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Reimbursement Pathways for New Diabetes Technologies in Europe: Top-Down Versus Bottom-Up

David Seidel, PhD[1], Francesca Boggio Mesnil, MSc[2], and Antonio Caruso, PharmD, MSc[1]

Abstract

Reimbursement by payers (policy makers and budget holders) is critical for the uptake and use of new diabetes technologies. The purpose of this article is to describe the different reimbursement pathways that exist for new diabetes technologies in five selected European countries using examples of recent reimbursement decisions. Countries can be grouped into one of three categories: "top-down" (where reimbursement decisions are usually made by policy makers, eg, France), "bottom-up" (where reimbursement decisions are usually made by budget holders, eg, Italy and Spain) and "mixed" (where reimbursement decisions can be made by both policy makers and budget holders, eg, Germany and England). Whatever category a specific country falls into will have different implications from a market access perspective.

Keywords

coverage, diabetes, evidence, funding, payers, reimbursement

New diabetes technologies have emerged in European countries over the last years. These include but are not limited to flash glucose monitoring (FGM), continuous glucose monitoring (CGM), and sensor-augmented pump (SAP). Stakeholders who influence the uptake and use of new diabetes technologies include patients, providers, and payers. Ideally, patients should be willing to use the technology, providers to prescribe it, and payers to pay for it. If this does not hold true for only one of the stakeholders, the technology's uptake and use can be seriously threatened. Nevertheless, it may be argued that a new diabetes technology is unlikely to reach scale without reimbursement by payers. This is certainly the case in countries where patients are usually not expected to pay out of pocket, at least for the majority of health services. By contrast, providers issue claims and submit them to payers who, in turn, cover the cost based on the taxes or insurance premiums collected from patients (privately insured patients cover the cost themselves initially and claim the money back from their insurer afterward).

Heinemann et al[1] have suggested that the high cost of new diabetes technologies such as CGM explains the reluctance of payers in Europe to promote widespread use. The purpose of this commentary article is to describe the different reimbursement pathways that exist for new diabetes technologies in five European countries: Germany, France, England, Italy, and Spain. These countries represent the largest markets for medical technologies in Europe,[2] and reimbursement pathways for new diabetes technologies are relatively heterogeneous across them.[3]

Payers

It is important to create a common understanding about who payers are and how they make decisions. Two types of payers can be distinguished—policy makers and budget holders. Policy makers can make reimbursement decisions or recommendations at the national level that are binding for the budget holders. Budget holders, on the other hand, manage a budget for a segment of the population that may or may not be geographically defined. The budget can be allocated centrally based on taxes (England, Italy, and Spain) or be collected by the budget holders through premiums (Germany and France). As can be seen in Table 1, the distinction between policy makers and budget holders exists in all five countries. It should be noted that, depending on the country,

[1]Roche Diabetes Care GmbH, Mannheim, Germany
[2]Executive Insight AG, Baar, Switzerland

Corresponding Author:
David Seidel, PhD, Roche Diabetes Care GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany.
Email: david.seidel@roche.com

Table 1. Main Policy Makers and Budget Holders in Selected European Countries and Reimbursement Pathways for New Diabetes Technologies.

Country	Main policy maker(s)	Main budget holder(s)	Reimbursement pathway
Germany	• Federal Joint Committee (GBA) • Institute for Quality and Efficiency in Health Care (IQWiG)	• Public health insurers • Private health insurers	Mixed[a]
France	• National Authority for Health (HAS) • Economic Committee for Healthcare Products (CEPS)	• Statutory health insurance	Top-down[b]
England	• National Institute for Health and Care Excellence (NICE)	• Clinical commissioning groups (CCGs)	Mixed[a]
Italy	• Ministry of Health	• Regions • Local health authorities (ASLs)	Bottom-up[c]
Spain	• Ministry of Health and Social Policy	• Autonomous communities (ACs) • Regional health services	Bottom-up[c]

[a]Reimbursement decisions can be made by both policy makers and budget holders.
[b]Reimbursement decisions are usually made by policy makers.
[c]Reimbursement decisions are usually made by budget holders.

policy makers are also sometimes referred to as national payers and budget holders as local or regional payers.

