ORIGINAL ARTICLE

Continuous Glucose Monitoring and Global Reimbursement: An Update

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Abstract

Real-time continuous glucose monitoring has been available for a decade and reimbursement for the technology has been slowly growing. Reasons for the various rates of reimbursement and adoption are explored in this article and the status of country-wide reimbursement is discussed.

Keywords: Continuous glucose monitoring, Reimbursement, Cost-effectiveness analysis.

Introduction

PERSONAL USE CONTINUOUS glucose monitoring (CGM), also called real-time CGM (RT-CGM), has been demonstrated to reduce hyperglycemia and hypoglycemia by providing patients with real-time actionable information about their current blood glucose levels, the rate and direction of glucose changes, and alerts/alarms when blood glucose values exceed or fall below specified thresholds.¹ Randomized controlled trials (RCTs) have shown that RT-CGM significantly lowers HbA1c without increasing the risk of hypoglycemia in patients with type 1 diabetes mellitus (T1DM) and that efficacy is correlated with frequency of CGM use.^{2–4} Guidelines and position statements support the use of RT-CGM in patients with T1DM and in selected patients with type 2 diabetes (T2DM),^{5–9} and many experts believe that CGM will eventually replace traditional self-monitoring of blood glucose (SMBG) in intensively managed patients.

Although RT-CGM has been available for more than a decade, and the evidence base for its clinical efficacy has grown, adoption has been relatively low, particularly outside the United States, and coverage by global reimbursement authorities has been limited.¹¹ Barriers to more widespread reimbursement of RT-CGM include (1) lack of independent, robust, randomized clinical trials demonstrating *both* improved outcomes for hyperglycemia and hypoglycemia in *specific patient* populations; (2) a relatively insufficient evidence base about the value of RT-CGM in patients receiving multiple daily insulin injections (MDI) versus use of RT-CGM in combination

with insulin pump therapy; and (3) limited published data on cost-effectiveness^{11,1} This article reviews the current status of reimbursement of RT-CGM in industrialized countries as well as major barriers to broader reimbursement.

Status of RT-CGM Global Coverage and Reimbursement

Table 1 summarizes the current status of RT-CGM global reimbursement.

United States

Nearly all commercial payers, covering ~200 million lives, have issued positive RT-CGM coverage determinations for patients with T1DM and about a quarter have positive coverage policies for insulin-taking type 2 diabetes patients. The government funds most of the remaining U.S. population through entitlement programs such as Medicare and Medicaid.

In early 2017, the Centers for Medicaid and Medicare Services (CMS) issued an administrative ruling (CMS 1682-R) declaring that “therapeutic” CGM will be eligible for Medicare coverage.¹² Therapeutic CGM was defined as FDA-approved CGM devices that provide information to patients that can be used to make diabetes treatment decisions without confirmatory finger-stick testing (also called finger-stick replacement or nonadjunctive use). Coverage criteria include intensively managed insulin-taking patients who perform four or more SMBG/day, are taking multiple insulin injections or using an insulin pump, and will require frequent adjustment of insulin based on the reading from the therapeutic CGM.

TABLE 1. CURRENT STATUS OF GLOBAL REAL-TIME CONTINUOUS GLUCOSE MONITORING COVERAGE AND REIMBURSEMENT

<i>Country</i>	<i>Funding model</i>	<i>Payer</i>	<i>Coverage/reimbursement of RT-CGM</i>
United States	Employers	Commercial	Yes for T1DM and some for insulin-requiring T2DM
United Kingdom	Government National taxes	Medicare National Health Service	Yes for “therapeutic CGM” Limited coverage for sensor-augmented pump through NICE recommendation; regional clinical commission groups for standalone RT-CGM.
Sweden	Social system funded from contributions by employees	Tenders; regional	Yes; coverage available through regions; not on the national approved list
Norway	Social system funded from contributions by employees	Tenders; regional	Yes; coverage available through regions; not on the national approved list
France	Social system funded from contributions by employees	HAS; national	Positive health technology assessment; no reimbursement in place yet for RT CGM
Germany	Social system funded from contributions by employees	G-BA; national	RT-CGM for T1DM and T2DM
Switzerland	Private insurance	National	Yes
Italy	National taxes	Provincial (Regional)	Full reimbursement in Piemonte and Basilicata; individual case determinations elsewhere
Spain	National taxes	Provincial	No
Belgium	Social system funded from contributions by employees	Regional	Partial funding through hospital DRG (Care Pathways)
Slovenia	National taxes	National	Yes; pediatrics only
The Netherlands	Social system and private insurance	National	RT-CGM available through hospital DRG systems
Czech Republic	National taxes	National; patient capitation	Partial reimbursement for receivers and transmitters; patient copay
Slovakia	National taxes	National	Limited to pediatrics; patient co-pay
South Africa	Private insurance	Individual funding request—funded from patients’ savings insurance plan	Reimbursed up to savings limit; patient co-pay
Israel	Universal medical insurance plans	Regional	Yes; fully funded for pediatrics

