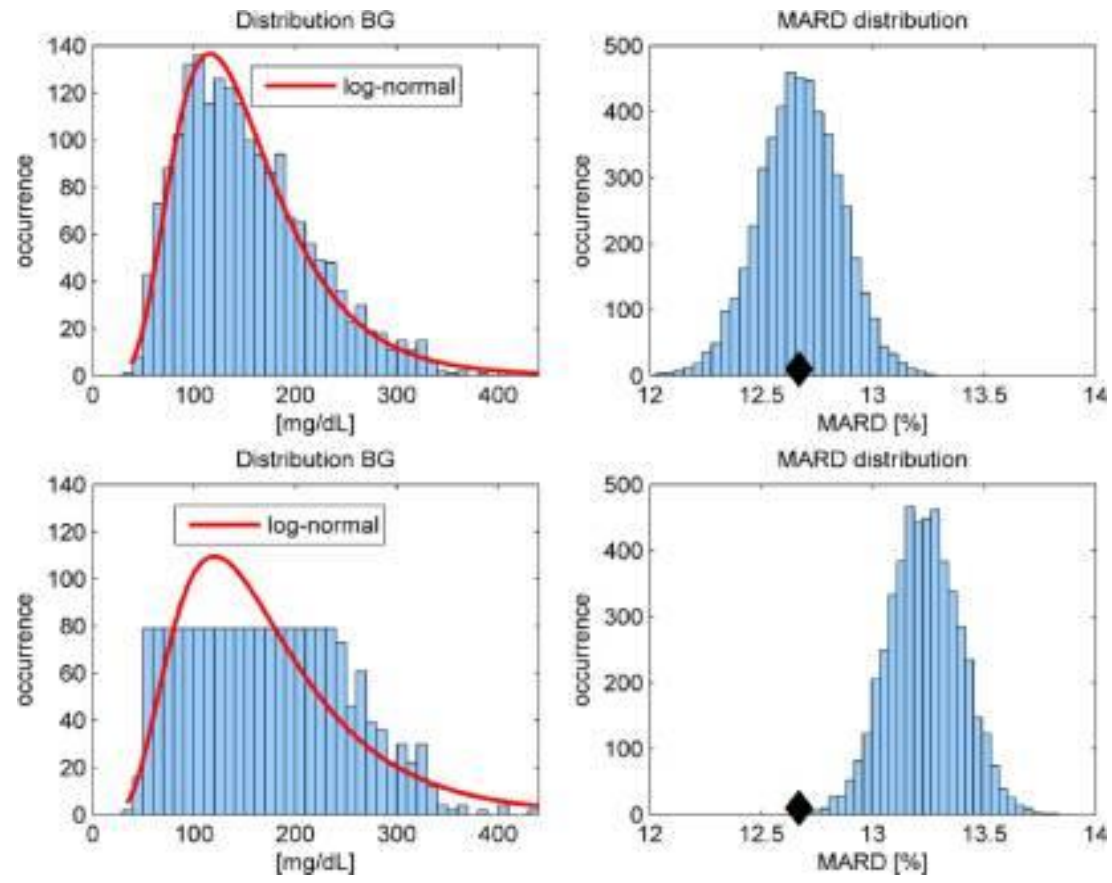
3. The Receiver. A receiver receives and interprets results from a CGM device, and usually takes the form of a tablet or a handheld device. Both the transmitter and receiver communicate via Bluetooth – however, a receiver does not require period "replacement" due to its portable nature. However, not all CGM "receivers" take the form of an entirely separate product. More recent generations of CGMs, such as Senseonic's Eversense and Medtronic's Guardian Connect utilize an application which can be used in a smart phone, rather than a portable physical device, thus driving down the up-front costs of such a product. We will be analyzing the costs innate to CGMs and their implications vis-à-vis market penetration and sales later in this report

Exhibit 9: A Timeline of CGM Devices



SMBGs vs CGMs. SMBGs primarily differ on a technical layer from CGMs based on the type of glucose monitored. SMBGs monitor blood glucose, whereas CGMs monitor glucose found within one's interstitial fluid. As mentioned earlier, this is because of the sensor used by CGM devices, which is inserted into the subcutaneous tissue rather than the blood directly. However, these two readings do not necessarily correlate, due to the fact that they are entirely different mediums. To this end, one key metric in determining the accuracy of a CGM with regards to real blood glucose level is the Mean Absolute Relative Difference (MARD). Clinical tests gauging the accuracy of a CGM relative to a SBGM thus evaluate the difference between the measured glucose levels of both devices as measured across multiple points of time. Low MARD scores thus imply an accurate CGM device.

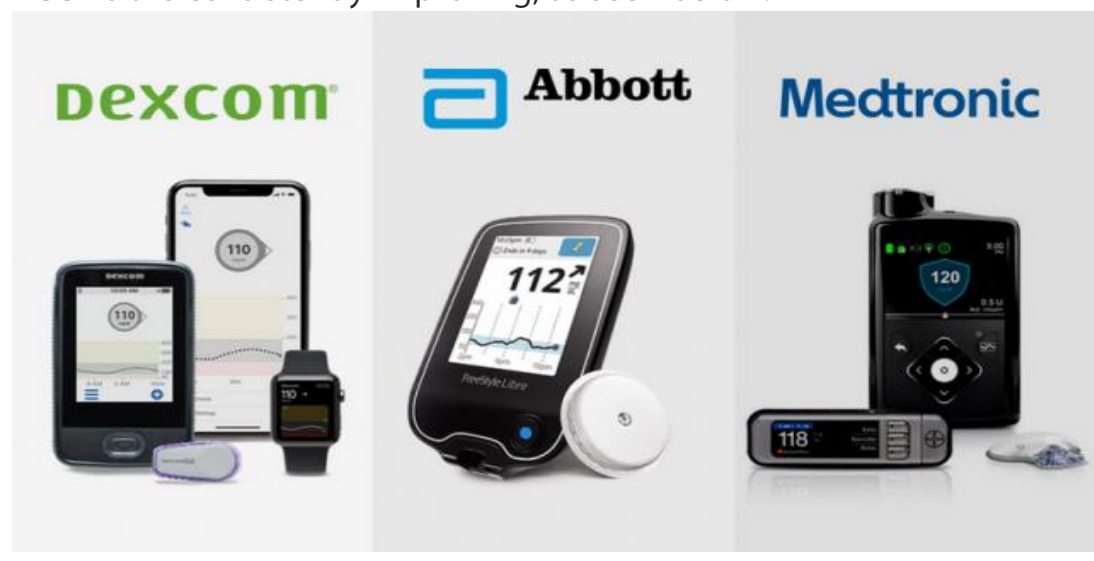
Exhibit 10: Performance Comparison of CGM Systems



Source: Journal of Diabetes Science and Technology (2015)

The inclusion of MARD is important as the very nature of CGMs preclude the ability us to use HbA1c as a marker for their effectiveness. Prior to the introduction of CGMs, HbA1c, or glycated hemoglobin were used to obtain an accurate insight into blood sugar levels as well as the relative accuracy of SMBGs vis-à-vis each other. However, this is clearly not applicable in the case of CGMs as mentioned earlier. To this end, the measurement of MARD stands out as one of the only metrics to accurately ascertain the effectiveness of CGMs.

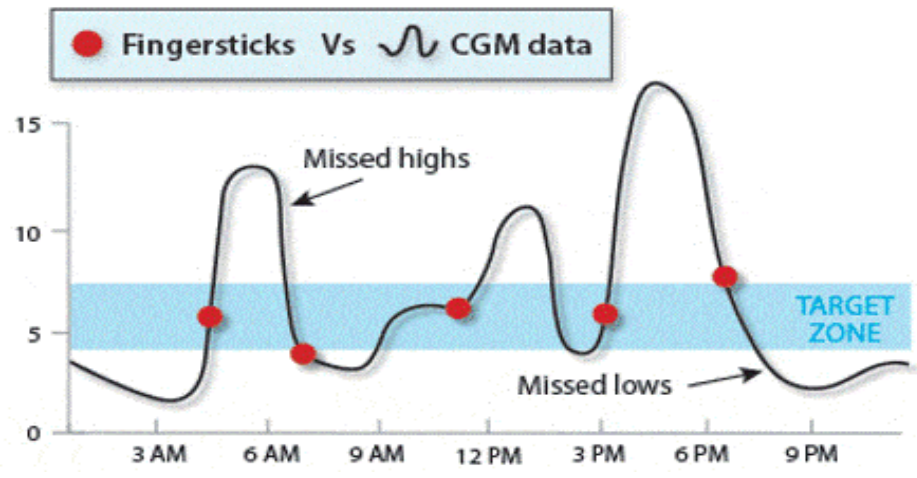
Positive Development. CGMs are not an inordinately new technology, yet if we were to take MARD as a metric, we can see that CGMs are consistently improving, as seen below:



