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Comparative analysis of regulatory, insurance and subsidy policies for continuous glucose monitoring devices with a health technology assessment approach: Comparison of selected countries and Iran

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Abstract

Continuous Glucose Monitoring (CGM) is an emerging and transformative technology in diabetes management that has gained a special place in global health systems in recent years. By providing the possibility of continuous measurement of interstitial glucose, this technology allows patients to observe their blood sugar fluctuations in real time and have better control over their disease. Despite proven clinical effectiveness and improving patients' quality of life, regulatory pathways, health technology assessment (HTA), and related insurance policies differ significantly across countries. The aim of this study is to conduct a comparative analysis of the regulatory and insurance pathways related to CGM technology in five selected countries—the United Kingdom, Germany, France, Canada, and Australia—and compare it with the current situation in Iran. The role of health technology assessment (HTA) in insurance decision-making and subsidy policies of these countries is also examined. This study is an analytical and policy-oriented review. Data were collected and analyzed from official documents, HTA reports, and regulatory guidelines published up to 2025. The focus of the analysis was on the relationship between HTA systems, the technical licensing process, and insurance coverage of CGM technology. The results showed that countries that benefit from a coherent HTA system have a more transparent and coherent decision-making process between technical licensing, cost-effectiveness assessment, and insurance coverage. In contrast, in Iran, despite the issuance of technical licensing by the Food and Drug Administration, there is no effective organizational connection between HTA, insurance institutions, and subsidy policies. As a result, some technologies have not yet achieved insurance coverage despite the high need of patients. The experience of selected countries shows that integrating HTA results into insurance and subsidy policies can lead to fairer decision-making and more sustainable access of Iranian patients to new technologies such as CGM.
Establishing an institutional mechanism to link HTA with insurance and regulatory processes is an essential step towards improving the health decision-making system in Iran.

Keywords: Health Technology Assessment, Glucose Monitoring, Reimbursement Policy, Regulatory Pathway, Diabetes.

Introducion

Diabetes is a major global health challenge, and accurate glucose control is essential to prevent its complications (1). In recent years, the use of digital technologies in diabetes management, including CGM, has been recognized as an effective strategy to promote self-care and improve metabolic outcomes (2). In CGM technology, a sensor is placed under the skin that measures the concentration of interstitial fluid glucose and transmits the data via Bluetooth to a receiver or mobile phone. These systems can issue real-time alerts for severe drops or rises in blood sugar and, in some models, even communicate directly with an insulin pump Despite these advantages, the process of CGM entry(3). In Iran, despite the adoption of the National Health Technology Assessment System assessment, and insurance since 2016, a strong implementation mechanism for linking HTA and insurance policies has not yet been formed(4). A comparative study of countries with successful experience in adopting CGM can guide Iranian policymakers in improving decision-making paths (5).

Methodology

This study employed a qualitative comparative policy analysis using a Health Technology Assessment (HTA) perspective to examine regulatory pathways, reimbursement mechanisms, and subsidy policies related to continuous glucose monitoring (CGM) devices. The objective was to identify policy models adopted in selected countries and compare them with the current situation in Iran in order to inform potential policy development for CGM coverage and access. A comparative descriptive study design was applied to systematically analyze policy frameworks governing the regulation, assessment, financing, and utilization of CGM technologies. The study focused on four main policy domains: regulatory approval processes, HTA and evidence evaluation mechanisms, reimbursement policies, and subsidy or pricing strategies. These domains were selected based on their critical role in determining the availability and affordability of medical devices in national health system, Countries were purposively selected to represent diverse health system structures and approaches to medical device coverage. Selection criteria included variation in healthcare financing models, the existence of formal HTA processes, and documented reimbursement policies for CGM devices. The selected countries included the the United Kingdom, Germany, France, canada , Australia and Iran, Data were collected from multiple sources to ensure comprehensive policy coverage. Primary sources included official documents from regulatory agencies the European Medicines Agency (EMA), the UK Medicines and Healthcare products Regulatory Agency (MHRA), and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Information related to health technology assessment and reimbursement decisions was obtained from major HTA organizations, including the National Institute for Health and Care Excellence (NICE), the Institute for Quality and Efficiency in Health Care (IQWiG), the Federal Joint Committee (G-BA) in Germany, and the Canadian Agency for Drugs and Technologies in Health (CADTH), where relevant. Additional information was retrieved from national health insurance policy documents, government reports, international databases such as the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD) he collected data were analyzed using a comparative policy matrix that enabled cross-country comparison across the predefined domains. Policy mapping was conducted to illustrate how each country regulates and finances CGM technologies within its health system. Subsequently, a gap analysis was performed to identify differences between international practices and the current regulatory and reimbursement environment in Iran (5).