DRG, diagnosis-related group; GBA, Gemeinsamer Bundesausschuss (Federal Joint Committee); HAS, Haute Autorité de Santé (French National Authority for Health); NICE, National Institute for Health and Care Excellence; RT-CGM, real-time continuous glucose monitoring.

To receive commercial coverage for RT-CGM, policies typically require some type of “certificate of medical necessity” from the treating clinician stating the patient has poorly controlled diabetes (e.g., HbA1c more than target level, history of recurrent and/or severe hypoglycemia, and history of diabetic ketoacidosis) despite receiving best practices treatment. Some commercial coverage policies do not require this certificate and the clinician may simply write a prescription to initiate RT-CGM.

Examples of RT-CGM coverage policies by two large U.S. commercial payers, which are largely representative of commercial payers’ stance toward RT-CGM, are summarized hereunder. The Blue Cross Blue Shield Federal Employees Health Plan, which covers 4,300,000 federal employees and dependents, considers RT-CGM to be medically necessary when the following situations occur despite use of best practices:

1. patients with T1DM have recurrent, unexplained, severe (generally blood glucose levels less than 50 mg/dL) hypoglycemia that puts the patient or others at risk; or

2. pregnant patients have poorly controlled T1DM, which includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis.

Aetna, a large commercial payer with ~20 million members, covers RT-CGM when medically necessary in adults aged 25 years and older with T1DM and in younger persons with T1DM who have had recurrent episodes of severe hypoglycemia despite appropriate modifications to their insulin regimen and compliance with self-monitoring of blood glucose (at least 4 finger-sticks/day).

Reimbursement Outside of the United States

Canada

Some private payers in Canada have reimbursement policies for RT-CGM, but most health services provided in Canada are funded by the government and decisions regarding

reimbursement of RT-CGM are made by individual provincial health authorities. Ontario is the largest province in Canada and has a well-defined health technology assessment program, the Ontario Health Technology Advisory Committee (OHTAC), which often serves as the bellwether for other provinces. In 2011, an OHTAC evaluation of RT-CGM concluded that there was no compelling data to support reimbursement.¹³ In 2017, the OHTAC began a new evaluation of RT-CGM that presumably will include more recently published clinical and cost-effectiveness studies; the final decision regarding reimbursement of RT-CGM is expected in late 2017.

Australia

Government funding through the National Diabetes Services Scheme for RT-CGM (which is limited to devices that have real-time alerts and alarms) began in early 2017 and will initially focus on the pediatric population (<21 years) who meet age-specific criteria. This reimbursement coverage decision was due in large part to the efforts by patient and professional advocacy organizations in Australia.

Europe

In Europe, gaining approval for commercialization of medical devices (Conformité Européenne [CE] mark) is typically a faster process than in the United States. As a result, medical device manufacturers often will launch a new product in the European Union (EU) before commercialization in the United States. However, approval by a regulatory agency does not guarantee that a product will be widely accessible in the market; rather, broad reimbursement by a national or third party payer is needed to provide access. The average time between EU product approval and broad country-level reimbursement ranges from 1 to 6 years. Because most countries in the EU have publicly financed healthcare systems, with each country making its own decisions about reimbursement, criteria vary considerably across member nations. Efforts are underway by European medical technology organizations to standardize requirements for health technology assessments, but harmonization of requirements is not expected soon.

