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National Diabetes Canter

المجلس الصحي السعودي
Saudi Health Council

Diabetes Digital Health Guide in Saudi Arabia

Diabetes Digital Health Guide in Saudi Arabia: An Evidence-Based Guide for Policy Development

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Glossary of terms:

AID	Automated Insulin Pump.
CSII	Continuous Subcutaneous Insulin Infusion.
CGM	Continuous Glucose Monitoring.
CHI	Council of Health Insurance.
COVID	Coronavirus Disease.
DTSQ	Diabetes Treatment Satisfaction Questionnaire.
EBP	Essential Benefit Package.
FGM	Flash Glucose Monitoring.
FSL	FreeStyle Libre.
GMI	Glycemic Management Indicators.
HbA1c	Hemoglobin A1C
HCP	Health Care Professional.
HTA	Health Technology Assessments.
IQ	Intelligence Quotient.
MENA	Middle East and North Africa.
MDI	Multiple Daily Injection.
MOH	Ministry of Health.
NCMDR	The National Center for Medical Devices Reporting.
NHS	National Health Services.
NICE	National Institute for Health and Care Excellence.
NPHIES	National Platform for Health and Insurance Exchange Services.
PSUR	Periodic Safety Update Report.
SFDA	Saudi Food and Drug Authority.
SNDC	Saudi National Diabetes Center.
T1D	Type 1 Diabetes.
T2D	Type 2 Diabetes.

Summary

The Saudi National Diabetes Center (SNDC) has developed a comprehensive Diabetes Digital Health Guide for Policy Development addressing the critical national challenges in diabetes care management amid rising disease prevalence. This guide comes at a crucial time when Saudi Arabia has positioned itself as a leader in digital transformation across various sectors, including healthcare.

A panel of experts convened by SNDC; including representatives from the public and private clinical practice, SNDC, Saudi FDA, Council of Health Insurance (CHI); conducted an extensive analysis of the current status of diabetes digital health solutions in Saudi Arabia. The assessment revealed that while the Kingdom offers one of the most highly-regulated and diverse ranges of diabetes digital solutions globally, significant accessibility barriers persist.

The guide identifies 5 key barriers to digital health adoption and proposes 13 strategic initiatives designed to transform the current diabetes care model into a more innovative, efficient, flexible, safe, and cost-effective system of care delivery. This pioneering guide serves as a comprehensive resource for stakeholders across the healthcare spectrum, including policymakers, regulatory bodies, clinicians, academicians, and industry partners. It provides strategic direction for navigating the digital health landscape, understanding global best practices, and implementing effective digitalization strategies in Saudi Arabia's diabetes care sector.

Key Deliverables

- Comprehensive assessment of current digital health solutions: availability, regulations and policies, and local clinical studies.
- Identification of 5 major barriers to the wide utilization of diabetes digital solutions in Saudi Arabia.
- Development of 13 strategic transformation initiatives to increase the utilization and accessibility to diabetes digital solutions.
- Strategic roadmap for enhanced accessibility.
- Framework for digital health integration in diabetes care.

1) Scope

In response to the rapidly evolving landscape of digital health technologies and their transformative potential in diabetes care, this comprehensive report examines the current state, challenges, and opportunities in implementing digital health solutions for diabetes management in Saudi Arabia. The report provides an in-depth analysis of emerging technologies, implementation frameworks, and evidence-based recommendations targeted at multiple stakeholders in Saudi Arabia: healthcare policymakers seeking to integrate digital health into national healthcare strategies, healthcare professionals (HCPs) implementing these technologies in clinical practice, academic researchers advancing the field through scientific inquiry, industry partners developing innovative solutions, and key stakeholders involved in healthcare delivery and technology adoption. Through this analysis, we aim to bridge the gap between technological innovation and practical implementation while addressing critical aspects of accessibility and clinical outcomes in diabetes care in Saudi Arabia.

In this report, we provide: 1) A comprehensive review of the Saudi Food and Drug Administration (SFDA)-approved continuous glucose monitors (CGMs) and insulin pumps; 2) An evaluation of the available local studies investigating the effectiveness, safety, utilization, and cost-effectiveness of diabetes digital solutions in Saudi Arabia; 3) A review of the regulatory framework governing diabetes digital solutions in Saudi, from pre-approval to post-approval SFDA processes, 4) An overview of the current regulations and policies influencing patients access to diabetes digital solutions in Saudi Arabia, and what insights can be drawn from global best practices, and 5) A strategic roadmap for enhancing the accessibility to diabetes digital health solutions in Saudi Arabia.

2) Introduction

Diabetes poses a significant health and economic burden in Saudi Arabia and the Middle East and North Africa (MENA) region, with the region experiencing the highest prevalence rates globally (1). The increasing incidence and prevalence of diabetes have led to a strain on the region healthcare systems, necessitating substantial resource allocation for disease management and treatment of complications. The health burden of diabetes in Saudi Arabia is evident in the rising rates of cardiovascular diseases, renal failure, non-traumatic amputation, and blindness associated with poorly controlled diabetes (2). Moreover, the economic impact of diabetes and its complications is substantial, encompassing direct medical costs for the management of diabetes and its complications, and indirect costs due to worsened quality of life, absenteeism and reduced productivity at work, and premature mortality (3; 4). The high prevalence of diabetes in Saudi Arabia presents a considerable challenge to the nation's healthcare infrastructure and economic development. This underscores the urgent need for developing and implementing more accessible, efficient, and cost-effective strategies for both preventing new cases of diabetes and improving the management of existing ones to prevent diabetes complications.

Over the recent years, Saudi Arabia has established itself as a leader in digital transformation, implementing cutting-edge technologies across various sectors and launching ambitious initiatives like the Ministry of Health (MOH) Vision for E-Health (5), highlighting its commitment to becoming a technologically advanced nation. The MOH vision for E-Health is led by entities such as the Digital Transformation Unit, the Vision Realization Office, the MOH, and other stakeholders as part of the broader and comprehensive Kingdom's Vision 2030. In light these initiatives, diabetes digital health technologies offer tremendous potential for transforming diabetes care in Saudi Arabia.

In diabetes, the utilization of continuous glucose monitors (CGMs) and insulin pumps, coupled with smartphone apps and cloud-based platforms, can significantly enhance the quality, accessibility, efficiency, and cost-effectiveness of diabetes management (6). These technologies enable real-time glucose monitoring, automated insulin delivery, and data-driven decision making, allowing for more precise and personalized treatment regimens. By providing patients with continuous feedback and healthcare providers with comprehensive data, diabetes digital health solutions can improve glycemic control, minimize risk of complications, and enhance overall quality of life among people living with diabetes. Such innovative management strategy is expected to yield significant reductions in the healthcare expenditure associated with diabetes and its complications. Moreover, these technologies can bridge geographical barriers, extending specialized diabetes care to remote areas and alleviating the strain on healthcare facilities. The potential for remote monitoring and virtual consultations can increase the efficiency and safety of healthcare delivery and reduce the need for frequent in-person visits and potentially lowering the overall healthcare costs. As Saudi Arabia continues to invest in its healthcare infrastructure and digital transformation, the adoption of diabetes digital health technologies aligns perfectly with the country's vision for a more efficient, accessible, and technologically advanced healthcare system.

3) Overview of the SFDA-Approved Diabetes Digital Solutions

In this section, we focus our discussion on the currently SFDA-approved CGMs and insulin pumps.

