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COMMENTARY

# Reimbursement for Continuous Glucose Monitoring: A European View

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## Abstract

Different systems for continuous glucose monitoring (CGM) are available on the European market. There is no unlimited reimbursement for CGM use in any European country, but in some countries, reimbursement exists for certain clinical indications. The aim of this commentary is to describe the different reimbursement situations across Europe for this innovative but costly technology, as a prelude to establishing more uniform use. From the perspective of many scientists and clinicians, a number of randomized controlled trials have demonstrated the efficacy of real-time CGM versus self-monitoring of blood glucose, at least for hemoglobin A1c reduction. Nevertheless, according to many health care professionals and potential CGM users, national health services and health insurance organizations are reluctant to reimburse CGM. Imminent technological and manufacturing developments are expected to reduce the day-to-day costs of CGM.

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## Introduction

When the first system for continuous glucose monitoring (CGM) came on the market, an old dream came true for diabetes patients and diabetologists. The hope was that CGM would be supportive in reducing the daily variations in glycemia in people with diabetes and thereby also prevent hypoglycemia and hyperglycemia. In this sense, CGM does not simply represent a different type of self-monitoring of blood glucose (SMBG); this technique opens up totally new perspectives for the self-management of diabetes and paves the way for an artificial pancreas.

As so, one would expect that, 10 years after launch, CGM systems would represent the standard in diabetes therapy, with costs being fully reimbursed by health insurance systems. This is certainly not the case, and it is important to discuss the reasons for the slow acceptance. Clearly, first generations of CGM devices had a number

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**Abbreviations:** (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (GBA) Gemeinsamer Bundesausschuss, (HAS) Higher Health Authority, (HbA1c) hemoglobin A1c, (IQWiG) Institute for Quality and Efficiency in Health Care, (MoH) Ministry of Health, (NICE) National Institute for Health and Clinical Excellence, (SAP) sensor-augmented pump, (SMBG) self-monitoring of blood glucose

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of technical shortcomings, and current CGM systems also have a number of drawbacks and limitations:

- Sensors have to be replaced after a few days,
- There is a need to insert the sensor through the skin into the subcutaneous adipose tissue,
- Accuracy of the sensor measurement is not always optimal, and
- There is a need for initial calibration with a SMBG sample and for frequent recalibrations.

Having considered some key general aspects of CGM reimbursement, the aim of this article is to provide company-independent detailed insight on the reimbursement situation in nine different European countries. Little has been published about this topic and we hope to stimulate debate on unifying reimbursement policies.

## Cost of Continuous Glucose Monitoring

Assuming that the daily costs for CGM use are approximately 5–10 € per day, this would amount to €3000 per year per patient. Being conservative and assuming that there might be 1 million potential users with type 1 diabetes in Europe, this would total approximately €3 billion each year. This number quickly explains the reluctance of health insurance companies to promote widespread use of such a cost driver which, from their point of view, has no clear or unique benefit to warrant such an investment: CGM is not a lifesaving intervention. Many patients with diabetes survive relatively well with SMBG alone or even without any regular monitoring of their daily blood glucose excursions. On the other hand, a huge proportion of patients with diabetes do not achieve satisfactory glycemic control, which enhances the risk of developing diabetes-related late complications. The use of CGM might be of help in this respect.

Manufacturers claim that the considerable costs of CGM systems are due not only to a sizeable investment in the lengthy development and approval process, but also to the elaborate production process of the systems themselves (in particular, the actual sensors), a substantial part of which is still performed manually. Once automated production becomes possible, we hope that the cost per sensor will fall significantly. Perhaps other innovative CGM systems will come to the market with improved accuracy and manufacturing processes that will lower the costs of CGM systems.

Use of CGM requires time by health care professionals to train patients as well as to see the patients afterward for repeated visits to the diabetes outpatient centers for interpretation of the CGM profiles. The costs of this time must be added to the cost of CGM systems.