Review of Related Literature and Studies

A. Previous studies related to this topic have been conducted by several researchers which are mentioned in Table 1.

B. Researchers conducting studies on CGM policy and insurance coverage are included in Table 2.

Table 1. Summary of previous studies on the comparative analysis of continuous glucose monitoring (CGM) Devices (35).

Author	Country	Year	Method	Key Findings
Beck	United States	2017	Regulatory Review	CGM devices require the stringent FDA Premarket Approval (PMA) pathway.
Klonoff	United States	2018	Comparative Review	Regulatory approval for CGM devices occurs faster in Europe than in the United States.
Heinemann	European Union	2019	Regulatory Comparison	Significant differences exist in safety standards and regulatory requirements.
Herman	United States	2015	Cost-Effectiveness Analysis	CGM is cost-effective for patients with type 1 diabetes (T1D).
Palmer	United Kingdom	2018	HTA (NICE Evaluation)	Targeted reimbursement coverage for CGM was recommended.
Roze	France	2019	Health Economic Modeling	CGM use reduces hospitalization costs.
Riemsma	United Kingdom	2020	HTA Review	CGM demonstrates high effectiveness in high-risk patients.
Bergenstal	United States	2018	Policy Analysis	Expansion of CGM policies has increased patient access.
IQWiG	Germany	2020	Health Technology Assessment	CGM is fully covered by statutory health insurance.
PBAC	Australia	2021	Health Technology Assessment	National reimbursement increased CGM utilization.
Farhadi	Iran	2020	Cost-Effectiveness Analysis	CGM was found to be cost-effective in the Iranian context.
Rahimi	Iran	2022	Policy Analysis	Lack of a clear subsidy policy for CGM technologies in Iran.

Table 2. Previous studies on policy-making and insurance coverage of continuous glucose monitoring (CGM) (36).

Author	Country	Type of Coverage	Year	Type of Study
Bergenstal et al	United States	Medicare Coverage	2017	Insurance and Subsidy Policies
Sherr et al.	United States	Variations in Coverage	2020	Insurance and Subsidy Policies

		Across States		
Drummond et al	International	Differences in Insurance Reimbursement Decisions	2019	Comparative Studies
David M. Nathan	United States	Diabetes Research and Glucose Monitoring Technologies	2020	CGM Research
Peters et al	United States and European Union	Shorter Market Entry Time for CGM in Europe Compared with the United States	2020	Regulatory Studies
Ministry of Health HTA Office	Iran	Persistent Challenges in Pricing Policies	2021	Emerging Health Technologies
Andrew J. Palmer	United Kingdom	NHS Coverage Policies	2022	Insurance and Subsidy Policies

Results

United Kingdom:

In the United Kingdom, the main regulatory body for medical devices is the MHRA, which operates under the Medical Device Regulation. After receiving the CE mark or UKCA, the manufacturer must submit a health technology assessment application to NICE (7). In addition to clinical evidence, NICE calculates cost-effectiveness in terms of 'cost per quality-adjusted life year (QALY)' in its assessments. If a technology costs less than £30,000 per QALY, it is usually approved by the NHS (8). In 2022, NICE recommended the Dexcom G6 system for patients with type 1 diabetes in its TA944 report for diabetes type 2 only in certain circumstances (9). The reasons for the lack of full coverage of some models were limited evidence in non-market populations and higher cost than traditional monitoring.