3.1 Continuous Glucose Monitors (CGMs)

A Continuous Glucose Monitor (CGM) is a wearable device that continuously monitors interstitial glucose, provides real-time glucose readings, and displays those data on a receiver or smartphone app. Moreover, CGMs can alert users to high or low glucose levels and help them make more informed and personalized decisions about diet, exercise, medications, and other aspects of diabetes management. In addition, CGMs offer an option to transmit glucose data, through the cloud, to remote caregivers including healthcare professionals (HCPs). The latter feature empowers people living with diabetes and their HCPs as they practice personalized medicine, makes the clinic visits more efficient and safer, and facilitates telemedicine visits whenever needed. As of September 2024, the date of writing this report, there are twelve CGMs approved by the SFDA. Table 1 summarizes the key features of the eleven CGMs that are commercially available in the Saudi market.

3.2 Insulin Pumps

Insulin pumps have revolutionized the management of type 1 diabetes, offering improved glucose control and quality of life for patients. These devices come in various forms, including open-loop pumps and automated insulin delivery (AID) systems. Open-loop pumps require manual input for insulin dosing; while AID systems, also known as closed-loop systems or artificial pancreas, represent the latest advancement, integrating continuous glucose monitors (CGMs) with insulin pumps to automatically adjust insulin delivery based on real-time glucose readings. Studies have shown that these technological advancements have significantly improved glycemic control, reducing HbA1c levels and time spent in hypoglycemia (7;8;9).

Moreover, better glucose management has led to a decrease in diabetes-related complications, such as retinopathy, nephropathy, and cardiovascular disease. The potential for cost-effectiveness of AID systems is also promising, as improved outcomes will likely lead to reduced long-term healthcare expenditures associated with diabetes complications. While initial costs of these devices may be higher, the long-term benefits in terms of health outcomes and quality of life suggest that insulin pump therapy, particularly AID systems, could be a cost-effective solution for managing type 1 diabetes. (10;11;12)

Another way to classify insulin pumps is by whether the pump is tubed or tubeless. Tubeless pumps offer increased convenience with a patch-like design. Some tubeless pumps are open loop and others are hybrid closed loop (i.e AID). Table 2 summarizes the key features of the seven SFDA-approved insulin pumps that are commercially available in Saudi as of September 2024, the date of writing this report.

4) Local Evidence Examining the Effectiveness, Safety, and Cost-effectiveness of Diabetes Digital Health in Saudi Arabia

A narrative review was performed in PubMed from 2019 until 2024. The search terms were "insulin pump, continuous glucose monitoring, or diabetes technology in Saudi Arabia." We limited the search to studies that examined the effectiveness and safety of diabetes technologies in patients with type 1 and type 2 diabetes in Saud Arabia. Table 3 summarizes the findings of the studies that met those criteria.

4.1 Continuous Glucose Monitors (CGMs)

The studies exploring the performance of CGMs in patients with type 1 diabetes (T1D) and type 2 diabetes (T2D) aimed at evaluating the level of glycemic control, treatment satisfaction, and overall quality of life among people living with diabetes.

4.1.1 Glycemic Control and Quality of Life in Type 1 Diabetes

In T1D, use of continuous and flash glucose monitoring systems was associated with significant improvement in glycemic control and quality of life across different age groups.

4.1.1.1 Glycemic Control:

Numerous studies showed that CGMs improve glycemic control in people with T1D. For example, in pediatric patients, the use of CGM resulted in a notable reduction in hemoglobin A1c levels from 10.8% to 9.1% over nine months, particularly benefiting those with poor baseline glycemic control (13). Similarly, adults using CGM for one-year experienced a decrease in hemoglobin A1c from 9.8% to 8.6% (14), demonstrating the effectiveness of CGM in improving glucose levels across different ages. (Table 3)

4.1.1.2 Quality of Life:

For younger individuals with T1D (ages 14-21), the transition from the conventional finger-prick method to CGM has significantly improved the mental well-being and treatment satisfaction of these individuals. The WHO-5 Well-Being Index in one study increased from 45.1% to 93.6%, and the Diabetes Treatment Satisfaction Questionnaire (DTSQ) score increased from 14.4 to 31.7, indicating enhanced psychological health and satisfaction (15). Likewise, during the COVID-19 lockdown, patients with T1D who had access to telemedicine and CGM were more likely to maintain good glycemic control, highlighting the key role of CGM and telemedicine in providing remote healthcare services that are essential for continuity of care and quality of life (16). (Table 3)

4.1.2 Glycemic Control and Quality of Life in Type 2 Diabetes on Multiple Daily Injections (MDI)

For people with type 2 diabetes who use multiple daily insulin injections (MDI), the utilization of CGM helped improve both glycemic control and treatment satisfaction.

4.1.2.1 Glycemic Control:

A 12-week study revealed that patients with T2D on MDI who transitioned to CGM experienced a significant improvement in hemoglobin A1c, with levels dropping from 8.2% to 7.8%. Furthermore, the frequency of hypoglycemic events decreased from an average of 4.4 to 1.2 per month, indicating the role of CGM in stabilizing glucose levels and minimizing adverse events in insulin-dependent T2D patients (17). (Table 3)

4.1.2.2 Quality of Life:

Patients with T2D on MDI reported increased satisfaction with glucose monitoring using CGM, as reflected in improved DTSQ and Glucose Monitoring Satisfaction Survey scores. These findings highlight the role of CGM in enhancing self-management confidence and improving overall quality of life in people with T2D on MDI (17). (Table 3)

4.1.3 Glycemic Control Type 2 Diabetes Not on Insulin Therapy

In a one-year study, T2D patients using the intermittently-scanned (isCGM) system experienced an HbA1c reduction from 8.3% to 7.9%, showing sustained benefits over time. The study found a strong correlation between the Glycemic Management Indicator (GMI) and lab-measured HbA1c, validating GMI's accuracy as a proxy for HbA1c levels. This demonstrates that CGM can effectively support glucose control in T2D patients who do not require intensive insulin. (18)

The findings of local studies, conducted on people with T1D and T2D who live in Saudi Arabia, are consistent with the findings of global studies and highlight the important role of CGM systems in improving the glycemic control and quality of life of people with T1D and T2D, irrespective of age or baseline hemoglobin A1C. (Table 3)

4.2 Insulin Pump (Continuous Subcutaneous Insulin Infusion)

4.2.1 Insulin Pump in people with type 1 diabetes during regular days

We reviewed local studies that assessed the effectiveness and safety of insulin pump therapy when used in people with T1D. Some of the studies provide comparisons between users of insulin pumps versus Multiple Daily Injections (MDI) in pediatric and adult patients as follows:

4.2.1.1 Quality of Life:

Patients using insulin pumps reported improved health-related quality of life, better scores in diabetes management satisfaction, fewer treatment-related challenges, and reduced anxiety about glucose control (19).

4.2.1.2 Glycemic Control:

Studies revealed that insulin pump use offers better glycemic control, with consistently lower A1C levels and less glycemic variability compared to MDI. (20;21;22)

4.2.1.3 Psychological and Social Impact:

While insulin pump users had better overall well-being and adherence, they experienced more concern about disease management. (19)

4.2.1.4 Long-Term Benefits:

Insulin pump users demonstrated sustained HbA1c improvements over time (20)

4.2.2 Insulin Pump in people with type 1 diabetes during Ramadan fasting

Studies on automated insulin delivery (AID) systems, like the MiniMed 780G pump, showed safe and effective glucose management during Ramadan fasting, with high sensor and auto mode engagement and reduced hypoglycemia risk. Overall, Pump therapy was associated with better glycemic control and quality of life among people with T1D who attempted to fast during Ramadan. AID systems are especially effective during the fasting periods, reducing rates of severe complications such as hypoglycemia and ensuring glucose stability and ability to fast most days of Ramadan. (23;24;25;26)

4.3 Gaps in the local scientific literature

The adoption of advanced diabetes technologies such as insulin pumps and CGMs, in Saudi Arabia is on the rise. However, there remains many unanswered questions and several gaps and limitations in the currently available data. There is lack of high-quality localized studies specific to the Saudi population, where a large number of patients are enrolled from multiple centers to assess the intermediate and long-term efficacy, safety, and cost-effectiveness of the use of automated insulin pumps. In addition, studies focused on patient reported outcomes are needed. Moreover, there is high need for a transformative approach to diabetes care that utilizes the currently available diabetes digital health tools to address the current gaps in clinical care of people living with diabetes in Saudi Arabia.