Unlike U.S. payers, which primarily focus on clinical effectiveness in decisions regarding coverage, the EU payers often consider both clinical evidence and economic impact when evaluating products for reimbursement. Generating high-quality evidence to support reimbursement of new medical devices poses challenges because of relatively rapid technological innovation and short product lifecycles. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) has a defined medical technology appraisal process; NICE assessments are used by the National Healthcare Service to inform funding priorities. NICE clinical guidelines (NG17 and NG18)⁹ provide guidance for RT-CGM use in subsets of adults and children who present with clinical criteria, such as impaired awareness of hypoglycemia, extreme fear of hypoglycemia, or hyperglycemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite conducting finger-stick tests at least 10 times per day. In 2015, NICE issued a diagnostic guidance document (DG21) for sensor-augmented pump therapy, which includes T1DM patients who have episodes of disabling hypoglycemia de-

spite optimal management with continuous subcutaneous insulin infusion.¹⁰

In Germany, the determination for coverage is driven primarily by the clinical evidence. The Institute for Quality and Efficiency in Health Care is an independent scientific institute that may only accept commissions from the Federal Ministry of Health or Federal Joint Committee (G-BA), which is the highest decision-making body of the self-government of physicians, dentists, hospitals, and health insurance funds in German Health Care. The G-BA decides which medical services will be reimbursed by the statutory health insurance funds. In 2016, the G-BA announced RT-CGM will be reimbursed for insulin-dependent type 1 and type 2 patients.

Other countries have various reimbursement assessment criteria, but fundamentally focus on RCTs, economic modeling, and real-world evidence. Some EU countries are considering “coverage with evidence determination” as well as “performance-based risk sharing agreements” for new pharmaceuticals and perhaps for medical devices.

Barriers to Reimbursement of RT-CGM

Evidence for reducing hypoglycemia events

Clinical evidence from RCTs supports the efficacy of RT-CGM for reducing HbA1c in both well-controlled and poorly controlled T1DM patients without increasing the risk for hypoglycemia.^{14–26} The primary goal of most clinical studies of RT-CGM conducted to date has been to demonstrate that the technology significantly reduces HbA1c even though these devices also should decrease the risk of hypoglycemia, which is a major barrier to patients achieving glycemic targets.²⁷ Although several studies have shown that use of RT-CGM significantly reduces time spent in hypoglycemia in T1DM patients,^{14,16,28} initial RCTs evaluating RT-CGM were not designed or adequately powered to determine the efficacy of RT-CGM for reducing the frequency of hypoglycemic events in general and severe hypoglycemic events in particular. Patients at high risk for severe hypoglycemia (those with a history of severe hypoglycemia or hypoglycemia unawareness) were purposely excluded from the trials and the study sample sizes were not large enough to compare the incidence of severe hypoglycemia, which is a relatively infrequent event.

For some reimbursement authorities, reducing the frequency of hypoglycemic events is a key outcome for determining the clinical value of RT-CGM. A recently published randomized, open-label crossover design study examined the effects of RT-CGM on time spent in normoglycemia (70–180 mg/dL; primary end point) and incidence of severe hypoglycemia (requiring third party assistance; secondary end point) in patients with T1DM and impaired awareness of hypoglycemia in The Netherlands.²⁹ Patients spent significantly more time in normoglycemia (65% vs. 55.4%, $P < 0.0001$) and had significantly fewer severe hypoglycemic events (14 events vs. 34 events, $P = 0.033$) when using RT-CGM than when self-monitoring blood glucose. These findings indicate that RT-CGM can reduce the incidence of severe hypoglycemic events in a high-risk population. Large clinical trials involving patients with a wide range of risk for hypoglycemia are needed to address the question of whether