Budget holders have a responsibility to provide the necessary funding to enable the reimbursement decisions or recommendations by the policy makers; however, funding cannot always be guaranteed. In addition, in some countries, budget holders can also make reimbursement decisions on their own without any involvement of the policy maker. Therefore, which payer decides whether to pay is quite different between countries, as will be illustrated with examples of recent reimbursement decisions in the following. For this purpose, the countries in scope of this article are grouped into one of three categories: "top-down" (where reimbursement decisions are usually made by policy makers), "bottom-up" (where reimbursement decisions are usually made by budget holders), and "mixed" (where reimbursement decisions can be made by both policy makers and budget holders).

Reimbursement Pathways

Top-Down: France

The main policy maker and health technology assessment (HTA) body in France is the National Authority for Health (Haute Autorité de Santé; HAS). HAS is authorized to assess medical technologies and publish guidelines for the statutory health insurance. The statutory health insurance is the budget holder and covers almost the entire population (99%). Two important committees are the Medical Device and Health Technology Evaluation Committee (Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé; CNEDiMTS), which is part of HAS, and the Economic Committee for Healthcare Products (Comité Economique des Produits de Santé; CEPS).[4] Based on an assessment of FGM conducted by CNEDiMTS, HAS published a reimbursement recommendation in July 2016. FGM, according to the recommendation, provides added clinical benefit over the current standard of care (ie, self-monitoring of blood glucose) in patients with diabetes who use insulin more than three times per day.[5] Ten months later, in May 2017, CEPS reached an agreement with the manufacturer on the price of the technology, resulting in a reimbursement decision by the French Ministry of Health. Consequently, patients with diabetes who meet the criteria defined by HAS can get FGM prescribed by a diabetologist and have the cost reimbursed by statutory health insurance.[6]

Bottom-Up: Italy and Spain

The National Health Service in Italy (Servizio Sanitario Nazionale) consists of 19 regions and two autonomous provinces (budget holders). They are responsible for the delivery of care through a network of local health authorities (aziende sanitarie locali; ASLs) as well as public and private accredited hospitals. While the common benefits basket is defined by the Ministry of Health (policy maker), including the health services that should be provided by all regions, the regions are free to provide health services beyond this at their own expense.[7] There is a national guideline for the treatment of diabetes issued by the relevant societies,[8] but the guideline is not binding for the regions. And even though the Ministry of Health can in principle allow new diabetes technologies onto the market or exclude them from the market, it rarely uses its power for that purpose.[9] Hence, reimbursement decisions are left to each individual region, which is illustrated very well by the case of CGM: there is currently full reimbursement for CGM in two regions (Piedmont and Basilicata), whereas all other regions reimburse CGM on a case-by-case basis.[10]

Similar to Italy, the Spanish National Health Service (Sistema Nacional de la Salud) is decentralized into 17 autonomous communities (Comunidades Autónomas; ACs). The ACs together with regional health services (budget holders) have responsibility for the provision of care and contracting of health services from providers. They can complement or upgrade the common benefits basket defined by the Ministry of Health and Social Policy (policy maker).[11] To give an example, some ACs (including Catalonia, Valencia, Castilla–La Mancha, and Extremadura) reimburse SAP for certain patients with diabetes who initiate insulin pump therapy.[1]

Mixed: Germany and England

The Federal Joint Committee (Gemeinsamer Bundesausschuss; GBA) is the main policy maker in Germany together with the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG), the country's main HTA body. Supervised by the Federal Ministry of Health, the GBA is authorized to make legally binding reimbursement decisions for people covered by statutory health insurance (approximately 88% of the population), which is delivered by more than 100 public health insurers (budget holders). In addition, there are around 40 private health insurers that cover 11% of the population (budget holders).[12] In November 2012, the GBA commissioned IQWiG to perform an assessment of the available evidence for real-time CGM, which was published in March 2015.[13] More than one year later, in June 2016, the GBA made a reimbursement decision for patients with type 1 and 2 diabetes who are treated with intensive insulin therapy, and in whom therapy goals are difficult to achieve.[14] Importantly, the reimbursement is for a class of systems, that is, all approved real-time CGM systems on the market.