4.4 Potential areas for improvement

To improve our studies on diabetes technology, the following steps could be taken:

1) **Expand Study Populations:**

- Include diverse patient groups from various regions of Saudi Arabia to ensure broader applicability.

2) **Conduct Multicenter Research:**

- Collaboration between experts from multiple diabetes centers across Saudi Arabia is highly needed.

3) **Utilize Longitudinal Data:**

- Focus on intermediate and long-term studies that aim to examine the effectiveness and sustainability of improved glucose control and quality of life among users of diabetes technologies.

4) **Integrate Digital Health:**

- Utilize national health platforms to integrate and monitor diabetes-related data and provide personalized diabetes care.

5) **Collaborate with global experts in areas where local expertise is limited:**

- Partner with global institutions and experts to train local researchers to advance the field of diabetes digital research

6) **Research Funding**

- **Diabetes digital health research needs to be prioritized in research grants.**

5) The Journey of a Diabetes Digital Solution: Navigating the Regulatory Landscape in Saudi Arabia

5.1 The Role of SFDA in Safeguarding Public Health

The Saudi Food and Drug Authority (SFDA) plays a vital role in protecting public health in Saudi Arabia by overseeing the regulation of food, drugs, medical devices, and cosmetics. Established in 2003, the SFDA has continuously improved its regulatory practices to meet the evolving needs of the nation, significantly contributing to public health, economic development, and regulatory innovation. Aligned with the Kingdom's Vision 2030, the SFDA is essential in shaping a healthier, safer, and more prosperous Saudi Arabia.

Over the years, the SFDA has implemented strong regulatory frameworks that enhance public health and safety across the Kingdom. A notable achievement in this regard is its commitment to digital transformation, which has streamlined regulatory processes and improved efficiency and transparency. This approach has positioned the SFDA at the forefront of global best practices, ensuring that Saudi Arabia remains a leader in public health protection and regulatory excellence. Through these ongoing advancements, the SFDA continues to be a key force in driving the Kingdom's public health agenda while supporting broader economic and social goals.

5.2 SFDA Medical Devices Law And Regulation Framework

Saudi Arabia's medical device regulations are governed by the (Medical Devices Law), which was issued by Royal Decree No. (M/54) on 06/07/1442 H, alongside its Executive Regulation issued by Board Resolution No. (3-29-1443) on 2/19/1443 H. This regulatory framework ensures that all medical devices meet keen safety and quality standards before being approved and placed in the market and distribution in the Kingdom. A medical device is defined by the SFDA as follows: "Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means". The MD law covers medical devices' whole **(Figure 1)** cycle and focuses on safety and quality and performance standards and requirements. Moreover, SFDA has published many requirements documents for various aspects of medical device regulation to create a transparent framework for manufacturers and healthcare providers to follow, ensuring regulatory compliance at every stage of the device lifecycle. (27;28)

Examples of published regulatory and technical requirements documents:

- Requirements for medical device marketing authorization.
- Clinical trials of medical devices.
- Safe use of medical devices in healthcare facilities.
- Shipments clearance of medical devices at ports of entry.
- Advertising and conducting awareness campaigns for medical devices.
- Inspection and quality management systems.
- Post-market surveillance of medical devices

5.3 Premarket Scientific Evaluation

The Saudi Food and Drug Authority (SFDA) has implemented a comprehensive multi-step premarket process for regulating medical devices in Saudi Arabia. This process guarantees that all devices meet essential safety, quality, and performance standards before they can be launched in the market. As part of this process, the technical files for each device undergo a scientific evaluation and assessment to ensure that the device's components and intended use comply with the relevant safety and quality regulations **(Figure 2).**

Medical Device Marketing Authorization Requirements that shall be maintained and provided within the device's technical files

- Device Description and Specification, Including Variants and Accessories.
- Information to be Supplied by the Manufacturer.
- Design and Manufacturing Information.
- Essential Principles of Safety and Performance.
- Benefit-Risk Analysis and Risk Management.
- Product Verification and Validation.
- Post Market Surveillance Plan.
- Periodic Safety Update Report (PSUR) and Post-Market Surveillance Report

5.4 Post-Market Regulatory Activities

SFDA has a set of activities to monitor medical devices after they are released on the market, to ensure the safety and performance of the medical device, and to prevent any optional risks from the devices. Moreover, SFDA publishes and shares many safety communication contents with healthcare providers and public users that can provide helpful recommendations and advice that enhance the safety of medical devices during use.

SFDA Post market Activities consist of a proactive and reactive process such as:

- Investigating adverse events and complaints.
- Issuing safety alerts and following up the implementation of any related preventive and corrective action.

- Safety analysis and risk management.
- Conduct and Review Post market Clinical evaluation studies

5.5 Regulation And Approval of Diabetes Medical Devices

The Saudi Food and Drug Authority (SFDA) plays a crucial role in regulating advanced medical devices and treatments for diabetes, ensuring they meet the highest safety, efficacy, and quality standards. The SFDA is responsible for evaluating and approving a wide range of devices used in diabetes management, including blood glucose monitors, insulin pumps, and continuous glucose monitoring (CGM) systems. These devices are essential tools for patients, enabling them to manage their condition effectively and improve their quality of life. This includes regulating remote monitoring devices for chronic conditions like diabetes, which can improve patient outcomes and reduce the burden on healthcare systems.

Beyond the marketing authorization approvals, the SFDA continues to monitor the safety and performance of medical devices post-market, ensuring they maintain regulatory compliance over time. This ongoing oversight is particularly important for diabetes-related devices, which are used widely and must remain reliable and safe. The National Center for Medical Devices Reporting (NCMDR) plays a vital role in investigating adverse events and complaints related to these diabetic devices, allowing the SFDA to promptly address any safety concerns and ensure that patients receive the best possible care.

During the period (2021 till Oct. 2024), the National Center of Medical Device Reporting has received and investigated 427 complaints and adverse events related to home use of diabetic devices. Moreover, 253 safety alerts have been published and shared with healthcare providers with advice and recommendations to prevent any associated risks.

5.6 Future Trends: Focus On Digital Health and Remote Monitoring

Looking toward the future, the SFDA is increasingly focused on the growing field of digital health and remote monitoring; with advancements in telemedicine, Artificial intelligence, and wearable health technologies, the SFDA aims to create a regulatory framework that accommodates these innovations while ensuring safety and efficacy. As digital health technologies continue to evolve, the SFDA will play an essential role in ensuring that Saudi Arabia remains at the forefront of healthcare innovation, providing safe, reliable, and effective solutions for the nation's health needs.

Through its robust and coherent regulatory processes, the SFDA continues to enhance the quality of healthcare in Saudi Arabia, supporting the Kingdom's Vision 2030 goals of fostering a healthier, more prosperous society.

6) Patients' Journey to Diabetes Digital Solutions: Navigating the Accessibility Framework in Saudi Arabia

The journey of people living with diabetes to accessing diabetes technology in Saudi Arabia varies significantly depending on whether they are treated in the public or private health sector. Figure 3 demonstrates the typical pathway to insulin pump therapy for people with diabetes in Saudi Arabia. As of now, the pathway to acquiring CGMs is not streamlined neither in the private nor the public health sector. Most insurance companies and public clinics develop their own guidelines for who is eligible for CGMs. These guidelines can vary significantly as a result of the lack of national guidance. In this section, we highlight the strengths and limitations of the public and private health sectors in Saudi Arabia and how this may impact the patient journey to diabetes technology.