Germany:

In Germany, technical approval of medical devices is carried out by the BfArM and CE marking is a requirement for market entry (10). However, to be included in the insurance reimbursement list, the technology must be assessed by IQWiG. In 2016, CGM for type 1 patients was included in the federal health insurance list following a comprehensive assessment by IQWiG (11).. However, newer systems such as implantable CGM are still in the cost-effectiveness evaluation phase. .Reasons for the delay in coverage of some devices include: Lack of head-to-head studies with standardized methods, Concerns about educational costs, and differences in efficacy across age groups (12).

France:

In France, medical technology assessment is conducted under the supervision of the HAS, which examines two key indicators: Service attendu (SE) or expected effectiveness, Amélioration du service attendu (ASA) or added value of treatment (13).

CGMs with a high ASA score are included in the Liste des Produits et Prestations Remboursables (LPPR) and are reimbursed by insurance. However, if the ASA is low (e.g., level IV or V), the device is simply licensed and not insured (14). This distinction has led to some models, such as the FreeStyle Libre, being quickly insured, while newer models have been removed from the list due to inadequate evaluation.

Canada:

In Canada, the federal system has led to insurance policy varying between provinces.

Health Canada is responsible for technical licensing, but the economic evaluation is conducted by CADTH (15). In its 2023 report, CADTH demonstrated the effectiveness of CGM in reducing hypoglycemia but considered it cost-effective only in patients with type 1 diabetes (16). As a result, provinces such as Ontario and British Columbia have insured CGMs, but in some areas patients still have to pay the full cost.

Australia:

In Australia, the TGA is responsible for device approval and the PBAC conducts cost-effectiveness analysis (17). Since 2017, the national NDSS program has insured the use of CGM for children and pregnant women. However, newer models are still in the economic evaluation phase. The main reasons for the lack of insurance coverage are concerns about increased financial burden and the lack of evidence in the type 2 diabetes population (18).

Iran:

In Iran, the entry route for CGMs is through the Food and Drug Administration (IFDA) and the Medical Devices Committee (19) However, unlike in developed countries, there is no mandatory mechanism for conducting HTA assessment before insurance decisions are made As of 2014, only a few limited brands (Dexcom, Medtronic, FreeStyle) have been licensed for entry, and as of 2015, various models from China have been licensed for import, but none are directly covered by basic direct insurance, and all imported products are subject to various government subsidies. The reasons for this are: Weak coordination between the Ministry of Health, insurance organizations and IFDA, and currency fluctuations that cause price instability (20).

Comparative analysis of subsidy and insurance policies in selected countries

The comparative findings show that subsidy policies in developed countries mainly follow three fundamental principles: Scientific basis for decision-making (HTA-based policy), Targeted Subsidy, Post-reimbursement review (21). In the countries studied, the allocation of CGM subsidies and insurance is made only after a multi-stage process that includes a detailed economic evaluation and a budget impact analysis:

United Kingdom:

In the United Kingdom, the NHS has designed a partial reimbursement policy for CGM based on NICE recommendations. The subsidy is only available to high-risk groups (such as children with type 1 diabetes and pregnant women with diabetes). In fact, the subsidy is applied as a “cost-sharing” in the form of a prescription through the NHS, rather than directly to the importing company (21). In this country, HTA acts as a prerequisite for financial policy. Without NICE approval, no device can be marketed as an insurance product, even if it is technically approved by the MHRA.

