

## Diabetes Device Reimbursement in the EU-5

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### Abstract

The reimbursement landscape for new and innovative diabetes devices in Europe is very heterogeneous and nontransparent, with each country employing different mechanisms, pathways, and requirements. This article provides an overview of how diabetes device reimbursement works in the outpatient setting in the five major European Union markets (France, Germany, Italy, Spain, and the United Kingdom; the EU-5). It will be of particular interest to manufacturers of innovative devices. Markets are first categorized as either a centralized or a regionalized reimbursement decision-making system, and implications for device reimbursement are explored. In the second part, specific requirements and success factors for wide reimbursement in the EU-5 are analyzed in detail. Gaining early acceptance by the main influencers (key opinion leaders and payers) is the first step. Equally important is the provision of convincing evidence, be this clinical, health-economic (cost-effectiveness), or a demonstration of cost savings (budget impact). In some countries, local usage data may be a requirement as well. Lastly, as payers' willingness to pay stems directly from their perceived value of a device, a key success factor and a necessary precondition for manufacturers is to set the right price.

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**Abbreviations:** (CCG) clinical commissioning group, (CGM) continuous glucose monitoring, (HbA1c) hemoglobin A1c, (HTA) health technology assessment, (KOL) key opinion leader, (NHS) National Health System, (NICE) National Institute for Health and Care Excellence, (RCT) randomized controlled trial

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