TABLE 2. SUMMARY OF COST-EFFECTIVENESS STUDIES OF REAL-TIME CONTINUOUS GLUCOSE MONITORING

Study	Country	Perspective	Model type	Interventions	Population	Time Horizon	ICER	Funding
Huang et al. ³⁴	United States	Societal	Markov	RT-CGM (pump and stand-alone) vs. SMBG	Age ≥25 years with HbA1c ≥7%	Lifetime	\$98,679 per QALY	JDRF
McQueen et al. ³⁷	United States	Societal	Markov	RT-CGM (pump and stand-alone) vs. SMBG	Adults with HbA1c ≥7% and ≤10%; mean HbA1c of 7.6%	33 Years	\$45,033 per QALY	No funding
Riemsma et al. ³⁸	United Kingdom	UK NHS (no indirect costs included)	Markov	MiniMed Veo system vs. MDI + SMBG	Mean age of 41.6 years and HbA1c of 7.26%	Lifetime	Base case: MiniMed Veo system vs. MDIs + SMBG: €123,375	NHS
				MiniMed Veo system vs. CSII + SMBG			MiniMed Veo system vs. CSII + SMBG: €730,501	
				MiniMed Veo system vs. CSII + CGM			MiniMed Veo system vs. CSII + CGM: €422,849	
				Integrated CSII + CGM (Vibe) vs. MDIs + SMBG			Integrated CSII +CGM (Vibe) vs. MDIs + SMBG: €133,323	
				Integrated CSII + CGM (Vibe) vs. CSII + SMBG			Integrated CSII +CGM (Vibe) vs. CSII + SMBG: €668,789	
				Integrated CSII +CGM (Vibe) vs. CSII + CGM			Integrated CSII + CGM (Vibe) vs. CSII + CGM: Dominated	
Kamble et al. ³⁵	United States	Payer	Markov	SAP vs. MDIs	Adults with HbA1c > 8.3%	60 Years	\$229,675/QALY (3-day sensors); \$168,104/QALY (6-day sensors)	Medtronic
Ly et al. ³⁶	Australia	Payer	Decision analytic model	SAP + LGS vs. CSII	Age ≥12 years with hypoglycemia unawareness	6 Months	\$14,884 per severe hypoglycemic event avoided; \$42,503 per QALY	Medtronic
Roze et al. ³⁹	Sweden	Societal	Markov	SAP vs. CSII	Age 27 years with HbA1c of 8.6%	Lifetime	\$54,698/QALY	Medtronic
Roze et al. ⁴¹	United Kingdom	UK NHS (indirect costs not included)	Markov	SAP + LGS vs. CSII + SMBG	Age 27 years with HbA1c of 8.6%	Lifetime	£12,233 per QALY	Medtronic
Roze et al. ⁴⁰	France	Payer	Markov	SAP + LGS vs. CSII + SMBG	Two cohorts: (1) Uncontrolled HbA1c at baseline: mean age 36 years with HbA1c of 9% (2) Elevated risk for hypoglycemic events: mean age 18.6 years with HbA1c of 7.5%	Lifetime	Uncontrolled HbA1c at baseline cohort: €30,163 per QALY	Medtronic

CSII, continuous subcutaneous insulin infusion; ICER, incremental cost-effectiveness ratio; JDRF, Juvenile Diabetes Research Foundation; LGS, low glucose suspend; MDI, multiple daily injections of insulin; NHS, National Health Service; QALY, quality-adjusted life year; SAP, sensor-augmented insulin pump.

the technology can reduce the incidence of severe hypoglycemic events in nonselected patients.

Value of RT-CGM in patients using MDI

Until recently, the preponderance of RT-CGM research has involved intensively managed insulin-treated patients receiving insulin pump therapy in combination with RT-CGM (sensor-augmented pump therapy). However, rates of insulin pump use among patients with T1DM vary internationally, ranging from <10% in some European countries to up to 38% of patients in select populations in the United States,^{30,31} with the majority of patients often treated with multiple daily injections (MDI). Because studies of sensor-augmented pump therapy are unable to determine the independent contributions of the technology components, it is increasingly important to evaluate the contribution of RT-CGM as a standalone intervention in patients receiving MDI, as has been done in several recently published RCTs.^{16,22} These studies show that standalone RT-CGM is significantly more effective than conventional blood glucose monitoring in patients with T1DM treated with MDI, reducing HbA1c by -0.43% to -0.60%. In addition, a prospective, nonrandomized, real-life clinical trial demonstrated that RT-CGM combined with either insulin pump therapy or MDI provided a comparable and significant reduction in HbA1c in comparison with the combination of insulin pump therapy/MDI and self-monitoring of blood glucose.³²

Cost and Evidence of Cost-Effectiveness

Cost-effectiveness analyses (CEAs), including cost-utility analysis, are integral components of reimbursement considerations in many countries outside of the United States. Budget impact analysis (BIA) is often also required both in and outside of the United States. When conducting a BIA of RT-CGM, it is important to consider costs that may result from failure to give patients access to RT-CGM, including the risk for short-term morbidity and mortality, costs of emergency treatment for severe hypoglycemic episodes (ambulance/EMS services, emergency department visits, and hospital admissions), and costs of long-term complications associated with poorly controlled diabetes.