## Cost-Benefit Analysis of Continuous Glucose Monitoring Systems

There are emergent cost-benefit analysis data on CGM systems, indicating cost-effectiveness relative to SMBG.[1,2] In these analyses, the authors use health economic models and assumptions to investigate whether the use of CGM systems optimizes glycemic control to such an extent that the reduction in the cost of treating diabetes-related complications outweighs the cost of using the CGM systems or even makes their use cost saving. Usually, quality-adjusted life years gained and the corresponding incremental cost-effectiveness ratio are calculated to provide evidence for cost-effectiveness.

## European Perspective

Following are brief descriptions of the reimbursement status in some representative European countries.

### *France*

There is no reimbursement for CGM in France. Sensors are financed through hospital budgets (mainly for inpatients). France has a two-tier system—the Higher Health Authority (HAS) determines the case for reimbursement. Then, if acceptable, the Ministry of Health (MoH) proposes a price. The Guardian (Medtronic) and Navigator (Abbott) were submitted but were declined because of "only moderate improvement in patient care." Dexcom has not applied. Medtronic has applied for "Veo plus CGM," but there is still a question of efficacy compared with pump alone. The HAS requested a large clinical trial focused on hemoglobin A1c (HbA1c) and hypoglycemia, which should also provide additional economic data, to validate the case. An application for temporary reimbursement for the Medtronic trial was approved by the MoH in January 2012. The design of this study is still pending. Final reimbursement will depend on its results.

### *Germany*

When CGM systems were brought to the market in Germany, the manufacturer tried to get them listed—in the same way as blood glucose meters—in the so-called resource catalog. Devices that are listed in this catalog can be prescribed and are reimbursed. However, there are strict guidelines regarding the price, and—because

there is a fixed reimbursement budget available for all devices used—manufacturers of other types of devices objected to the listing of CGM systems in the resource catalog.

Insurance companies regard CGM as a "new diagnostic and therapeutic method," but this has yet to be approved. To obtain approval, the method must meet very high standards; it must represent a true medical innovation. There is no general reimbursement for therapeutic use of CGM in Germany. However, in single cases, the Medical Service of the Health Insurance supported cost coverage by a given health insurance company if the need in the individual case was well documented. Thus, the quality of such applications is crucial to its success. The patient and his doctor (or diabetes nurse) have to document very clearly and in detail how CGM use helps improve certain parameters in this individual patient. The "working group for diabetes technology" (Arbeitsgemeinschaft diabetogische Technologie) of the German Diabetes Association has published a consensus paper on CGM use[3] that summarizes all published studies and provides a list of indications for use of CGM.

Health insurance companies have applied for a cost-benefit assessment by the Federal Joint Committee [Gemeinsamer Bundesausschuss (GBA)]. The GBA has accepted this order and asked the Institute for Quality and Efficiency in Health Care (IQWiG) to make a critical analysis of all available studies with CGM systems (focused on randomized controlled trials). It could easily take 3–5 years for the IQWiG review process, the subsequent assessment by the GBA, plus the decision by the MoH to be completed. If the GBA rejects reimbursement of CGM systems, no insurance company can reimburse CGM. However, by establishing a round table in Germany, we hope that better communication can be established among all parties involved. This might also be of help in arranging an agreement that allows reimbursement, without too much bureaucracy, for certain patients that fulfill strict criteria.

### *Israel*

Reimbursement for CGM in Israel is relatively broad. Reimbursement indications include children (aged 0 to 8 years) with type 1 diabetes who face difficulties in achieving glucose control and who have suffered from reoccurring episodes of low glucose levels [<3.9 mmol/liter (70 mg/dl)] more than four times per week recorded by a glucometer during at least 2 weeks (not necessarily consecutive) in the period 6 months prior to the request, children aged 8–18 years who have suffered two recorded hypoglycemia events of significant clinical importance (<2.8 mmol/liter [50 mg/dl]), and women planning pregnancy with poor glycemic control receive CGM before and during pregnancy for a total duration of up to 18 months. Adults with type 1 diabetes and hypoglycemia unawareness have been included in coverage, although unawareness has not been fully defined. The need to document two episodes of severe hypoglycemia by emergency services or emergency room visits is mentioned in a release by the health ministry's chief executive officer. All patients will need a documented recommendation of a specialist in diabetology.