Germany:

In Germany, the compulsory health insurance system (SHI) operates on the basis of an IQWiG assessment and a G-BA decision(22). sufficient evidence of “improvement of quality of life” or “reduction of indirect costs” are included in the reimbursement list. Subsidies are usually paid from collective insurance funds, and the producer is required to negotiate the price with the government (23). This system is highly transparent and prevents the introduction of expensive technologies without real effectiveness.

France:

France uses a hybrid model: after authorization by the HAS, the device benefits from a direct government subsidy if it has a high ASA score. However, if the therapeutic added value is low, the device is allowed to be sold but is not covered by insurance and subsidies. For this reason, some devices (such as first-generation CGMs) are available on the market

but are not reimbursed by insurance. This structural separation has prevented unnecessary financial burdens on the health system (24).

Canada:

In Canada, the subsidy system is provincially based. CADTH only provides technical advice and each province makes the final decision. In some provinces, subsidies are paid for patients under 25 years of age or with type 1 diabetes, but not in others. Some provinces even cover different CGM models based on different cost-effectiveness analyses (e.g. Libre only for patients with severe hypoglycemia) (25).

Australia:

The Australian government fully subsidizes CGM for specific groups through the National Diabetes Services Scheme (NDSS). Data collected from users are used for post-market analysis to review reimbursement policies if effectiveness decreases. This close link between subsidy and clinical monitoring is a core principle of Lifecycle HTA (26).

Table 3. Comparative overview of countries regarding HTA, insurance coverage, and subsidy policies (26).

Subsidy Program	Insurance Coverage	HTA	Country
NHS	Coverage approved following NICE recommendations	NICE; the main regulatory authority for medical devices is MHRA	United Kingdom
G-BA-IQWiG	Coverage provided through statutory health insurance funds	Technical approval of medical devices by BfArM	Germany
HAS	Generally not covered by insurance	Medical technology assessment conducted by HAS	France
CADTH	Insurance coverage decisions are made at the provincial or territorial level	Health Canada responsible for technical licensing	Canada
NDSS	National Diabetes Services Scheme (NDSS)	TGA responsible for device approval; PBAC conducts cost-effectiveness assessment	Australia
Partially subsidized by the government	No clear mechanism for insurance coverage	Iran Food and Drug Administration (IFDA) and the Medical Equipment Committee	Iran

Status of CGM subsidy and coverage in Iran

In Iran, CGM devices are mainly imported through the official import route with a license from the Food and Drug Administration. Despite official registration, there is no clear national framework for assessing cost-effectiveness or determining subsidy levels. Currently, the government pays part of the cost through a foreign exchange subsidy for equipment imports, which is applied at the level of the importing company, rather than the patient, rather than being targeted [Currently, the government pays part of the cost through a foreign exchange subsidy for equipment imports, which is applied at the level of the importing company, rather than the patient, rather than being targeted (27) This policy has several major problems: Lack of transparency: it is not clear exactly how the foreign exchange subsidy affects the final price for the patient, Lack of link to effectiveness: the subsidy is not allocated based on clinical need or HTA analysis, Conflict of incentives: some importers adjust the final price to market fluctuations despite receiving preferential exchange rates (28).

Why are some devices licensed in Iran but not insured?

This phenomenon is due to a structural gap between three key institutions: The Food and Drug Administration (technical licensing), The Ministry of Health's Deputy Director of Health (clinical policy), Insurer organizations (financial decision-making). (29) In other words, in Iran, import permits are issued based on safety and technical performance, but domestic cost-effectiveness studies and HTA assessments are required for insurance which are often not performed (29).

The role of HTA in reforming subsidy policy in Iran

Health technology assessment (HTA) as a scientific and policy tool can bridge the gap between technology authorisation and insurance decisions; by generating domestic cost-effectiveness evidence, identifying target groups based on disease burden and economic consequences, and modeling the financial impacts on insurance and government budgets (30). International studies have shown that the use of HTA in determining subsidies for diabetes equipment reduces unnecessary costs by 30–50 percent (31). In Iran, if HTA is made a prerequisite for insurance decisions, it can prevent the misallocation of subsidies and provide more targeted coverage for children, adolescents, and pregnant women(31).