CEAs and cost-utility analyses are important to capture the potential cost offsets of RT-CGM associated with reducing the risk of long-term diabetes complications, which may not develop until decades after diagnosis. CEA models depend on robust clinical data and, therefore, may not be completed and published until years after a new technology has been evaluated in clinical trials and commercialized. Because RT-CGM technology is developing at a rapid rate (with new versions of RT-CGM showing improvements in accuracy and usability), CEAs may be obsolete by the time clinical data for new devices are published.³³ In the past decade, eight publications have examined the cost-effectiveness of the RT-CGM in patients with T1DM (Table 2).³⁴⁻⁴¹ The results of these studies are presented in terms of cost per quality-adjusted life year (QALY) or cost per hypoglycemic event avoided. Results are wide ranging, possibly because of differences in assumptions that form the basis of the models. It is important to note that these CEAs have only considered the costs associated with long-term diabetes complications because there has been little evidence that RT-CGM signifi-

cantly impacts hypoglycemia, which is associated with both short- and long-term costs.

The results from CEA models of RT-CGM may not be compelling to payers for several reasons. First, most studies estimated the value of RT-CGM over a long time horizon (e.g., the patient's lifetime) even though the average retention of a U.S. commercial health plan member is typically a few years, and U.S. payers traditionally focus on 1-3-year periods corresponding to their budget and contracting cycles.⁴² Second, almost all economic models of RT-CGM are complex Markov models, which payers may not find credible because of the use of many assumptions or lack of transparency.⁴³ Third, most studies reported the economic value of RT-CGM in terms of cost per QALY gained, which may have limited relevance, meaningfulness, validity, and reliability to all payers.⁴⁴ Fourth, models based on a societal perspective (which include both direct and indirect costs) may not be relevant to payers who are exclusively concerned with direct costs. Thus, CEAs of RT-CGM must be adapted so they are relevant to individual payers and countries that often have different priorities and willingness-to-pay thresholds.

It is important to note that only two of the eight published CEAs evaluated standalone RT-CGM,^{34,37} whereas others evaluated sensor-augmented pump therapy^{35,36,38-41}; the CEA performed by Huang et al. was based on outcomes from the Juvenile Diabetes Research Foundation trial, in which intervention group patients could have received either sensor-augmented insulin pump therapy or MDIs plus RT-CGM.

Difficulty understanding these CEAs may be because of several reasons. First, these analyses have been based on research that has not differentiated between methods of insulin delivery or types of RT-CGM devices. Second, the clinical data used for modeling may not be representative of results achieved in real-life settings. Lastly, patients' trust in the accuracy of their RT-CGM device may affect adherence and also prompt patients to become less reactive (reacting to alerts and alarms) and more proactive (using the data to anticipate glucose changes and respond early and aggressively) in managing their diabetes.⁴⁵ There is ample evidence that the efficacy of RT-CGM is well correlated with adherence.^{18,20,21,23,28,46-51} Thus, it is reasonable to posit that more accurate RT-CGM devices could result in better efficacy. Because CEAs incorporated into health technology assessments typically include the entire category (i.e., all RT-CGM devices), these analyses may not reflect differences in outcomes related to device performance and patient compliance.

Conclusion

RT-CGM is becoming a standard of care for insulin-requiring patients in the United States, and is gaining greater acceptance in other industrialized nations. Access to RT-CGM is expected to grow as more CEAs are combined with clinical evidence in select patient populations. Considerations for reimbursement should include RT-CGM used as a standalone device or as part of a sensor-augmented pump system, as well as when used as a necessary component of any artificial pancreas or closed loop system.

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