6.1 Public Sector:

As of today, most people with diabetes in Saudi Arabia are cared for by the public healthcare sector, where they benefit from free healthcare services, including diabetes management and some basic digital health solutions. However, they often face longer waiting times, limited access to advanced diabetes digital solutions, and potential bureaucratic hurdles in obtaining advanced innovations such as automated insulin delivery (AID) systems and continuous glucose monitors. Many diabetes centers in the public sector do not offer insulin pump therapy. A very few clinics offer a limited number of insulin pumps, and these are mostly open loop pumps (as opposed to AID systems). Local experts estimate the utilization rate of insulin pumps among people living with T1D in Saudi to be less than 1-3%. Due to the limited availability of insulin pumps in the public clinics and the long waiting list of patients, public clinics often develop very stringent criteria for people with T1D who are eligible for insulin pumps. These criteria may include having a hemoglobin A1C of less than 7 or 7.5% for example, excluding patients with diabetes who live with poorly controlled glucose and may arguably be in more need for insulin pumps.

Likewise, CGMs are available in limited quantities in the public healthcare sector and is only dispensed by endocrinologists or family physicians/internists who have additional training in diabetes. Interruption of CGM supply is a frequent issue that people with diabetes face in the public sector. As it is the case for insulin pumps, public clinics have their own stringent criteria for dispensing CGMs, albeit more relaxed criteria than those used for insulin pump therapy.

6.2 Private Sector:

The private sector, on the other hand, offers quicker access to diabetes management and advanced diabetes technologies. While insurance coverage in the private sector is often perceived as advantageous, it can sometimes paradoxically become a significant barrier to accessing diabetes technology devices and may negatively impact patients' overall health. Despite the potential for more comprehensive coverage, private insurers may implement stringent criteria and complex approval processes for diabetes digital solutions including CGMs and insulin pumps. These barriers can include restrictive eligibility requirements, caps on coverage for specific devices, or excluding diabetes technology devices from the insurance policy. To regulate this, the CHI has issued a policy for insurance coverage of insulin pumps **(Figure 4)**. This policy, however, has several limitations and is expected to be updated soon. For instance, people with T1D who are older than 12 years of age are required to have a hemoglobin A1C of 8.5% or greater for at least two consecutive times in addition to having one or more other criteria to be eligible for insulin pump therapy **(Figure 4).**

Likewise, insurance coverage for CGMs is limited in many insurance companies and there is no official guidance by CHI on who among people with diabetes should be reimbursed for CGM. This gap in policy has been realized and is expected to be addressed by CHI in the near future.

7) Navigating Reimbursement for Diabetes Digital Solutions in Saudi Arabia

The number of people with diabetes in Saudi Arabia who are getting health insurance is on an upward trajectory **(Figure 5)**. Therefore, the establishment of comprehensive policies and regulations governing health insurance has become a pressing matter.

7.1 The Council of Health Insurance (CHI) Role:

The Council of Health Insurance (CHI), a Saudi governmental body established in 1999 by Royal Decree No. M/10, oversees and regulates the cooperative health insurance system. Its vision is to become an international leader in preventing and improving the value of healthcare services for insurance beneficiaries. Its mission is to enhance beneficiaries' health through a regulatory environment focused on prevention and enabling stakeholders to promote equity, transparency, and value-based healthcare. In late 2023, Cabinet Resolution No. (85) adjusted CHI's mandate. The Insurance Authority now exercises all competencies related to the insurance sector, including those outlined in the Cooperative Health Insurance Law and the Insurance Companies Control Law. Until a new insurance bylaw is implemented, the IA will continue to operate under existing regulations, rules, and instructions.

CHI's Role:

- Implementing mandatory health insurance.
- Identifying those eligible for mandatory coverage.
- Approving and qualifying healthcare providers Supervising the operation of the NPHIES platform (SHIB):

NPHIES is a unified electronic service platform which is Saudi Arabia's National Platform for Health and Insurance Exchange Services launched by the Cooperative Health Insurance Council (CHI) and the National Center for Health Information (NHIC) and led by the Sehati Company. NPHIES is a comprehensive digital solution designed to modernize the healthcare sector by facilitating real-time information sharing and automated claim processing and aims to improve healthcare delivery and patients' outcomes.

The NPHIES platform enables seamless communication between healthcare providers, insurance companies, and patients, promoting efficient and coordinated care. Its secure and standardized data exchange system ensures the confidentiality and integrity of patient information, while also streamlining administrative processes and reducing paperwork.

Council of Health Insurance (CHI). NPHIES. https://www.chi.gov.sa/

7.2 Essential Benefit Package (EBP):

The EBP, updated in October 2022, outlines coverage for medical devices based on medical necessity and, when available, health technology assessments (HTA). Currently, the EBP includes specific coverage criteria for insulin pumps only. (Essential benefit Package 2022, Chapter 2, Point H). Figure 1 describe the evolution in EBP and the current health insurance background.

While the policy offers open coverage for necessary medical devices, it lacks detailed specifications for medical necessity, potentially leading to coverage gaps and inconsistencies across insurance plans. To address this, CHI is currently working on a medical devices formulary to provide unbiased evaluation and coverage criteria, ensuring equitable and efficient access to resources.

7.3 Current Status:

The Council of Cooperative Health Insurance (CHI) has established a unified health insurance policy covering diabetes and its related medical devices, including blood glucose meters, test strips, and insulin pumps. However, specific coverage protocols, such as those for insulin pumps, are required.

7.3.1 Current Gaps and Barriers:

- Lack of detailed coverage guidelines, especially for new technologies.
- Potential gaps in standardized clinical practice guidelines.
- Limited availability of locally published Health Technology Assessment (HTA) studies.

7.3.2 Advancement Needs:

- Standardized clinical practice guidelines for diabetes technologies.
- Cost-reduction strategies.
- locally published HTA studies

7.3.3 Additional Considerations:

- Research on the clinical and economic benefits of advanced diabetes technologies.
- Stakeholder engagement to address challenges and develop solutions.

By addressing these gaps and implementing the suggested advancements, Saudi Arabia can improve diabetes management and enhance the quality of life for individuals with diabetes.

8) Insights From Global Strategies and Best Practices

Globally, the coverage and accessibility of diabetes digital solutions such as CGMs and insulin pumps remain a complex issue. While these technologies have proven to significantly improve diabetes management and quality of life for many patients, their adoption is often hindered by factors such as high costs, limited healthcare budgets, varying reimbursement policies, and limited specialized healthcare professionals and diabetes centers. Many countries are grappling with the challenge of balancing the potential long-term health benefits and cost savings of these technologies against their immediate financial impact on healthcare systems (29;30;31). As a result, eligibility criteria for coverage often prioritize specific groups of patients, such as those with poorly controlled diabetes, recurrent acute or chronic complications, … etc. (32;33). The disparity in access to diabetes digital solutions not only exists between countries but also within countries, reflecting broader socioeconomic inequalities in healthcare access. As diabetes prevalence continues to rise globally, policymakers and healthcare systems in developed countries started to realize the need to adopt the strategy of "paying more upfront for future savings". As a result, insurance coverage for these technologies and public sector support have been recently broaden in many countries to make these life-changing technologies more widely available to those who need them most **(Tables 4 and 5)**

For instance, the National Health Service (NHS) in the United Kingdom provides CGMs and insulin pumps free of charge to eligible patients, based on clinical need and specific criteria set by the National Institute for Health and Care Excellence (NICE). In December 2023, the National Institute for Health and Care Excellence recommended that automated insulin delivery systems should be rolled-out in a phased implementation, over the next 5 years to thousands of people with type 1 diabetes. The eligibility criteria for insulin pump therapy are very inclusive and include: A) adults with hemoglobin A1C of 7.5% or greater or have disabling hypoglycemia despite best possible management with at least one of the following: 1) traditional insulin pump, 2) real-time CGM, or 3) intermittently-scanned CGM; B) Children or young people (under 18 years old) with type 1 diabetes; or women with type 1 diabetes who are pregnant or planning to become pregnant.