SMBGs vs CGMs

Monitoring of glycemic events. The key selling point of CGMs is its ability to provide continuous monitoring, with the inclusion of alerts if a CGM were to measure glucose levels entering the dangerous hypo/hyper glycaemic ranges. This is incredibly important, as while SMBGs might be able to provide a highly accurate blood glucose reading during a certain point in time, such methods (such as fingersticks) might miss hypo/hyperglycemic events:

Exhibit 11: Monitoring using fingersticks vs CGM



Source: Medtronic (2019)

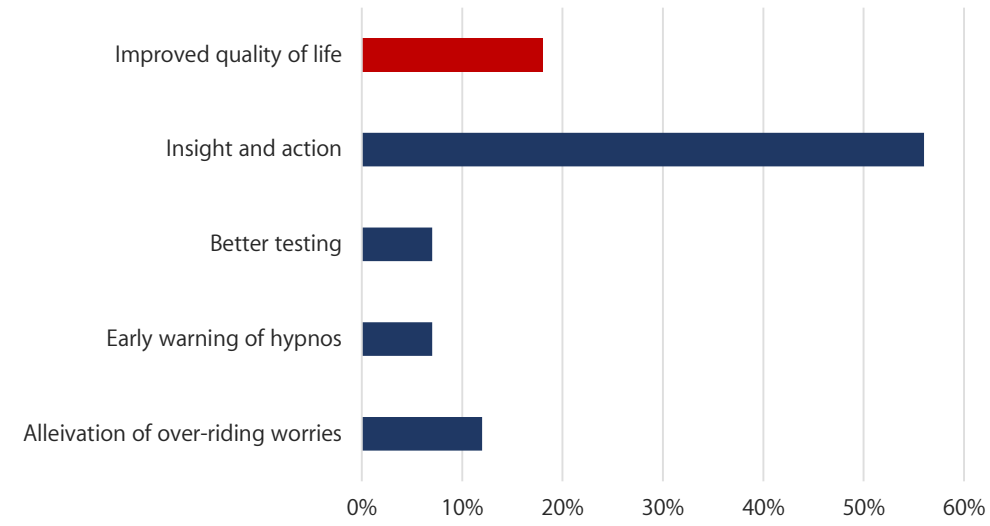
This is incredibly important, as such events, if not properly addressed, could lead to catastrophic consequences for Type 1 and insulin-intensive Type 2 Diabetics. Such patients inherently require external sources of insulin (such as an insulin pen / pump) in order to restore blood glucose levels – as such, the fundamental inability for SMBGs to alert their users to such events places them at risk. In contrast, CGMs retain the functionality to alert their users in the event of such events, thereby allowing for a patient (or their immediate caregivers) to administer insulin as required. Indeed, CGMs such as Dexcom enable for users to set their own "target range" if patients wish to control their blood glucose levels beyond merely preventing hypo/hyper glycemic events. As a result, multiple clinical studies (as seen below) have evidenced improving blood glucose levels arising from CGM-led insulin therapy, thus attesting its effectiveness.

To this end, CGMs retain a clear advantage over SMBGs with regards to their ability to promptly inform Type 1 / Insulin-Intensive Type 2 Diabetics of glycemic events in order to prevent long-term medical harms, as well as to enforce more rigorous, personalized treatment plans

Trend Data. We also believe that CGMs could be integrated with predictive analytical technologies in order to better forecast and predict hypo/hyperglycemic events. This is an advantage unique to CGMs – as mentioned earlier, SMBGs inherently do not store trend data. Even if patients were to weather the intense discomfort involved with continuous blood glucose prick tests, such data would be inherently inferior to the realtime readings picked up and stored by CGMs to begin with. This is an advantage which is not immediately apparent, as such predictive tools have yet to enter the R&D pipeline. However, we believe that even if CGM devices do not incorporate built in predictive analytics, doctors and healthcare professionals would have ready access to the data needed to formulate such calculations, thereby resulting in an increased standard of treatment and diagnosis as a whole.

Ease. SMBGs are typically viewed as invasive and highly inconvenient, due to the need for constant prick tests which can and humiliating for patients. This is highly evidenced in patient surveys, who cite such reasons as a factor behind a switch to CGMs:

Exhibit 12: Factors behind switch to CGM



Source: BMO Capital Survey (2018)

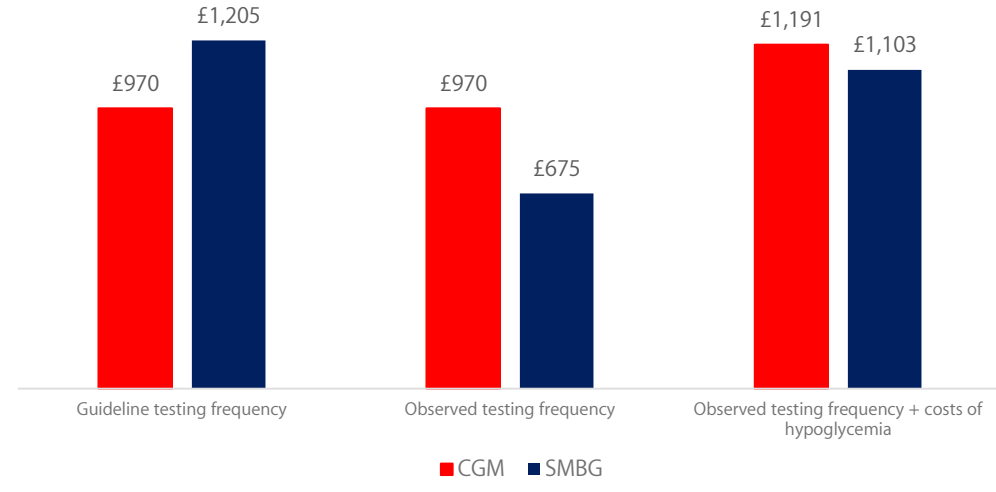
CGMs, on the other hand, are inherently less invasive than SMBGs. While sensors must be injected every 10 days (for most CGMs), such injections are not likely to decisively inconvenience users relative to that posed by SMBGs. Moreover, CGMs increasingly do not require calibration using a manual SMBG device. Devices such as the Dexcom G5 required manual calibration on a regular basis – however, the Dexcom G6 and Abbott's FreeStyle Libre are both factory calibrated, thus eliminating the need for CGM users to subscribe to invasive SMBG tests. To this end, the calculus between SMBGs and CGMs is not a false choice, but rather, a markedly decisive one for users who seek a less invasive, more convenient product.

Lessening the Medical Burden. We can also see that the constant monitoring and storage of glucose data will further speed up medical consultations and treatment recommendations by point of care doctors. Historically, healthcare professionals did not have regular access to a composite database of blood glucose levels, thus necessitating time-consuming tests in order to ascertain a short term trend to inform treatment. Ultimately, such tests might not be accurate or a reflective trend of long term, systemic problems / trends, thus mitigating the effectiveness of recommended treatments.

CGMs, however, store historical data on a 24/7 basis, which can be shared with either healthcare providers or caregivers (due to such data being stored on the cloud). This thus reduces the time required for an effective diagnosis, thereby leading to greater clinical efficiency.

Cost. While use of CGM is often associated with high costs due to the upfront cost of the machine, CGM is more cost-efficient when compared to daily use of test strips under the suggested testing frequency for Type 1 patients. Furthermore, when costs of treating hypoglycemia are taken into account, costs of using CGM and SMBG are approximately at par, even when used at observed testing frequency.