### *The Netherlands*

Reimbursement for CGM in the Netherlands is limited to three groups: adults with HbA1c >64 mmol/mol (>8%) despite intensive efforts to lower HbA1c, pregnant women with diabetes (type 1 and type 2), and children. In 2010, the Dutch Diabetes Federation made a positive and detailed assessment of CGM and proposed a wide range of indications. In November 2010, the Health Care Insurance Board approved reimbursement as part of the basic health insurance for these three groups. Approximately 50% of hospitals were selected as a "CGM center" that would distribute CGM and receive reimbursement. Approximately 50% of these CGM centers have now started. The negotiated price assumes sensor use 75% of the time by a given patient. Some issues still need to be addressed, such as, patients with hypoglycemia unawareness who could benefit from CGM but have no reimbursement, and whether there is a basis for continuous CGM use in pregnant women.

### *Slovenia*

There is a relatively positive situation in Slovenia. The country's small size (population 2,050,189) allows for a well-managed and publicly funded centralized medical system. Diabetes products are generally covered with the following indications for CGM: full reimbursement in patients <8 years old to protect against damage to the developing brain, pregnancy (type 1 and type 2 diabetes on intensive insulin treatment), and patients with severe hypoglycemia or hypoglycemia unawareness (limited to 40 sensors and 1 transmitter per year per person). The approving authorities had accepted diabetes as a dangerous disease early on, greatly facilitating discussions. Despite this wider imbursement, neither Abbott nor Dexcom have applied for approval.

### *Spain*

The Spanish National Health Service provides universal coverage with free access to health care and is publicly funded—mainly through taxation. The central government provides financial support to each region based on population and demographic criteria. Regions can decide to add extra services, technologies or procedures to their own regional health care basket. In addition, private health care financing also exists in Spain, representing 23.7% of the budget spent in 2003. Out of the yearly fixed global budget, the hospital must allocate budget to medical devices, technologies, procedures, and services included in the National Catalogue of Services. Under these conditions, as an example, continuous subcutaneous insulin infusion (CSII) was first included in the National Catalogue of Services relatively late in 2004. This explains why currently less than 5% of type 1 diabetes patients in Spain use insulin pumps.

Regarding CGM, there is no national agreement on financial support for CGM. The Working Group of New Technologies of the Spanish Diabetes Society developed new guidelines and recommendations for the use of CGM in 2009 (also available in English at www.sediabetes.org). In this document, a list of clinical and experimental situations in which CGM may have special interest was summarized. In addition, in 2011 the Agency for Health Information, Evaluation, and Quality of Cataluña in Spain evaluated the available clinical evidence on the efficacy and safety of real-time CGM systems.[4] In this meta-analysis, real-time CGM was considered helpful compared with SMBG in a mixed population of adult and pediatric patients with poor metabolic control. The document underlined that real-time CGM is only a tool, for which success depends on the motivation of patients in using this technology. Despite the favorable national documents supporting a more widespread use of CGM, there is still no national agreement for financial support of CGM technology. Only a limited use of CGM systems is allowed for diagnostic or investigational purposes in some advanced diabetes centers, mainly located in tertiary hospitals. There are some exceptions to this general rule. In some regions such as the Comunidad Valenciana, Cataluña, Extremadura, or Castilla-La Mancha, new pump users of Medtronic devices are occasionally allowed to start with a sensor-augmented pump (SAP). Additionally, for patients belonging to the Mutualidad General de Funcionarios Civiles del Estado, a special group of state official employees, who have type 1 diabetes and in which pump therapy has been recommended, a SAP has also been authorized in some cases. In summary, SAP therapy is still an exception in Spain and is not listed in the portfolio services of the National Health System.

### *Sweden*

The situation in Sweden is uncertain. In general, to obtain coverage, manufacturers must submit an application to the national reimbursement agency, which evaluates treatments based on efficacy, cost-effectiveness, and a cost comparison with current products. In September 2009, following a Medtronic submission, the agency agreed to cover CGM only for pump patients with strict indications: patients must have a HbA1c >86 mmol/mol (>10%) or evidence of two or more severe hypoglycemic events/year. Children testing >10 times/day are also covered, though, in all cases, coverage is rescinded if the desired effect (especially in terms of compliance) is not achieved after 3 months of therapy. As the submission in Sweden is branded and product specific, this does not cover Abbott and Dexcom devices.