In the United States, coverage for Continuous Glucose Monitors (CGMs) and insulin pumps varies among private insurance plans, with many requiring prior authorization and documentation of medical necessity. Medicare covers CGMs for qualifying patients, while coverage for insulin pumps is typically more widespread. Likewise, Australia's healthcare system, through the National Diabetes Services Scheme (NDSS), subsidizes CGMs for people under 21 years old with type 1 diabetes and some adults who meet specific criteria. Insulin pumps are covered under private health insurance in Australia, with some government assistance available for children.

Despite these more relaxed regulations and policies, access to diabetes digital solutions in developed countries can still be challenging due to varying eligibility criteria, lack of digital health awareness, and regional disparities in healthcare delivery. (34;35;36;37;38;39)

9) Roadmap to Improving Accessibility to Diabetes Digital Health in Saudi Arabia

Both the public and private healthcare sectors in Saudi Arabia have made strides in improving diabetes care, but challenges remain in ensuring equitable access to diabetes technology across the country. The public sector's strength lies in its broad reach and affordability, while the private sector excels in offering rapid access to innovations. Bridging the gap between these two sectors, improving coordination, and addressing the barriers to access to diabetes digital solutions in both sectors is crucial in improving the overall quality of diabetes care, reducing the health and economic burden of diabetes on individuals and the overall healthcare system. The current disconnects between the two health sectors and gaps in their policies not only frustrate patients and healthcare professionals but also undermine the potential health benefits and long-term cost savings that these digital solutions can offer.

We believe that the Saudi healthcare system needs to address several barriers impeding access to digital health solutions for diabetes management including the following **(Table 6):**

1) High cost of technology: The cost of diabetes technologies like CGMs and insulin pumps can be prohibitive, making it difficult for those with lower socioeconomic status to access these solutions . With millions of people living with diabetes in Saudi Arabia, the country's purchasing power creates a substantial market for diabetes management and diabetes technologies. This leverage allows the government and private insurances to negotiate prices, influence product penetration into the country, and shape the industry standards.

2) Shortage of endocrinologists, diabetologists, and specialized healthcare professionals:

National initiatives are needed to expand the workforce of endocrinologists, diabetologists, diabetes educators, and dietitians. This can be achieved by incentivizing medical graduates who pursue these specialties of training. In addition, diabetes technology training programs are needed to increase the workforce of healthcare professionals with experience in diabetes digital health. Moreover, endocrinologists,

diabetologists, diabetes educators, and dietitians who utilize diabetes digital tools in their clinics should be allowed to bill for services such as CGM and pump initiation, reading and interpreting CGM and pump reports, and other technology related clinical services. Likewise, a policy that mandates insurance coverage for diabetes educator visits is crucial to ensure the effective and safe use of diabetes digital solutions.

3) Limited awareness about the availability, benefits, and effective utilization of diabetes digital solutions: There's a need to educate both healthcare providers and patients about the benefits and effective use of diabetes digital solutions . Insurance coverage policies could potentially include provisions for education and training programs.

4) Lack of comprehensive policies and regulations to facilitate the accessibility of diabetes digital solutions: Strategies and policies that promote the accessibility and affordability of diabetes technology in Saudi Arabia are needed. It is crucial to develop quality and safety standards that ensure the safe and effective use of diabetes digital solutions in Saudi Arabia. This can be accomplished by leveraging real-world evidence, pre-SFDA approval studies, and post-marketing surveillance, which are firmly rooted in SFDA's requirements and processes. In addition, it is recommended that a patient registry be established to enhance data collection and clinical insights (27)

5) Limited local studies that examine the clinical and cost-effectiveness of diabetes digital solutions in Saudi Arabia: There is a clear gap in the generation of evidence related to diabetes digital health within Saudi Arabia. It is of high priority to capitalize on the country's well-established digital infrastructure and foster partnerships between industry, academic institutions, and research centers. These partnerships should focus on conducting local clinical trials and real-world studies to evaluate the safety, effectiveness, clinical outcomes, and cost efficiency of diabetes digital health solutions. These studies can be part of the pre- and post-SFDA approval processes.

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"MA has served on an advisory panel for Medtronic, Insulet, Abbott, VitalAire, SYAI, Vertex, Karaz, Sanofi, and Dexcom; has received honoraria for speaking from Abbott, Eli Lilly, Medtronic, Novo Nordisk, Sanofi, VitalAire; and has received research support from Medtronic and Sanofi"

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Table 1: Key features of SFDA-approved CGMs

	FreeStyle Libre 2	FreeStyle Libre 3	Dexcom G6	Dexcom G7	Dexcom One+	Guardian Connect	Sibionics	AIDEX	RIGHTEST iFree	Sincare iCan	Sugar BEAT (Company	POCTech
Approved Age for use, years	4 and older	4 and older	2 and older	2 and older	2 and older	7	18 and older	12	18 and older	18 and older	18-70 years old	14 years and older
Warm-up time (hrs)	1	1	2	0.5	0.5	2	1	1	2	2	1	1
Maximum wear time (days)	14	14	10	10.5	10.5	7	14	14	14	15	14	14
Calibrations required (# per day)	0	0	0	0	0	0	0	0	2 calibration during warm-up and 1 calibration/day)	0	Daily	Daily
SFDA-cleared sites	Upper arm	Upper arm	abdomen & back of the upper arm (indicated for patients age 2 years & older) or the upper buttocks (ages 2-17 years)	abdomen, back of the upper arms for all; and upper buttocks for 2-6 years old	abdomen, back of the upper arms for all; and upper buttocks for 2-6 years old	abdomen and back of Upper arm (14+); abdomen and upper buttocks (7-13)		Abdomen and upper arm	Arm	abdomen	Upper arm	Upper arm or middle abdomen

Approved in Pregnancy (US FDA, SFDA, EMA)	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No
MARD, %	9.2	7.8	9	8.2	8.2	10.9	8.83	9.08	8.80%	8.71%	11.92 %	9.6%
Display device	Smartphone or reader	Smartphone or reader	Smartphone or reader	Smartphone or reader	Smartphone or reader	Smartphone only	Smartphone and reader	Smartphone or reader	Smartphone	Smartphone	Smartphone	Receiver
Drug interactions	Vit C >500 mg/day	Vit C >500 mg/day	Hydroxyurea	Hydroxyurea	Hydroxyurea	Acetaminophen and hydroxyurea	Possible acetylsalicylic acid, ascorbic acid	Unknown	Unknown	Unknown	Unknown	
Integration with insulin pumps, smart pens, caps	No	Yes	t:slim X2	t:slim X2, OmniPod 5, NovoPen 6, and InPen	**No**	InPen	No	Equil Insulin Pump	No	**No**	**No**	**No**
All-in-One sensor and transmitter (one piece)	Yes	Yes	No	Yes	Yes	No	Yes	No	No	**No**	**No**	**No**
Estimated Cost	$	$	$$	$$	$	$$	$	$	$	$	$	$