Exhibit 13: Cost of using CGM vs SMBG Based On Testing Frequency



Source: Hellmund, Weitgasser and Blissett (2018)

Coverage: A Story of Business Models

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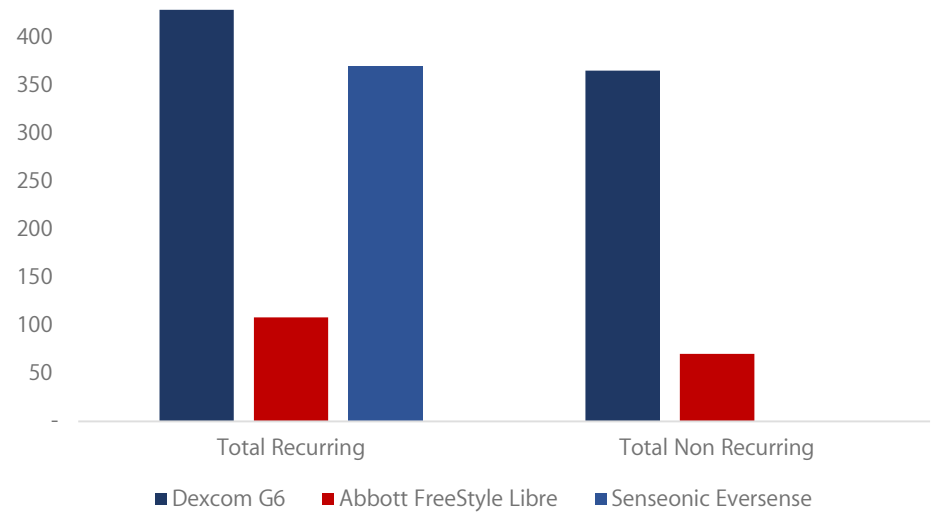
The Importance of Insurance Providers. As elaborated earlier, CGMs primarily consist of disposable sensors and transmitters, and receivers (usually in the form of an application, tablet or handheld device). As a result, the cost of a CGM borne by a patient is recurring in nature – while the receiver does not require constant replacement, the sensor and transmitter do, thus leading to high costs as seen below:

Exhibit 14: Costs of using CGM for a 30 Day Period



The differences in recurring costs can largely be attributed to the different technical natures of products. Abbott's FreeStyle Libre and Dexcom's G6 both utilize enzyme-based sensors which cannot garner accurate glucose readings after 10 days, however, the FreeStyle Libre does not involve a continuously transmitting transmitter, thus leading to a marked difference in recurring costs. Moreover, the lack of "continuous monitoring" has led to a markedly less complex receiver and data processing and storage systems, thus leading to low non-recurring costs as well. In contrast, Senseonic's Eversense sensor utilizes a fluorescent polymer approach, which enhances the sensor's useful life to 90 days, thus offsetting the inherently high costs associated with such technology. Senseonic has also excluded non-recurring revenue in the form of a data receiver, and instead packages an application to be used with a smart device.

We thus believe that the high recurring costs inherent to the ownership of a CGM device elevates the role of insurance companies in driving demand. Ultimately, the absence of insurance coverage for CGM devices would handicap the ability of low-income patients to own such devices, while the higher costs associated with CGMs relative to SMBGs would deter demand even amongst patients who might be able to front the cost of the former. To this end, we have thus analyzed 2 key players to insurance coverage in the US - public payers (Medicare) and private insurance providers,

Coverage. Both public and private payers are important in this debate, yet, we believe that trends within public healthcare insurance providers such as Medicare are likely to be more important. Medicare is the single largest source of insurance in the US (as seen below), especially amongst those above the age of 65. This is because employer-linked insurance packages, which form the bulk of private healthcare insurance policies, usually terminate after the age of 65 (the age of retirement) – thus entrenching Medicare as the primary source for healthcare coverage in this demographic. If we further concede that this demographic single handedly forms 39% of the market in the US, we can thus see that Medicare is a singularly important point of analysis in our understanding of how / if the cost of CGMs are adequately borne by patients.

Medicare Part B v. Part D. Medicare has recently deemed CGMs as a "durable medical equipment" (DME) eligible for coverage under Part B, as demonstrated below. This has opened the pathway for corresponding Medicare policies aimed at incentivizing the prescription of CGMs by doctors and healthcare professionals:

Code	Description	Payment Rates
95249	Setup of patient-provided CGM	$ 56.15
95250	Setup of physician-provided equipment	$ 156.58

Medicare Type	Coverage	Specific Coverage
Part A	Hospital Coverage	-
Part B	Medical Coverage	CGMs, Insulin Pumps
Part C	Medicare Advantage - Only Available with Private Coverage	-
Part D	Prescription Drug Coverage - Only Available with Private Coverage	Other Injectable Insulin

Sales Channels. However, despite such preferable policy shifts aimed at incentivizing physicians to prescribe / set-up CGMs, the industry as a whole is gradually shifting away from prescribed DMEs and towards DTC customer sales at pharmacies as a medium for sales. We believe that this shift is taking place for 3 reasons:

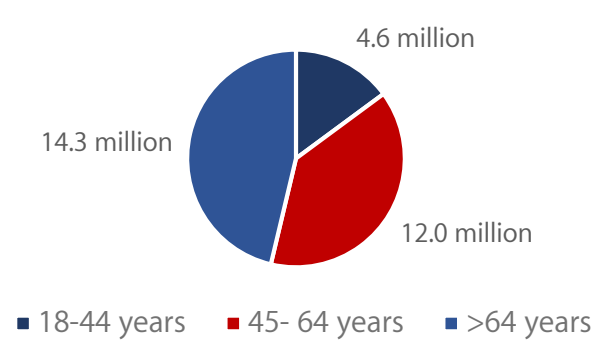
1. Physicians are only empowered to claim the aforementioned Medicare quotes if their patients are either Type 1 or insulin-intensive Type 2 patients. As demonstrated earlier, this amounts to a small fraction of the Total Addressable Market for patients with diabetes

2. Building brand value with customers in order to dominate pharmacy sales is more cost effective than targeted marketing and benefits directed towards physicians and other healthcare professionals. To this end, while CGMs sold at pharmacies are priced lower, this is offset by the resultant cost savings in marketing and sales expenses

3. Improved operating margins arising from faster new-patient onboarding, which has led to a 75% reduction in work effort and a 85% reduction in time to process, thereby translating into better operating margins

Dexcom is currently a market leader in this pivot towards pharmacy from DME as a sales channel. To this end, we believe that the cost savings generated from such a pivot will be emulated by the industry as a whole, thereby increasing the importance of insurance plans in covering prescribed pharmacy purchases. For the time being, however, Medicare Part D does not cover disposable sensors and transmitters as "prescription drug coverage" – and even so, only authorizes such a coverage with premiums from private insurance plans. As such, any developments in Part D coverage would have massive ramifications for companies seeking to change their sales channels in order to expand operating margins.

Exhibit 15: Diagnosed and Undiagnosed Diabetics



Source: American Diabetes Association (2018)

Market Analysis

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A Litany of Differences. The key players operating within the CGM market are Dexcom, Abbott, Medtronic and Senseonic. While the aforementioned companies may be classified as "CGM" manufacturers and designers, we must (as previously mentioned) concede a number of key differences:

CGM	Non-Adjunctive?	Durable Medical Equipment?	Sensor Life	MARD
Dexcom G6	Yes	Yes	10 Days	9%
Abbott FreeStyle Libre	Yes	Yes	10 Days	11%
Medtronic Guardian	No	No	6 Days	9%
Senseonics Eversense	No	No	90 Days	9%

CGM	Sensor Type	Transmitter	Receiver?	Real Time Alerts?
Dexcom G6	Enzyme-based	Yes	Yes - Separate Device	Yes
Abbott FreeStyle Libre	Enzyme-based	No	Yes - Separate Device	No
Medtronic Guardian	Enzyme-based	Yes	No - Application	Yes
Senseonics Eversense	Fluorescent polymer approach	Yes	No - Application	Yes

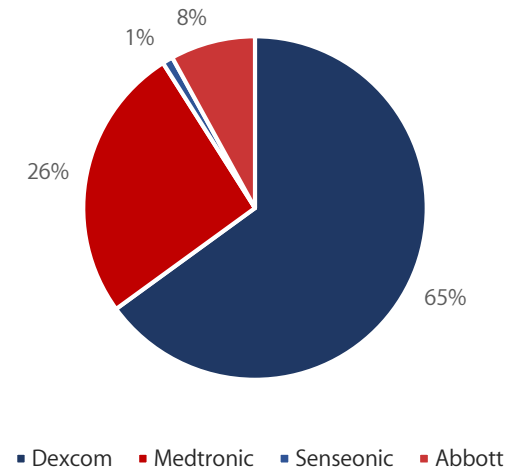
As per the aforementioned data, we can thus see that while CGM devices roughly serve to meet the same need amongst diabetic patients, each device is substantially different from its competitors. To this end, we thus conclude that these devices are not necessarily mutually exclusive – Senseonics' Eversense device, for instance, only targets long-term patients who are insulin intensive, yet who qualify for the coverage needed for the physician-supervised sensor replacement inherent to Eversense. In contrast, Abbott's FreeStyle Libre is priced lower due to the lack of a dedicated transmitter, real time alerts and a shorter-term sensor, thus implying a market of Type II patients who are not necessarily insulin intensive to the point of requiring constant monitoring and alerts. As such, we believe that while the CGM market is becoming increasingly crowded, such competition does not necessarily erode the innate advantages of established players, nor would it lead to one company necessarily benefitting at the expense of another.