Medical professionals lobbied for broader indications, but instead, the agency withdrew reimbursement altogether in June 2011. This decision was not based on the agency changing their view on the clinical efficacy of CGM but on their reasoning that the national reimbursement act does not apply to electronic devices. This supposition was contradicted by a Swedish court ruling in December 2011. The court ruling has been appealed by the agency, and while awaiting the final decision, CGM is still reimbursed according to the original indications. If the national reimbursement policy is eventually changed, then CGM (and other electronic devices) will probably be subsidized at the regional, county level.

### *Switzerland*

Reimbursement is available under certain criteria: patients with type 1 diabetes using a pump and with HbA1c ≥64 mmol/mol (≥8%) and/or frequent potentially life-threatening hypoglycemia and/or brittle diabetes with emergency room visits or hospitalization. Continuous glucose monitoring use must be reevaluated after 6 months, and long-term use must be approved by the health insurance provider. Continuous glucose monitoring can be prescribed only by a board-certified endocrinologist with training in CGM. In addition, sensor reimbursement applies only to diagnostic CGM and consultation time. Currently, there are only Medtronic sensors on the market.

### *United Kingdom*

In the United Kingdom, uptake of CGM use is low, with approximately 5–7% of CSII patients in large pump clinics

using CGM, but overall frequency is much less. Of those using CGM, approximately 85% are funded publicly by the National Health Service, with 10% self-funded and 5% funded by other sources such as donations and charities. To obtain National Health Service funding, physicians apply on a case-by-case basis to local budget-holding and commissioning organizations called primary care trusts, usually after a successful 2 to 3 month trial funded by the patient's hospital. Continuous glucose monitoring use is considered nonstandard; there are no dedicated guidelines on CGM use from the National Institute for Health and Clinical Excellence (NICE) as there are for CSII. Brief advice from the NICE on CGM is given in a guidance on treatment of type 1 diabetes and is somewhat confusing, limiting use to children with persistent glycemic variability or hypoglycemia unawareness and suggesting only diagnostic use in adults. While the NICE guidance is scheduled to be updated, with CGM specifically tagged for review, the system as a whole could also be in flux. Highly controversial proposals to abolish primary care trusts and reframe the role of the NICE (from a prescriptive to more of an advisory body) are being considered.

## Summary

Apparently, an innovative technology intended to benefit a large group of patients with diabetes is not widely reimbursed in Europe. Most probably, the health care systems in Europe will not be able to reimburse the cost of CGM without restriction; however, we should be able to convince reimbursement parties that the positive effects of CGM are convincing enough to justify the "investment" in certain patient groups. There might still be a need to perform a CGM study in Europe focusing on other patient groups that most probably will benefit the most from CGM; the proposal is to perform such a study in patients with a known history of severe hypoglycemic events (The EU-Glycaemia Study).

**Disclosures:**

Lutz Heinemann advises device companies like Roche Diagnostics and Sanofi in the development of new diagnostic approaches to diabetes therapy. He is a shareholder and consultant at Profil Institute for Metabolic Research, Neuss, Profil Institute for Clinical Research, San Diego, CA. He is head of the Arbeitsgemeinschaft diabetogische Technologie.

Javier Ampudia Blasco has received honoraria as speaker and/or consultant from Abbott, AstraZeneca, Bristol-Myers Squibb, Glaxo-SmithKline, LifeScan, Lilly, Madaus, MannKind Corp., Medtronic, Menarini, Merch Farma y Química, SA, MSD, Novartis, Novo Nordisk, Pfizer, Roche, sanofi-aventis, Schering-Plough, and Solvay. In addition, Javier Ampudia Blasco has participated in clinical trials supported totally or partially by AstraZeneca, Glaxo-SmithKline, LifeScan, Lilly, MSD, Novo Nordisk, Pfizer, sanofi-aventis and Servier.

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