Table 2: Key features of SFDA-approved insulin pumps`

	Automated Insulin Delivery (AID) Systems "*Artificial Pancreas*"				Open Loop (Manual) Pumps		
	OmniPod 5	Medtronic MiniMed 780G	Tandem X2 Control-IQ	Medtrum	OmniPod Dash	Accucheck Solo	Equil Patch Pump
Automated Basal Insulin Adjustment	Yes	Yes	Yes	Yes	No	No	No
Automated Correctional Doses	No	Yes	Yes	Yes	No	No	No
Target glucose for automated basal adjustment	110, 120, 130, 140, or 150 mg/dl	100, 110, 120 mg/dl	112.5-160 mg/dl	100, 110, 120 mg/dl	N/A	N/A	N/A
Optional Higher glucose target	150 mg/dl (Activity Mode Target)	150 mg/dl (Temp target)	140-160 mg/dl (Exercise target)	Yes	N/A	N/A	N/A
Optional Lower glucose target	none	none	112.5-120 mg/dl (sleep mode)	Yes	N/A	N/A	N/A
Maximum Capacity (Units of insulin)	200	300	300	200	200	200	200
Wear time (days)	3	3	3	3	3	3	3
CGM compatibility	Dexcom G6	Guardian 4	Dexcom G6 & G7	Medtrum sensor	No integration	No integration	No integration
Updatable Pump Software	Yes	Yes	Yes	Yes	No	No	No
Tubes	No (Patch Pump)	Yes	Yes	No (Patch Pump)	No (patch pump)	No (patch pump)	No (Patch Pump)
Re-charge required	the controller is rechargeable	Battery	Recharge (Micro USB)	Batteries	PDM is rechargeable	The diabetes manager needs to be charged every 2-3 days	Batteries
Approved Age for use, years	2 years	7 years & using 8 units/day or more	6 years	2 years	All ages	2 years	14 years
Cost	Has not been determined	$$$	$$$	$$	$	$	$

Table 3: Summary of local studies examining the effectiveness and safety of CGMs and Insulin Pumps in Saudi Arabia

Continuous Glucose Monitors (CGMs)							
Author/ Year of publication	Study Design/ follow- up	Number of Participants Intervention/Control	Age	Primary Endpoint/Objective/Outcome	Result	Conclusion	Limitation
Ayman A Al Hayek/ 2019 (15)	prospective study/12 weeks	33 with T1D using flash glucose monitoring (n:10 on insulin pump -n: 23 on MDI)	14–21 years	satisfaction and well-being by use Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the WHO-5 Well-Being Index (WHO-5)Questionnaire	Mean satisfaction score increased from 14.4 at baseline to 32.1 after 12 weeks. the overall well-being percentage score increased from 45.1% at baseline to 93.6%after 12 weeks ($p < 0.001$).	FSL usage in T1D increased satisfaction and a well-being compared with the SMBS	1-Lack of Control Group. 2-Small Sample Size 3-Single-Center Design 4-Observational study
Sahar Alharthi / 2021 (16)	Retrospective study/ 6 weeks	101/ T1D divided to 1-Attending telemedicine clinic (n: 41 2-Not attended (n:40)	median age of 23 years	Improvement in glycemic control metrics	Who are attended the clinic: Reduced average glucose from (180 to 159 mg/dl), GMI improved (from 7.7% to 7.2%), TIR increased from (46% to 55%), who are not attended the clinic no significant changes in glycemic control.	effectiveness of telemedicine in T1D using CGM	1-Short Follow-Up Period. 2-Selection bias in one center
Ayman A Al Hayek/ 2021 (27)	Prospective Study-Single cohort study/12 weeks	47/ T1D using insulin pump	13-21 years	diabetes self-management behaviors and glycemic indicators before and after the implementation of the FSL2 system	Baseline: HbA1c level was 8.3%, at 12 weeks: 7.9% (p = 0.064). TIR was 59.8 ± 12.6%, TAR 32.7 ± 11.6%, TBR 7.5 ± 4.3%, mean glycemic variability, standard deviation 63.2 ± 12.5 mg/dL, and the coefficient of variation 41.3 ± 11.4%. Total diabetes self-management score at the baseline 2.7 reaching 6.4 after 12 weeks. (p< 0.001)	Improved Diabetes self-management +Glycemic Control	1-Short Follow-up Duration: 2-Dropout Not Mentioned. 3-Limited Risk Factors Assessed, 4- Single and observational study

Ayman A Al Hayek/ 2021 (17)	Prospective Study- Single cohort study/12 weeks	52/T2D on MDI using FSM2	20-75 years	Change of A1C and Satisfaction after FDM2 insertion	HbA1c improved by 0.44% from 8.22%±0.69 (mean at baseline to 7.78% at 12 weeks, p<0.001 Two-fold, statistically significant improvement in glucose monitory satisfaction survey, and double in total treatment satisfaction	glycemic control and satisfaction are clinically significant after insertion FSL2	1- Not controlled cofounders. 2- type of the study. 3- Lack of control group and one center research.
Mohammed Alharbi/ 2022 (28)	Observational study	6,097 readers and 35,747 sensors.	No specific age	Correlation between number of scanning with HbA1C, TIR, Glucose metrics	Highest scanning frequency (32 scans/day) achieved 8.47% HbA1c, 46.4% TIR, 75.0 mg/dL SD; lowest (5.2 scans/day) 9.77%, 32.8%, 94.9.	All parameters of diabetes control are improved with higher numbers of scanning	1-Lack of demographic and clinical data, e.g age- type of diabetes 2- Absence of longitudinal analysis
Ibtihal Alyusuf/ 2022 (40)	Observational study/12 months	116 / TID 35% on insulin pump using FGM1	Mean age 26 years	Number of scanning to glycemic indices	1-Frequent scanning >10 scan/day: TIR: Increased from 43.5% to 54.5% at month 6 and to 49% at month 12. TAR: Decreased from 49% to 40.5% at month 6 and 45% at month 12. 2-Infrequent scanning **TIR** (42% to 52%) and **TAR** (51% to 44%) were noted only by month 12:	frequent scanning linked to faster and more substantial improvements of glucose control.	1- Unmeasured Factors as Behavioral, psychosocial were not assessed 2- retrospective study, single center.
Mohammed Alharbi/ 2022 (13)	Retrospective cohort study/Multicenter(32) /	1307/T1D	4-18 years	HbA1C at 3, 6 and 9 months	Baseline HbA1C 10.8% reduced to 9.8% at 3 months, 9.2% at 6 months and 9.1% at 9 months (p <0.001)	flash glucose monitoring significantly reduces HbA1c levels	1-Absence of Detailed Glucose Metric. 2- Limited Clinical Information
Ayman A Al Hayek/ 2023 (18)	Retrospective cohort study/ one year	93 /T2D	Meana age 48 years	effectiveness and sustainability of isCGM in T2DM patients not on	HbA1c improved significantly, from a pre-isCGM mean of 8.3% to 8.1% at 90 days, and further to 7.9% by	use of isCGM helps reduce HbA1c levels in	1-HbA1c Range only(7-10%) 2- Single-

				intensive insulin	the last 90 days (both with p < 0.001)	T2DM patients not on intensive insulin,	Center Design
Majed Alsahli/2024 (14)	Retrospective design/ one year	98/ T1D on MDI using FSL	>14 years	HBA1C, Satisfaction and Quality of life	HbA1C reduced from 9.83% to 8.6%. Satisfaction Over 85% Quality of life: 70.4%	significantly enhance satisfaction, quality of life and glycemic control	1-Lack of a detail adherence to FSM 2-single, observational study
Abdulaziz Altamimi /2024 (41)	Cross-sectional study/ 6 months	317/ T1D	Mean age 34 years	Glycemic control and Quality of life	Baseline a1c mean of 8.79%±1.63%- Ater 3 months; a1c mean of 8.24%±1.30% (p<0.001), and continue for 6 months	CGM significantly improved diabetes control, while improved quality of life was not significant.	1- recall bias 2-study design
Insulin Pump							
Auther/ Year of publication	Study Design/ follow- up	Number of Participants Intervention/Control	Age	Primary Endpoint/Objective/Outcome	Result	Conclusion	
Adnan Alshaikh /2020 (19)	Cross-sectional study/ 6 months	68 with T1D/ n:34 on MDI and n: 34 on CSII	0-18 years	Quality of life	Insulin pump group has a significant better scoring in 3 dimensions in Quality of life (Diabetes Problems, Treatment Problems, Worry Problems)	Insulin pump therapy improves quality on life	1-Gender Imbalance. 2-single and observational study 3-lack of longitudinal data
Amir Babiker/ 2022 (20)	Retrospective cohort study/ 3 years(2016-2018)	168 with T1D / n: 129 on MDI and n: 39 on CSII	<18 years	HbA1c at 1-2 and 3 years	CSII lower HbA1c 3-year compare to MDI, follow up period: 8.1% versus 10.1, P-value < .001 at 1 year, 7.5% versus 10.1% at 2 years, P-value < .001, 8.9% versus 10.3% at 3 years, P-value = .033.	Treatment with CSII resulted in lower HbA1c compared to MDI, which was continued to a 3-year period	1-Small numbers compared to control. 2-single tertiary center not represent the community 3 - retrospective 3 years introduced potential bias