Clearances. Moreover, if we were to analyze the market shares per CGM device, we can see that the market is heavily skewed towards devices which have been cleared as "non-adjunctive devices" by the FDA and "durable medical equipment" by Medicare. This is incredibly important, as such clearance is vital for CGMs to be marketed as a replacement to SMBG devices. Medtronic's Guardian, for instance, cannot be marketed as a product which can singularly inform insulin treatment packages due to its status as an "adjunctive" device, thus limiting its attractiveness amongst patients who would have to retain SMBGs anyway. In contrast, Dexcom's G6 and Abbott's FreeStyle Libre have been cleared as "non-adjunctive" devices which can inform treatment decisions, thus leading to both products maintaining a convincing dominance of the market thus far.

Similarly, the classification of CGMs as "durable medical equipment" enables for its coverage under Medicare, thus expanding their potential market. FDA approval and CGM approval are inherently interlinked – the FDA must have approved a CGM devices as a "non-adjunctive device" capable of singularly informing treatment decisions, in order for Medicare to approve coverage for said devices due to their importance in informing treatment plans. Devices which have not received an FDA "non-adjunctive" ruling are thus precluded from receiving Medicare coverage, thus negatively impacting their market penetration.

Market Share. Having analyzed the differences between each company's products, we can thus arrive at the following conclusions regarding the market for CGM devices:

Exhibit 16: Market Share (2018)

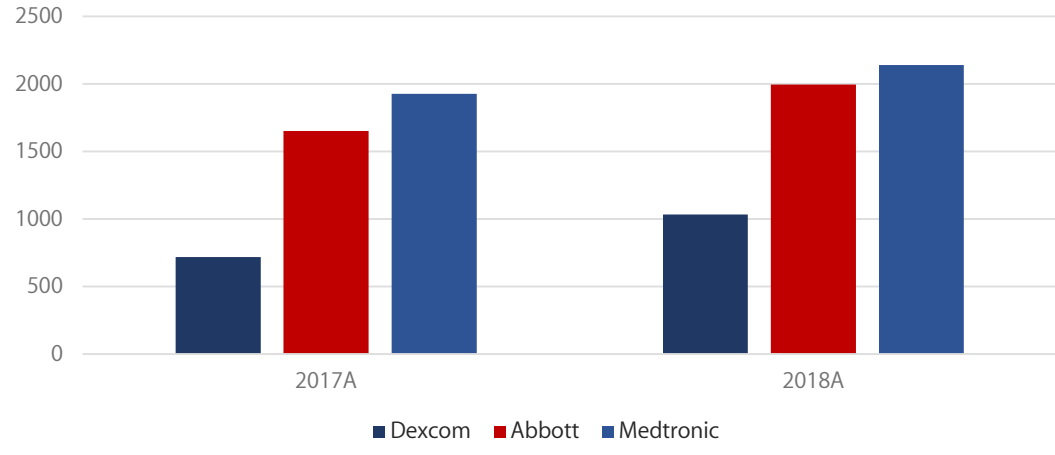


As the device which first received FDA and Medicare approval, we can thus see that Dexcom is leading the market in terms of market share in 2018. However, both Medtronic and Abbott retain substantial market shares, with management guidance potentially reflecting Medtronic capturing increasing market share in the near future. We believe that Medtronic's relatively strong market share despite its lack of of a "non-adjunctive label" is due to its integration of CGMs with insulin delivery system in the form of its 670G system, which replicates an "artificial pancreas" in automating insulin delivery based on CGM readings. Despite the FDA requiring SMBG readings to make direct, manual insulin adjustments, the innate appeal of an "artificial pancreas" has offset the relative inconvenience of requiring a separate SMBG device for calibration and confirmation. However, we can see that the market as a whole is pivoting towards the development of artificial pancreases as well, with both Dexcom and Senseonic announcing partnerships with insulin-pump makers to synergize a closed-loop diabetes management system:

CGM	Insulin Delivery	Product	(Expected) Release
Dexcom G6	Tandem	t:Slim X2	2018
Dexcom G6	Novo Nordisk	Integration with NovoPen 6 / Echo Plus	2019
Dexcom G6	Insulet	Omnipod Closed Loop System	2020
Medtronic	Medtronic	670G Closed Loop System	2018

Key Financials. As a result of the aforementioned benefits of CGM devices and their relative popularity vis-à-vis conventional SMBG devices, market leaders in the CGM sector have experienced phenomenal growth:

Exhibit 17: CGM Related Revenue



Source: Company Annual Report

Driver 1: Under-penetration of CGMs

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Pivot toward CGMs…

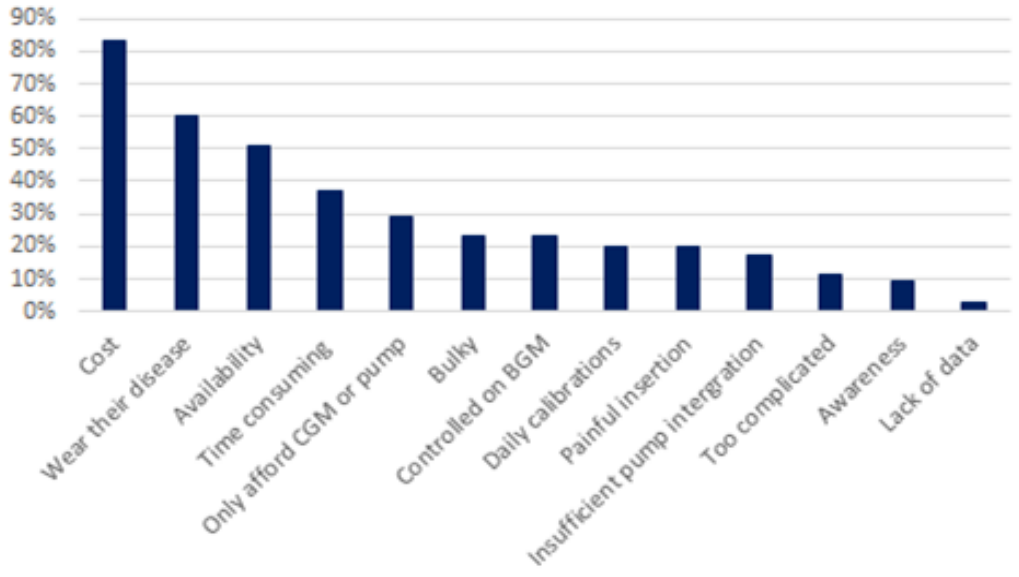
Popularity vis-à-vis SMBGs. As previously explained, CGMs provide better information than SMBGs. CGMs offer real time monitoring and data sharing for patients and their immediate points of care, thus reducing the risk of hypo/hyperglycemic emergencies going untreated. Crucially, data sharing options built into devices have allowed for doctors to quickly and efficiently view their patients' historical HbA1c levels, thus allowing for a quick yet accurate diagnosis. Recent research has shown that the better monitoring enabled by CGM leads to an observed lowering of HbA1c levels 0f 0.44% compared to SMBG (Sierra et al., 2017). This, combined with improvements in technology and coverage that have reduced the observed barriers to uptake, serve to make CGMs an increasingly favorable approach to glucose monitoring. This is why we have seen- and will continue to see- CGM gain increasing market share relative to SMBGs.

… yet systemic under-penetration

Increasing standalone popularity. As mentioned, CGMs are increasing in their popularity. However, we believe that the CGM market is sorely underpenetrated.

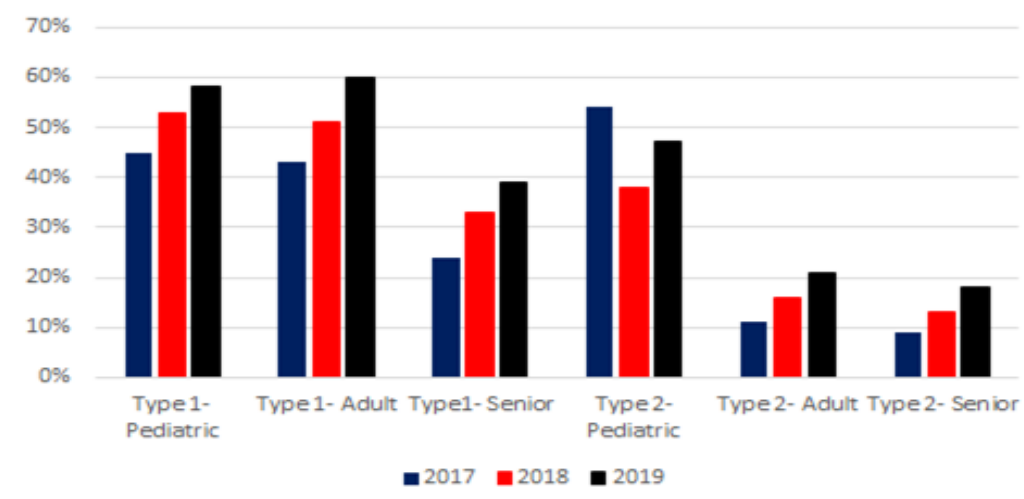
The figure below lists the reasons cited by Type 1 patients for barriers to CGM adoption. Cost remains the largest barrier, with other reasons relating to availability, stigma surrounding 'wearing their disease' and inconveniences associated with CGMs.