Proposed policy model for Iran

Based on the findings, the proposed model for reforming CGM policy in Iran could include four key steps: Establishing a National HTA Committee for Diabetes Devices with the participation of the Ministry of Health, insurance companies, the Diabetes Association, and the Food and Drug Administration, . Defining a dual path: first a technical assessment (IFDA) then an economic assessment (HTA), . Determining subsidy target groups: based on disease severity, risk of hypoglycemia, and economic status, Post-insurance monitoring: collecting real-world evidence to assess ongoing effectiveness (32).

Discusstion

However, the lack of coherent HTA evaluation and the failure to link subsidy decisions to evidence have prevented the realization of these cost-effectiveness. This is where HTA can play a transformative role—not just as a research tool, but also as a decision-making mechanism at the policy level. he findings of the comparative analysis indicate that health systems' approaches to continuous glucose monitoring (CGM) devices are not determined solely by technological advancement or market authorization. Rather, they reflect the institutional capacity of countries to link regulation, health technology assessment (HTA), financing mechanisms, and equity considerations in health. In other words, countries that have been more successful in integrating CGM into routine care are those that have managed to create coherence between technical approval, assessment of clinical and economic value, and the design of reimbursement or subsidy arrangements. The comparative analysis shows that countries with a coherent HTA structure have not only been more successful in adopting CGM, but have also been able to design more efficient subsidy policies. In contrast, in countries with insular decision-making structures—including Iran—the gap between technical authorization, clinical effectiveness, and insurance policy has led to inequitable access. In Iran, the economic burden of diabetes is estimated to exceed $5 billion annually, and blood monitoring costs account for nearly 20% of this figure (33). Given the high rate of diabetes complications, the use of CGM could be significantly more cost-effective than delayed treatment (34).