Nora Brazangi / 2022 (21)	A cross-sectional study	64 with T1D	Mean age 25 years	HbA1C level before and one years after the insulin pump insertion	The average HbA1C before is 9.5 % ± 2; and the average HbA1C after is 8.2 % ± 1.3. HbA1C average is decreased by 1.4 with a p-value <0.001	reduction in HbA1C significantly	1- secondary data extracted from existing records. 2- Not justified other cofounder. 3-single center. 4- not mention type of metronic pump was used
Selmen Wannes / 2022 (23)	case report/two successive Ramadan seasons	shifted from SAP-PGLM (MiniMed 640G) to AHCL (MiniMed 780G)	11 years old	effectiveness of these two insulin delivery systems during fasting	TIR 58% pre Ramadan reach to 60 to 72% in Ramdan in MiniMed 640g in 2021 vs TIR 70% pre Ramadan reach to 75% during Ramadan in MiniMed 780G in 2022 average blood glucose in Ramadan is 183 mg/dl in MiniMed 640G VS 135 mg/dl in MiniMed 780G	AHCL system provides statistically superior glycemic control	1-single-case design. 2- Confounding factors is not address
Selmen Wannes /2023 (24)	Observational cohort study	19 with T1D (n: 8 on MiniMed 670G)+(n: 11on MiniMed780G)	8-16 years	Effectiveness, safety HCL Glycemic control Metrics, through assessment pre-Ramadan and During Ramadan, categorized to fasting 11 vs non fasting 8	11 out 18 are fasted, all patients has the same result pre Ramadan vs Ramadan as: TIR (72.9 ± 8.1 vs. 74.5 ± 6.8, p = 0.17), the same TER (1.6 ± 1.3 % vs. 2.4 ± 2.1, p = 0.076), the same TAR (25.5 ± 8.1 vs. 23.1 ± 6.9, p = 0.062)	no significant different between fasting vs. non-fasting and S-HCL 670G vs. AHCL 780G system during Ramadan	1-the small sample size. 2-lack of control group 3- insulin requirements and dietary habits were not extensively controlled.4 -no long-term follow-up beyond Ramadan to assess the lasting effects of fasting on glycemic c
Nusaybah Alnaim/ 2024 (22)	Retrospective cohort study/2 years(2020-2022)	351 with T1D/n: 316 on MDI and n:35 on CSII	1-14 years	change of A1C for 9 months / events of DKA	The average HbA1c for those on the MDI regimen was 9.6 ± 2.2%, VS 8.8 ± 2.5% for those on CSII, with	use of CSII lead to better glycem	1- patients characteristics not equally distributed.

					a p-value of 0.045 --- DKA, (12%) of patients with diabetes on the MDI regimen experienced DKA, compared to (11.4%) of those on the CSII, p-value :0.9	ic control	2- other cofounder not will adjusted as education, motivation, family support
Mohammed Alsofiani /2024 (25)	Retrospective observational study (Gulf region)	449 with T1D on MiniMed 780G	247 < 15 y (55%) 202 > 15 y(45%)	metrics of glycaemia control before, during after Ramadan	Overall, 1-Pre Ramadan: TIR:71.7%- TAR 25.7%- TER 2.6%. 2- During Ramadan: TIR:70.6%- TAR 27.2%- TER 2.3% 3- 2- After Ramadan: TIR:70.5%- TAR 27.%- TER 2.5% (p <.0001 for all).	MiniMed 780G maintained a reassuring safety profile, with effectiveness	1- missing socio-demographic data 2- Potential Self-Reporting Bias
Mohammed Alsofiani /2024 (26)	prospective, noninterventional study	294 with T1D/ 5 groups:1- AID(n: 62). 2- Conventional pump+MDI(n:37). 3- Pump+SMBS(n:8). 4- MDI+CGM(n:155).5- MDI+SMBS(n:32).	Mean age 22 years	outcomes for different modalities of diabetes treatment during Ramadan	53% of AID users meeting the dual goal of sustained fasting and TIR ≥ 70%, compared to only 3% of conventional pump users and 44% of MDI + CGM users	\AID systems are a safe and the best option for T1D management during Ramadan,	1-Othe Confounding not adjusted as physical activities and dietion habit.

Table 4: Reimbursement Criteria for Continuous Glucose Monitors (CGMs) in the United States, United Kingdom, and Australia

Reimbursement Criteria for Continuous Glucose Monitors (CGMs)	
USA	
Medicare: The following individuals are eligible for Medicare: - 65 years and older - younger people with a disability - People with ESRD	**To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following initial coverage criteria (1)-(5):** 1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and, 2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and, 3. The CGM is prescribed in accordance with its FDA indications for use; and, 4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below: A. The beneficiary is insulin-treated; or, B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article (A52464)): - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or, - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met. **CGM Continued Coverage:** Every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan
Medicaid: The following individuals are eligible for Medicaid: - low-income people and families - children - pregnant - elderly - people with disabilities	**Criteria varies across states. However, the following eligibility criteria are used by most states:** o Diagnosis of Type 1 diabetes or certain cases of Type 2 diabetes o Use of intensive insulin therapy (multiple daily injections or insulin pump) o Frequent blood glucose testing (typically at least 4 times daily) o History of severe hypoglycemia or hypoglycemia unawareness o Demonstrated ability to use and interpret CGM data **Some states have the following additional eligibility criteria:** o An A1C higher than 7 or 8 % o Frequent experiences with severe low blood sugar o CGM prescribed by an endocrinologist
UnitedHealthcare: One of the biggest private health insurance companies in the US (>45 million people). Coverage is typically through businesses such as employer, individual, community, etc	**In general, the following eligibility criteria have to be met:** o Device is used according to FDA labeled indications, contraindications, warnings, and precautions o Medical necessity clinical coverage criteria are met: T1D and T2D on insulin o Individual is assessed by a provider every six months for adherence to the prescribed CGM regimen and treatment plan
UK	

NICE/NHS Publicly funded healthcare system in the UK. The NHS provides a wide range of health services to all legal residents of the UK.	<u>Eligibility criteria for CGM:</u> ***Individuals with T1D:*** o All individuals with T1D are eligible for either intermittently scanned continuous glucose monitoring or real-time continuous glucose monitoring, based on their individual preferences, needs, characteristics, and the functionality of the devices available. ***Individuals with T2D:*** o Individuals with T2D being considered for CGM will need to demonstrate that they meet one of the following eligibility criteria: 1. T2D managed with multiple daily insulin injections and one of the following: a. they have recurrent hypoglycemia or severe hypoglycemia b. they have impaired hypoglycemia awareness c. they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use a CGM device d. they would otherwise be advised to self-measure at least 8 times a day, OR 2. Individuals with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose. ***Pregnant women with T1D or T2D on insulin therapy:*** Offer rtCGM to all pregnant women with T1D to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. Offer isCGM, to pregnant women with T1D who are unable to use rtCGM or express a clear preference for isCGM. **Consider rtCGM for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:** • they have problematic severe hypoglycemia (with or without impaired awareness of hypoglycemia) OR • they have unstable blood glucose levels that are causing concern despite efforts to optimize glycemic control.
Australia	
The National Diabetes Services Scheme (NDSS) NDSS is an initiative of the Australian Government that commenced in 1987 and is administered by Diabetes Australia	**Eligibility expansion for *<u>all people with type 1 diabetes</u>* to access subsidized CGM and Flash GM products through the NDSS** Rollout commencing 1 July 2022