The National Institute for Health and Care Excellence (NICE), an executive body of the Department of Health, is the main policy maker and HTA body in the National Health Service (NHS) in England. It provides evidence-based guidance and develops quality standards for the more than 200 clinical commissioning groups (CCGs), that is, the budget holders. CCGs are clinically led organizations able to commission health services from a range of providers for local populations.[15] In 2008, NICE published a guidance that recommends insulin pump therapy for adults and children over 12 years of age with type 1 diabetes and recurrent hypoglycemia, or high HbA1c levels despite using insulin multiple times per day.[16] Although the CCGs have a responsibility to provide the funding required to enable this NICE guidance, funding cannot automatically be guaranteed.[15] In fact, a UK-wide insulin pump audit in 2012 found that almost one-fifth of CCGs have set fixed quotas for insulin pump therapy in adults.[17] In other words, patients may not be able to get an insulin pump and have the cost reimbursed by their local CCG even if they meet the criteria defined by NICE.

Budget holders in Germany and England can make reimbursement decisions on their own as well. Despite the fact that the top-down reimbursement decision for real-time CGM in Germany did not include FGM, two public health insurers started reimbursing FGM on a voluntary basis in July 2016.[18] Half a year later, in January 2017, several other public health insurers had followed and also put reimbursement policies for FGM in place.[19] Similarly in England where reimbursement decisions are ultimately made at the local level, the CCGs are free to commission new medical technologies in the absence of a positive NICE recommendation.[15]

Decision Making

Both types of payers have different perspectives: First, policy makers have more of a long-term perspective; they are interested in whether a new diabetes technology will achieve a desired outcome ("clinical effectiveness") at a reasonable price ("cost-effectiveness"). Policy makers usually ask for evidence from randomized controlled trials (RCTs) with at least validated surrogate endpoints such as HbA1c, and they often do comprehensive HTAs to systematically assess the benefits of a new technology. For example, the top-down reimbursement decision for real-time CGM in Germany was based on an assessment by IQWiG that included 13 RCTs with a total of more than 1700 patients.[13] While this assessment looked at a class of systems, some policy makers assess systems individually. In February 2016, NICE published an assessment of two SAP systems and recommended one of them as an option for patients with type 1 diabetes who have episodes of disabling hypoglycemia.[20]

Second, budget holders have more of a short-term perspective. They are also interested in clinical and cost-effectiveness; however, budget holders are mostly interested in whether a new technology can help them achieve their targets and what the financial impact on their budget is. For example, although some regions in Italy use HTA to support their reimbursement decisions as well, most regions do expect manufacturers to generate local real-world data (RWD) for new technologies with a significant budget impact, typically over a period of 1-2 years.[3] Furthermore, it should be noted that in health-insurance-based systems such as Germany budget holders are competitors and may cover a new technology simply because another budget holder is covering it (eg, to attract new customers or to retain existing ones). As a result, there are multiple factors that influence the decision making of budget holders: just like the populations that budget holders serve vary, so do their needs and priorities.

Conclusion

The three categories—top down, bottom-up, and mixed—can be used to describe the existing reimbursement pathways for new diabetes technologies in Germany, France, England, Italy, and Spain. They represent a useful classification for

Table 2. Relevant Criteria for Top-Down and Bottom-Up Reimbursement Pathways.

Criterion	Top-down reimbursement pathway	Bottom-up reimbursement pathway
Coverage	• National/large population	• Local/regional/payer-specific population
Evidence	• Usually randomized controlled trials (RCTs)	• Any type, particularly real-world data (RWD)
Timeframe	• Long	• Moderate

manufacturers when planning market access strategies in these countries and beyond. Whatever category a specific country falls into will have different implications: a top-down market access approach can give access to a national or large population in a certain country, but evidence requirements tend to be high and the process may take a long time. On the other hand, a bottom-up market access approach can give access to a local, regional, or payer-specific population—which is only a fraction of the population—yet evidence requirements tend to be lower, the process usually takes less time, and there is the possibility to scale (see Table 2). By better understanding the market access pathways of different countries, manufacturers can better anticipate the level of investment needed by country, for example, in terms of evidence generation. In addition, considerations can be made such as prioritizing market access in bottom-up (and mixed) countries with lower access barriers, followed by top-down countries.

Abbreviations

AC, autonomous community; ASL, local health authority; CCG, clinical commissioning group; CEPS, Economic Committee for Healthcare Products; CGM, continuous glucose monitoring; CNEDiMTS, Medical Device and Health Technology Evaluation Committee; FGM, flash glucose monitoring; GBA, Federal Joint Committee; HAS, National Authority for Health; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial; RWD, real-world data; SAP, sensor-augmented pump.

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