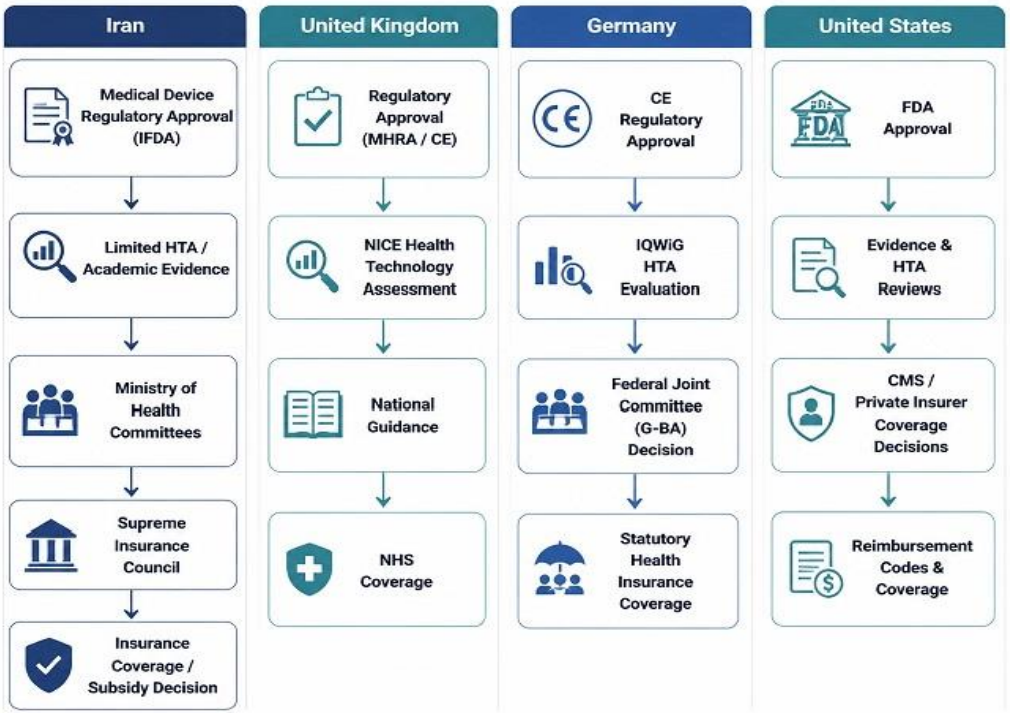

Figure 1. Comparison of the HTA working group formation and decision-making processes in Iran and selected countries (31).

In the selected countries, particularly the United Kingdom, Germany, and Australia, CGM has not been treated merely as a technological tool, but as a health intervention with measurable clinical, economic, and social consequences. These countries demonstrate that the use of HTA can lead to more rational decision-making—decisions that not only focus on clinical effectiveness, but also take into account financial sustainability, implementation capacity, and the equitable distribution of benefits. By contrast, the analysis of the Iran context suggests that the main gap lies not in the recognition of CGM as a technology per se, but in the absence of a coherent policy pathway for transforming this technology from an imported or specialist product into an accessible and prioritized health service. At present, one of the fundamental challenges in Iran is that medical device regulation, insurance decision-making, and supportive financing policies do not operate as part of an integrated chain. As a result, even when CGM is technically allowed to enter the market, the lack of insurance coverage and targeted subsidies substantially limits patients' real access to the technology. mainly accessible to patients with greater financial means. This is inconsistent with the principles of health equity, since many of the groups that derive the greatest clinical benefit from CGM—such as children with type 1 diabetes, patients experiencing severe hypoglycemia, and high-risk pregnant women—do not necessarily have greater ability to pay. Another important point is that in many countries, the expansion of CGM coverage did not occur suddenly or universally. Rather, it was implemented gradually through prioritized and phased coverage. This experience is highly relevant for Iran, because financial constraints, exchange-rate volatility, and budgetary pressures

make universal and immediate coverage for all eligible patients an unrealistic policy option. Under such conditions, an HTA-informed approach can help identify which patient groups derive the greatest benefit relative to the resources invested, thereby providing a rational starting point for policy action. The comparative analysis also shows that regulatory approval alone is not sufficient for successful technology adoption. Some countries, despite having advanced regulatory pathways, continue to face challenges related to unequal access because the financing and reimbursement components have not been adequately designed. Therefore, in Iran, an exclusive focus on registration, importation, or even domestic production of CGM—without considering patterns of use, payment mechanisms, and clinical infrastructure—will not be enough to ensure effective and sustainable adoption. From an HTA perspective, one of the major gaps in Iran is the shortage of local evidence regarding the economic and clinical outcomes of CGM. It should also be emphasized that the effectiveness of CGM is not determined solely by the technical characteristics of the device. Its value depends to a large extent on factors such as patient health literacy, training of healthcare providers, continuity of access to sensors, the existence of clear clinical protocols, and the capacity of the health system to interpret and use the data generated by the technology. Therefore, any policy aimed at expanding CGM in Iran should be designed from a systemic perspective and should not be reduced to a simple decision about procuring a medical product.

Conclusion

This study demonstrated that HTA plays a key role in the transition from untargeted subsidy policies to evidence-based policies. In developed countries, HTA not only determines insurance coverage of CGM, but also provides a mechanism for reviewing subsidies. In Iran, while CGM devices have received technical appr oval, the lack of comprehensive HTA has led to insurers being reluctant to cover them and subsidies being allocated without scientific linkage. Formal integration of HTA into insurance decisions and subsidy policies could correct this cycle and facilitate access to new technologies for diabetic patients. In short, HTA is a bridge between science and policy; a tool that, if properly institutionalized in the Iranian health decision-making structure, will not only ensure the financial and clinical effectiveness of technologies but also promote health equity.

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