Exhibit 18: Barriers to CGM Adoption



Source: JP Morgan Survey (2018)

Exhibit 19: CGM Penetration in Insulin Pump Patients, 2017-2019



Source: JP Morgan Survey (2018)

We can see that CGMs have barely penetrated the market for Type 1 and Type 2 diabetics, but are increasing in their year-on-year market growth. We believe that this is due to increasing wages and purchasing power, as well as the rising prevalence of diabetes as a whole. We believe that the purchase of such CGMs is strongly tied to purchasing power due to the nature of healthcare insurance in the USA, which offers varying degrees of coverage for the use of CGMs for Type 1 Diabetic patients. As such, considering that patients who subscribe to private healthcare would have to cover a certain portion of the costs anyway, and considering the incredibly serious nature of Type 1 Diabetes and the potential for CGMs to offer round the clock monitoring, we believe that CGMs will only become increasingly more popular and prevalent in the market. The global incidence of Type 1 diabetes is also increasing every year worldwide.

Country	Total New T1 Patients from 2019 to 2024
United States of America	864,234
India	309,174
Saudi Arabia	229,835
China, People's Republic of	183,069
Russian Federation	179,144
Germany	127,475
Poland	122,396
United Kingdom	121,703
Islamic Republic of Iran	101,204
Brazil	81,875
France	72,370
Italy	52,562

penetration above the 5% it currently stands among type 2 intensive. More recently, both Abbott and Dexcom have began researching CGMs that would be aimed at type 2 non intensive patients, who currently do not participate in the CGM market at all.

Prediabetes. The additive value of CGMs have also been proven in prediabetic patients, or patients whose blood glucose levels are higher than normal, but not yet high enough to be classified as diabetes. If undiagnosed or untreated, prediabetes can develop into type 2 diabetes. We believe that this is a growing problem – 70% of prediabetics in the US are eventually diagnosed with Type 2 Diabetes – however, we can see that this market is underpenetrated as well. Currently, no specialized drugs or devices exist for patients diagnosed with pre-diabetes.

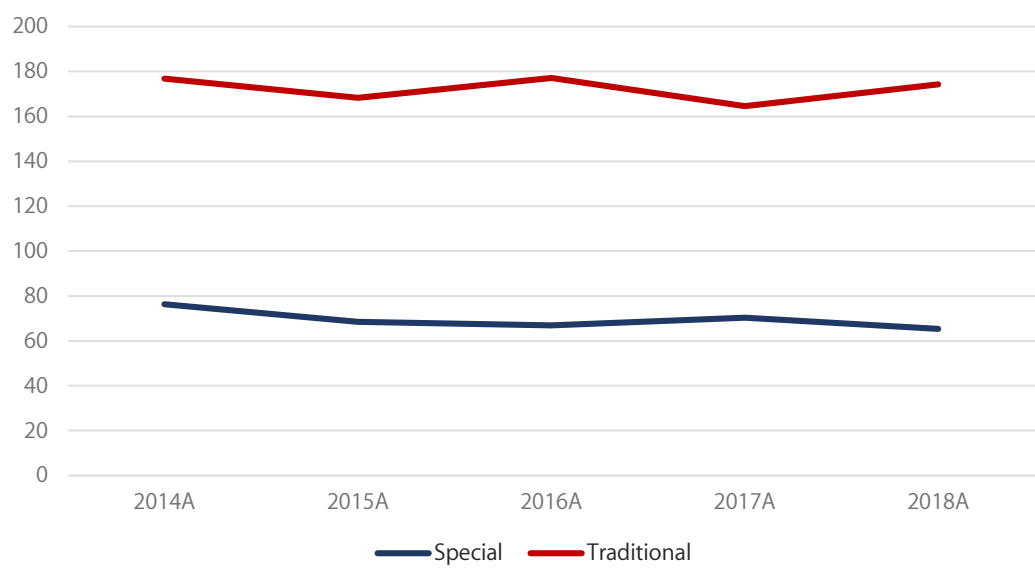
To this end, we believe that CGMs stand to capture a significant proportion of the prediabetic population. Scientific studies have revealed that CGMs are accurate in monitoring blood glucose levels below the Type 2 threshold (Chen, 2011), while pilot clinical studies suggest that the use of CGMs could lead to improved self-awareness and diabetes prevention amongst prediabetic patients (Bailey 2016).

Driver 2: Favorable Regulatory Environment

Faster FDA Regulatory Approval. As mentioned under our market analysis, FDA regulatory approval is pivotal for the mass marketing of a CGM device as a wholesale replacement of conventional SMBG equipment. To this end, the ability for CGMs to receive a "non-adjunctive" label is a vital driver for the growth of the CGM market.

To do so, however, CGMs historically required substantial testing and clinical trials in order to meet FDA criteria. This is defined as a 510k submission, wherein a medical devices manufacturer submits a pre-market submission to the FDA to demonstrate that the device is at least as safe and effective as a similar, FDA-approved device. This process, or a "traditional 510k" approval as shown below, was historically drawn out. Dexcom, for instance, required 212 days for the its G6 device to be cleared as a "non-adjunctive device" by FDA standards, which involved an array of clinical trials aimed at comparing the G6 with traditional SMBG devices on the market. With the clearance of the G6, however, the FDA has committed towards an accelerated system of approval under its "special" 510k scheme. As seen below, FDA approval times under such a scheme is close to a third of "traditional 510k" approval times due to lightened regulatory restrictions thereby leading to accelerated product approval in the future.

Exhibit 20: FDA Approval Times (No. of Days)



Source: FDA (2018)

We believe that this is incredibly important for 2 reasons:

1. The biggest barrier to market penetration is the FDA's process of approving CGMs as a "non-adjunctive device". As reflected below, devices which have received such a designation have performed better than those classified as an "adjunctive device", by virtue of the former's capability to replace SMBGs, rather than to merely act as a supporting tool.
2. Only CGMs prescribed as "non-adjunctive" might qualify for Medicare coverage as a "durable medical equipment", as noted earlier. To this end, an accelerated FDA approval regime premised upon lighter regulatory restrictions would innately expand the pool of CGM devices covered by Medicare, thereby expanding their market presence and penetration.

As such, we believe that an accelerated FDA regulatory and approval regime will exert an upward pressure with regards to the market penetration of CGMs, thereby driving demand and revenue.

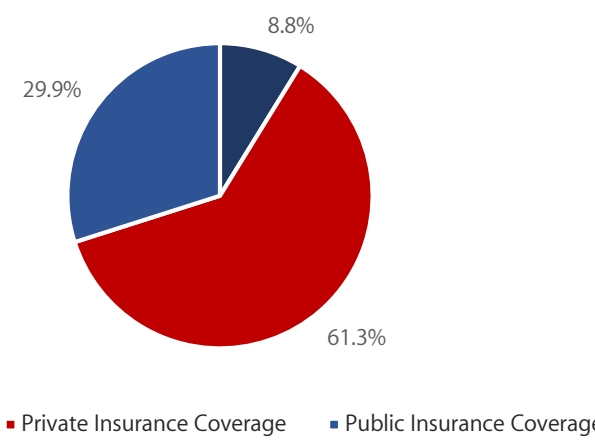
Medicare. As mentioned, Medicare coverage for CGM devices will be innately easier to obtain due to the FDA"s adoption of a "special 510(k)' policy with respects to such devices. Moreover, we believe that internal developments within Medicare, as well as its implications for private insurance coverage will further drive demand for CGMs

An Uphill Battle. Medicare has historically been averse towards the coverage of CGMs, even for those with Type 1 and insulin-intensive Type 2 Diabetic patients within the United States. Indeed, Medicare's official policy since 2017 has been to allow for the coverage of CGMs in cases wherein a demonstrable need has been proven by a licensed physician. However, from 2017 – 2018, Medicare has often denied the coverage of CGMs for patients with Type 1 and insulin-intensive Type 2 Diabetes, thus reducing the appeal of CGMs for patients who were reluctant to stomach the high recurrent costs inherent to such devices (as explained earlier).

However, in 2018, Medicare was successfully sued in court by a plaintiff (*Lewis vs Azhar, 2018)*, who argued that CGMs constituted a necessary device for his (Type 1) diabetes. Medicare legal representatives, on the other hand, argued that CGMs should be defined as a "precautionary" device, and thus, one not inherently vital for the treatment of Type 1 Diabetes. The court ultimately ruled in favour of the plaintiff, with the conclusion that CGMs should be classified as a "therapeutic" device for Type 1 Diabetic patients, thus justifying coverage under Medicare Part B. As such, we believe that while Medicare has been historically intransigent with respects to translating a "non-adjunctive" label into coverage, FDA rulings which accelerate the process of obtaining such a label as well as litigation over Medicare's policies will expand the latter's coverage of CGM devices. We believe that this is pivotal since as established earlier, Medicare accounts for the single largest source of healthcare insurance for Americans. As such, improved access to Medicare coverage will culminate in increased demand and patient access.

Private Providers. While private insurance providers sustain a wide ranging presence (as demonstrated below), we believe that such providers have largely adopted coverage of CGMs for Type 1 and inulin-intensive Type 2 patients. Even if certain insurance providers have not done so, we believe that the industry as a whole will pivot towards such coverage in line with Medicare – thereby further expanding the scope for CGM coverage.

Exhibit 21: Insurance Coverage in the US



Source: United States Census Bureau

Driver 3: International Growth

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A Growing Market…

A Global Problem. Although the highest incidence of Type 1 diabetes is found in Caucasoid populations (particularly in Northern Europe) and the lowest rates in Asia and South America, hikes in incidence of Type 1 diabetes has been observed in all markets. To illustrate, the incidence of Type 1 diabetes in 2010 was 40% higher than in 1998 according to Diabetologia. Yet CGMs have historically tended to be an "American" product: Out of US (OUS) sales amongst most major CGM players pale in comparison to sales made in the United States. However, we believe that this trend will likely change in the near future, due to a number of key factors:

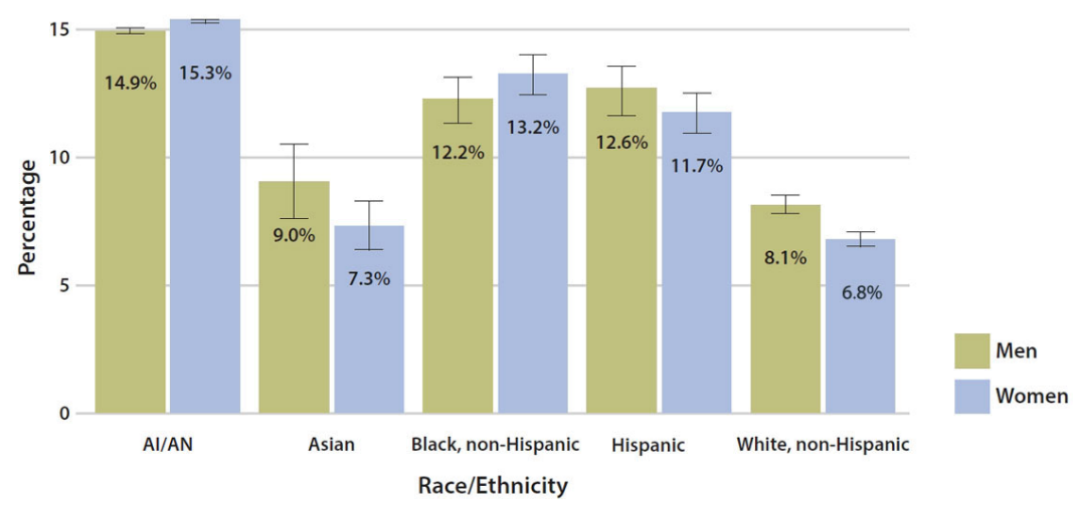
1. Emerging markets surge in T1 incidence

There has been a substantial increase in some previously resistant emerging market populations. As average households—encouraged by globalization and growing disposable income—start to consume and prefer calorie-rich dietary options and shift from physical jobs to desk jobs, the onset of Type 1 diabetes has gained momentum. For example, Shanghai, China, has seen the incidence of Type 1 diabetes in children under 14 increase 14.2% a year from 1997 to 2011. In comparison, the increase in Type 1 diabetes in historically high incidence Northern European countries has only increased by 1 – 3% a year. At this rate, in just four years—from 2016 to 2020—the incidence of Type 1 diabetes will double, and sextuple by 2025. In Zhejiang, China, incidence increased 12% per year between 2007 and 2013 for children under 14, but incidence increased by over 33% per year for children under 5. Even if some of this growth can be attributed to improvements in diagnosis, potential demand for CGM remains robust. (World Journal of Pediatrics)

2. T1 susceptibility in immigrant populations

The CDC report released in 2013 shows how white, non-Hispanic populations in the US are significantly more unlikely to be diagnosed with diabetes than other races/ethnicities. As such, there is evidence that Type 1 diabetes is not only correlated with genetics, but also environmental factors triggered by immigration. For example, length of time spent living in Sweden is correlated with risk of Type 1 diabetes: the offspring of immigrant women living in Sweden for 11 years or more have a 22% higher risk than offspring of women living in Sweden for 5 years or less. Immigrants to Israel from lower incidence countries have been observed to lose their protection against diabetes around adolescence: the younger the immigrant at the time of immigration, the higher the likelihood of getting Type 1 diabetes. As we can expect immigrants in richer countries to receive better health care coverage and income than before, the demand for CGM's should subsequently increase. (Diamond Project Group 2006) Countries with the highest net migration include the US, Germany, Canada, Russia, UK, Saudi Arabia, Italy, and France, many of which are listed below.

Exhibit 23: Percentage Diagnosed with Diabetes by Race/Ethnicity



Source: CDC Report (2013)

3. Cheaper and more cost-effective products entice low-income countries and demographics.

Improved Cost Effectiveness: The Dexcom G6 has improved sensor life from 7 days to 10 days in comparison to the G5. Dexcom expects to manufacture a device with a sensor life of 14 days by late 2019.

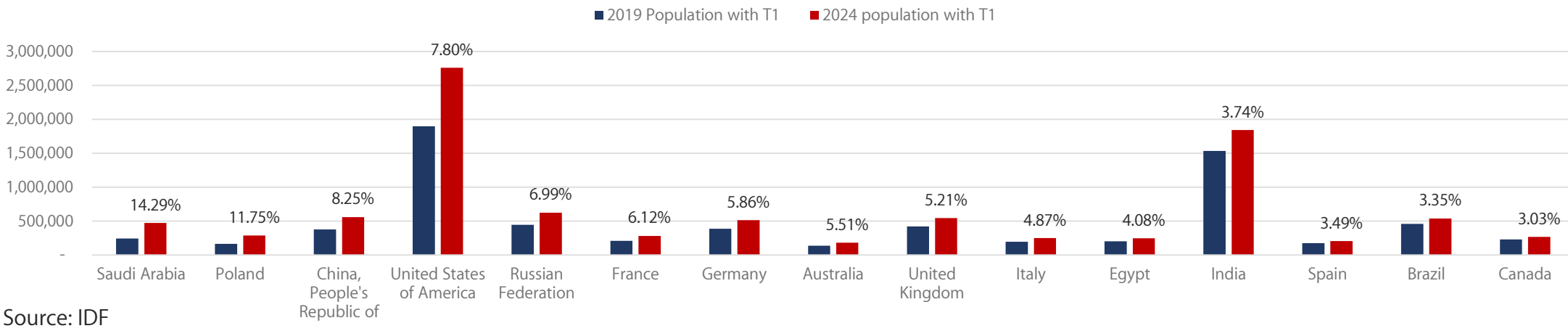
Lower Cost: The Dexcom G6, at $375 per transmitter bundle is 37% cheaper and 43% than the G5 and G4 at $599 per bundle and $660 per bundle respectively. The sensor pack for the G6 at $490 is also 41% cheaper than the G5 at $832. (List price)

…offering great opportunities for global players

Strategic Shifts. To this end, we can see that CGM manufacturers have reacted to potential growth abroad. For example, Dexcom has partnered with a myriad of distributors in South East Asia and Europe. Similarly, Abbott has expanded its Diabetes Care division with offices in pivotal markets such as Japan, India and China.

Potential in China. According to the Chinese Center for Disease Control and Prevention, adults in China had an overall prevalence of diabetes and prediabetes at 46.6% in 2013 than the US at 31.5% in 2017. In terms of population size, there are more than six times the number of diabetics and pre-diabetics in China than the US. As can be anticipated, Ascensia Diabetes Care, a Swiss tech company, has announced that it will be officially moving into the CGM space via a partnership with Huzhou, a China-based Zhejiang POCTech in 2019. A quick search on Alibaba reveals a lack of CGM listings—precisely none of adequate quality—in comparison to Amazon and Ebay. This suggests that the Chinese population has limited easy-access to CGM devices and what Chinese CGMs currently available are incomparable to the technology offered by the main US players.

Exhibit 22: Countries with Fastest Growing Population of Type 1 Diabetes



Source: IDF

Moats

High Switching Costs. A CGM device has a high upfront cost, specifically within the range of USD$600 – $1000, depending on insurance coverage and retailer. Moreover, a CGM kit requires replacement of sensors every week. When replacing these sensors, users must purchase the replacement sensors from the original manufacturer. As such, to switch from a current CGM system to a new system, customers must not only spend time learning about how to operate the new system, but also pay the high upfront cost.

Algorithms. As mentioned earlier, access to algorithms often form a high barrier to entry with regards to the adoption of a closed-loop artificial pancreas. Therefore, we believe that companies who proactively acquire such algorithms, either through inhouse development (Medtronic) or an acquisition (Dexcom with regards to Type 0) will retain a fundamental advantage over their peers with regards to the development of an artificial pancreas. Indeed, if we consider the added plans for the artificial pancreas in diabetes treatment (e.g. leveraging on predictive analytics and a rudimentary form of AI), the presence of algorithms as a barrier becomes all the more pertinent. To this end, we thus believe that algorithms will form a sizable barrier to entry for new firms seeking to enter the artificial pancreas market.

Coverage. While there are an array of CGM devices on the market / in development, only 2 have received coverage by CMS – Dexcom's G6 and Abbott's FreeStyle Libre. We believe that this substantially affects sales and product performance. For instance, Medtronic's Guardian Connect Mobile CGM received FDA approval for commercial distribution in March 2018. However, despite the launch of a major product, its revenue growth has largely remained the same from 2017 to 2018 at a meagre 2%. Indeed, despite receiving preferential partnership deals from healthcare insurance providers such as United Healthcare and Aetna, Medtronic has yet to record the same meteoric revenue growth rate experienced by Abbott and Dexcom following the launch of their 2018 CGM portfolios. To this end, we thus believe that CMS coverage is a vital point of differentiation between companies operating within the CGM market – companies with a proven brand image and track record of medical success such as Dexcom and Abbott are more likely to capture market share as a result of CMS coverage, relative to newer companies such as Medtronic.

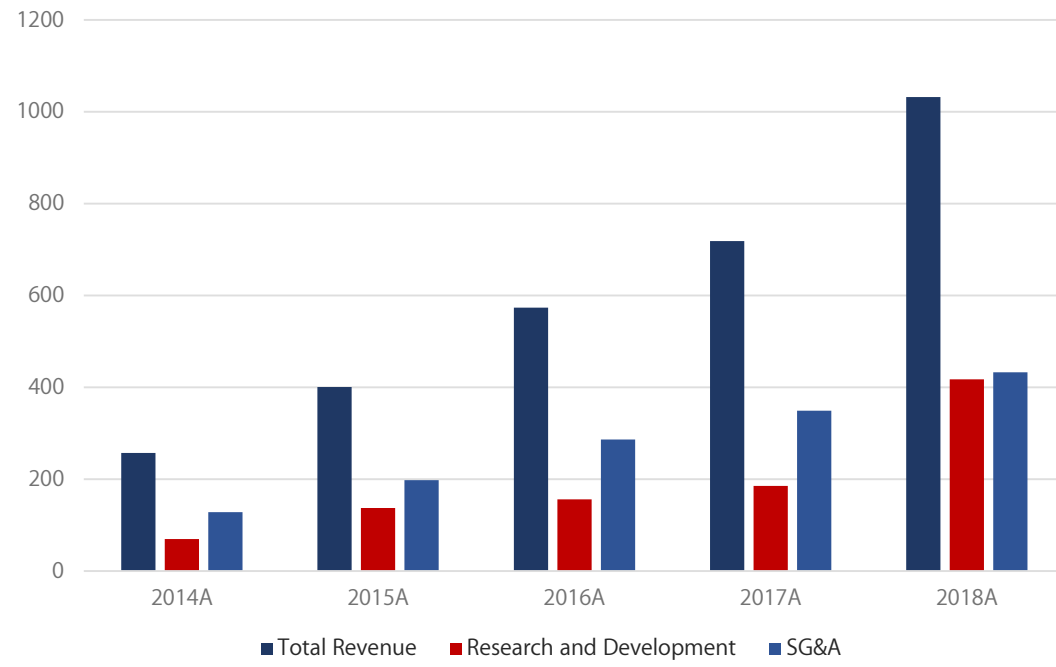
Costs of Development. Obtaining FDA approval, let alone CMS clearance, is not cheap – by expert estimates, companies manufacturing medical devices are likely to incur 31 million USD from concept to market, of which close to 77% is spent on FDA-dependent or related activities. We believe that the FDA's accelerated process for CGM approval will not substantially decrease such costs – as seen to the right, as costs associated with obtaining a 510(k) (which will decrease due to said accelerated processes) do not account for a sizable portion of total costs, as seen to the right:

As such, we believe that only companies with established sources of capital and liquidity will be able to sustain the costly process of developing CGMs, thus mitigating the possibility of new entrants to the market.

Patents and R&D. Much like any other healthcare device market, CGM-oriented firms invest heavily in R&D expenses and patents. The former is especially true amongst companies seeking to branch out into developing an artificial pancreas, or a closed-loop system of insulin delivery predicated upon continuous monitoring and automated insulin delivery. As such, we believe that companies which secure patents and invest heavily in R&D are likely to maintain their technological leadership which will deter new entrants, particularly with regards to CGM, where "catching up" to the market leader could prove prohibitively expensive.

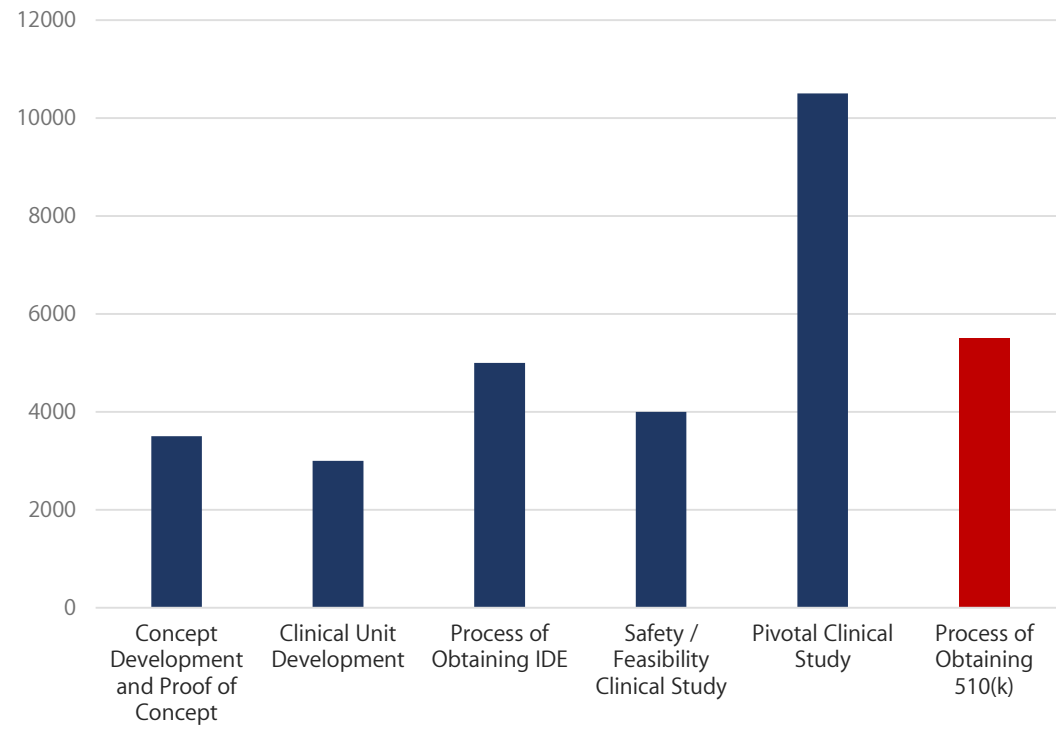
Sales and Marketing. While brand image might matter for patients, we can see that firms must be willing to incur significant expenses in sales and marketing in order to pander to healthcare professionals. We believe that this is evidenced by the % of Sales and Marketing as a percentage of Total Costs within established CGM players such as Dexcom and Abbott. To this end, companies without the cashflow to stomach such expenses might not be able to sustain their position in the market relative to their more aggressive competitors. We believe that this moat will become increasingly pertinent as more and more firm enter the CGM market.

Exhibit 24: Dexcom Revenue and Expenses (in Millions)



Source: Dexcom Annual Report

Exhibit 25: Costs Associated with Bringing Product to Market

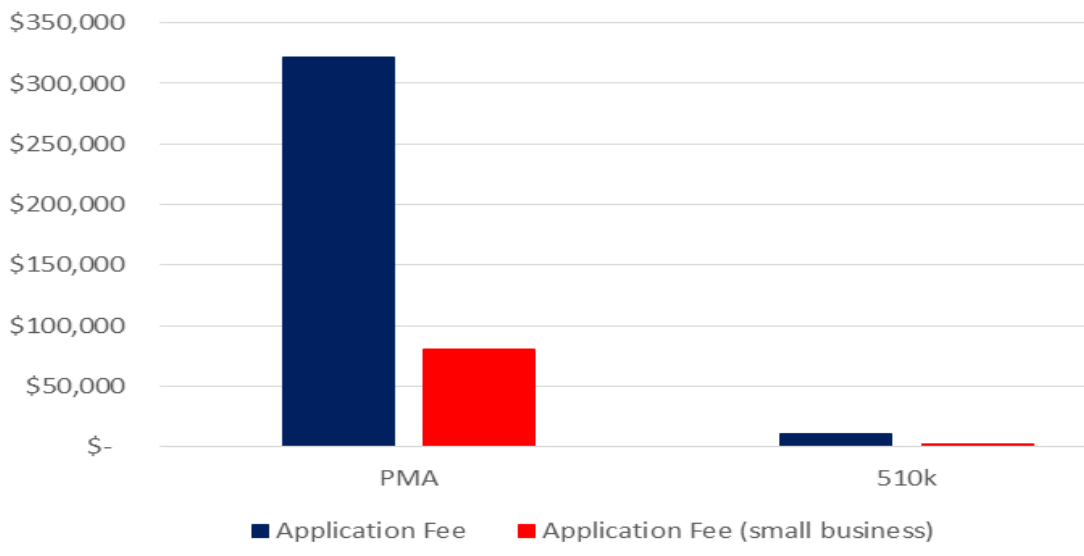


Source: US Food and Drug Administration (2018)

Risks

Regulatory Changes. As mentioned earlier, FDA regulations are a primary driver for the industry, with loosening criteria exerting an upward pressure on the market as a whole. The key issue on this front is the ability of CGM producers to get approval through a 510k instead of a PMA. On average, this is far less costly, as shown and is a much faster process. As of 2016, average time for approval of a 510k was 109 days, compared to 209 days for a PMA. Whilst any modifications to present devices are permitted to follow the 510k route at present, such assurance has not been granted for the development of future generations of CGM. If CGM producers fail to get permission from the FDA to use the easier 510k route for future devices, this will lead to a slowdown in the rollout of new products and a substantial increases in the costs of bringing new products to market.

Exhibit 26: 510k vs PMA Application Fees

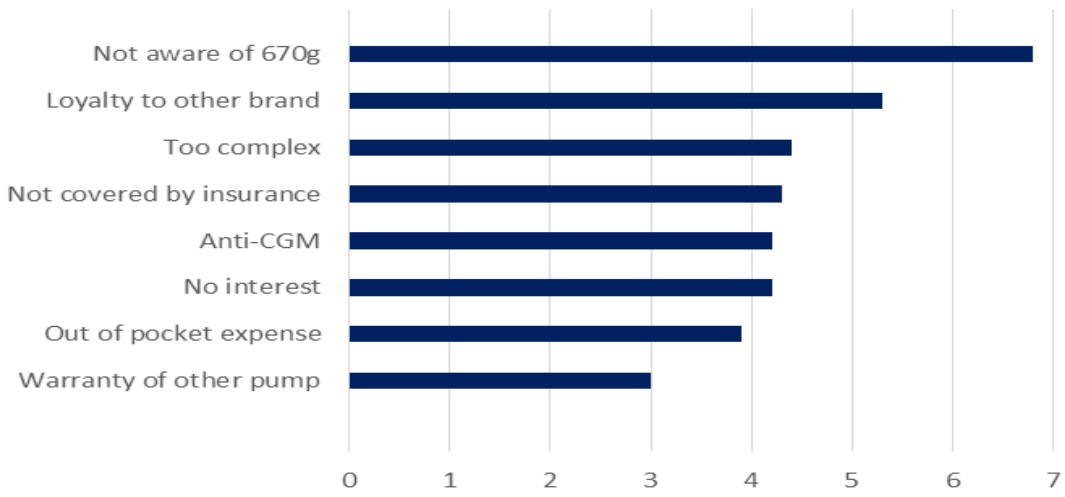


Source: US Food and Drug Administration (2018)

Technological Problems. One of the key reasons that CGM are gaining market share from SMBG is their superior technology that enables better tracking of blood glucose levels. In turn, this enables patients to better control their HbA1c levels (Sierra et al., 2017). If future generations of CGM devices are found to have technical flaws are become too complicated for users to operate, one of their main drivers for better penetration will be undermined. The figure below shows, with the exception of financial barriers, the two main causes for people not using an integrated system are lack of interest in CGM or even being "anti-CGM". Any technical issues will aggravate this existing barrier to uptake.

In particular, if there are issues with the approval/ rollout of the artificial pancreas when that time comes, it could undermine faith in the new technology. The result of this would be to substantially undermine one the markets most important growth drivers going forward. In turn, a failed artificial pancreas rollout would undermine the ability of the CGM producers to gain increased penetration into the type 2 market.

Exhibit 27: Reasons for Not Trying Medtronic's Integrated Closed Loop System
(1 = Most Important)

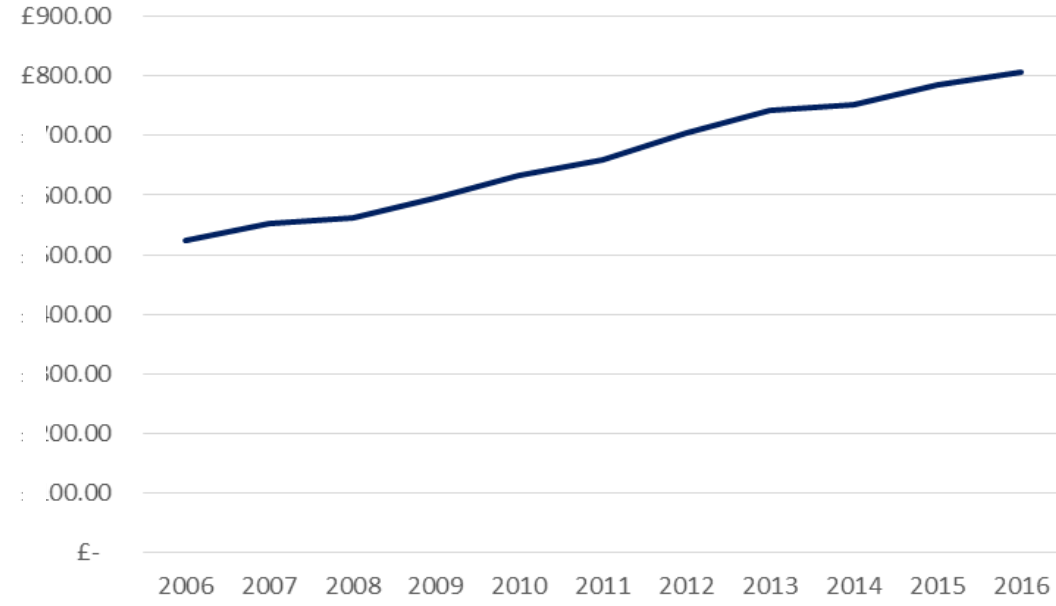


Source: BMO Capital Markets Survey (2018)

Coverage Policies. As earlier identified, patients' coverage is either through private insurance or through Medicare part B. We have identified Medicare part B coverage as a key reason for the increased penetration of CGMs and a reason for why this trend should continue. However, since CGMs became covered in 2017 for those with type 1 diabetes or type 2 insulin intensive, there have been issues with Medicare complying with the new coverage policies. Issues have centred around the coverage of strip tests that are needed to calibrate most CGMs, which are necessary to the performance of CGMs but Medicare are refusing to cover. This has lead to lawsuits being brought against the US department of Health and Human Services. If further legal issues arise or HHS change their stance on CGM coverage, the ability of those who are reliant on Medicare to partake in the CGM market will be diminished and CGM penetration may fall.

With regards to private insurers, the story is positive with more than 98% providing CGM coverage. However trends towards increasing deductibles have meant that total cost sharing for those with private insurance has increased steadily. This will feed through to higher out of pocket expenses for those using CGMs. If out-of-pocket costs of CGMs for those with private insurance rise substantially the attractiveness of CGMs relative to SMBG may be insufficient to inventiveness consumers from making the switch or retaining their current CGM treatment.

Exhibit 28: Total Cost Sharing for US Privately Insured Customers



Source: Peterson-Kaiser Health System Tracker (2016)

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