Table 5: Reimbursement Criteria for insulin pumps in the United States and United Kingdom

Reimbursement Criteria for insulin pumps	
USA	
Medicare: The following individuals are eligible for Medicare: - 65 yo and older - younger people with a disability - People with ESRD	Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.) **if criterion A or B is met and if criterion C or D is met:** **A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:** 1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method. 2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory's measurement method. 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl. B. Beta cell autoantibody test is positive. C. The beneficiary has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen: 1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent 2. History of recurring hypoglycemia 3. Wide fluctuations in blood glucose before mealtime 4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL 5. History of severe glycemic excursions D. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment. - Continued coverage of an external insulin pump and supplies requires that the beneficiary be seen and evaluated by the treating practitioner at least every 3 months. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a practitioner who manages multiple beneficiaries on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

Medicaid: The following individuals are eligible for Medicaid: - low-income people and families - children - pregnant - elderly - people with disabilities	**Varies by state. Here is an example from Louisiana Medicaid Program:** The beneficiary has completed a comprehensive diabetes education program and has been on a program of multiple daily injections of insulin (at least three injections per day) with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump; and has documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump; and meets two or more of the following criteria while on the multiple daily injection regimen: 1. Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent; 2. History of recurring hypoglycemia; 3. Wide fluctuations in blood glucose levels (regardless of A1C); 4. Demonstrated microvascular complications; 5. Recurrent severe hypoglycemia; 6. Suboptimal diabetes control (A1C exceeds target range for age); 7. Adolescents with eating disorders; 8. Pregnant adolescents; 9. Ketosis-prone individual 10. Competitive athletes; and 11. Extreme sensitivity to insulin in younger children. **OR** The beneficiary with Type I diabetes has been on a pump prior to enrollment in Medicaid and has documented frequency of glucose self-testing an average of at least four times per day during the month prior to Medicaid enrollment. In addition to meeting Criterion A or B above, the beneficiary with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or must be autoantibody positive (e.g. islet cell autoantibodies (ICA), glutamic acid decarboxylase (GAD65), the 40K fragment of tyrosine phosphatase (IA2), insulin autoantibodies (IAA), or zinc transporter 8 autoantibodies (ZnT8)). **Updated fasting C-peptide testing requirement:** 1. Insulopenia (defined as fasting C-peptide level less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method); and 2. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/dl. **NOTE: Levels only need to be documented once in the medical record** The pump must be ordered by and follow-up care of the beneficiary must be managed by a physician who has familiarity with continuous subcutaneous insulin infusion (CSII) and who works closely with a team of nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII.
UnitedHealthcare: One of the biggest private health insurance companies in the US (>45 million people). Coverage is typically through businesses such as employer, individual, community, etc.	External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes. Note: Programmable disposable external insulin pumps (e.g., Omnipod) are considered clinically equivalent to standard insulin pumps.

UK	
NICE/NHS Publicly funded healthcare system in the UK. The NHS provides a wide range of health services to all legal residents of the UK.	**Hybrid closed loop (HCL) systems are for:** o adults living with type 1 diabetes who have an HbA1c of 58 mmol/mol (7.5%) or higher, or have disabling hypoglycemia despite best possible management with at least one of the following: • continuous subcutaneous insulin infusion (CSII) • real-time CGM • intermittently scanned CGM o children and young people (under 18 years old) living with type 1 diabetes women, trans men and non-binary people living with type 1 diabetes who are pregnant or planning to become pregnant. The first phase of the roll-out to NHS integrated care systems will begin from April 2024.

Table 6: Current barriers to accessing diabetes digital solutions in Saudi Arabia and proposed strategies to overcome these barriers

Barrier	Proposed Strategies
1) High Cost of technology	1) Utilize the Saudi's purchasing power, considering the high number of people living with diabetes in Saudi Arabia. This purchasing power creates a substantial market for diabetes management and diabetes technologies. This leverage provides the government and private insurances with purchasing power to negotiate prices, influence product penetration into the country, and improve the technology affordability and accessibility. 2) Localize the production of diabetes digital solutions. This could potentially lower the costs of diabetes technology. 3) Increase funding and allocate more resources for the utilization, and eventually local production, of diabetes digital solutions
2) Shortage of endocrinologists, diabetologists, and specialized healthcare professionals	4) Encourage and incentivize medical graduates to pursue Endocrinology as their specialty of training and practice. 5) Establish a diabetes technology training programs for healthcare professionals who are interested in learning more about diabetes digital health 6) Provide incentives to healthcare professionals who utilize diabetes digital tools such as insulin pumps and CGMs (e.g. allow billing for CGM and pump initiation, reading and interpreting CGM and pump reports, etc.) 7) Enforce a policy that mandates insurance coverage for diabetes educator visits
3) Limited awareness about the availability, benefits, and effective utilization of diabetes digital solutions	8) Establish national initiatives aimed at raising the awareness about the benefits and effective use of diabetes technology among healthcare professionals and patients.
4) Lack of comprehensive policies and regulations to facilitate the accessibility of diabetes digital solutions	9) Establish national strategies and policies that promote the accessibility and affordability of diabetes technology 10) Develop quality and safety standards to ensure that diabetes digital solutions used in Saudi are safe and effective (e.g. real-world evidence, patient registries, pre-approval and post-marketing surveillance, etc.) 11) Enforce the concept of real-world evidence and mandate this on industry 12) Leverage the well-established digital infrastructure in Saudi Arabia.
5) Lack of interoperability of diabetes digital solutions and integration with electronic health records (HER)	13) National efforts to establish local standardized data-sharing and HER integration protocols is ongoing but needs to be accelerated.
6) Limited local studies that examine the clinical and cost effectiveness of diabetes digital solutions in Saudi Arabia	14) Foster partnership between industry and academic and research institutions to conduct local clinical trials and real-world studies on the technology safety, effectiveness, clinical outcomes, and cost effectiveness.

Figure 1: The SFDA medical device lifecycle

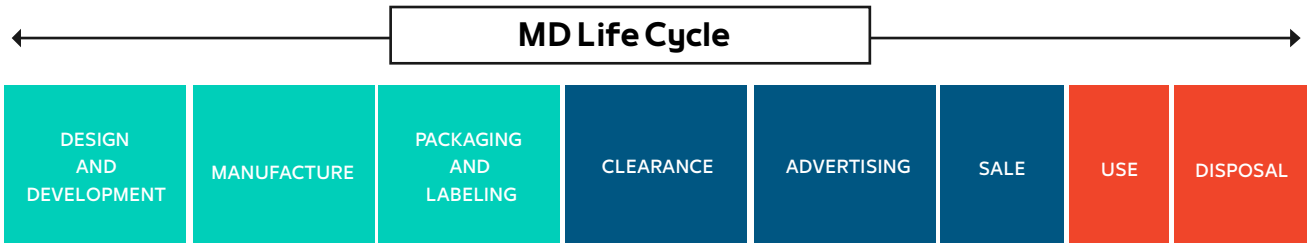


Figure 2: The SFDA scientific evaluation process of each diabetes device to ensure compliance with relevant safety and quality regulations

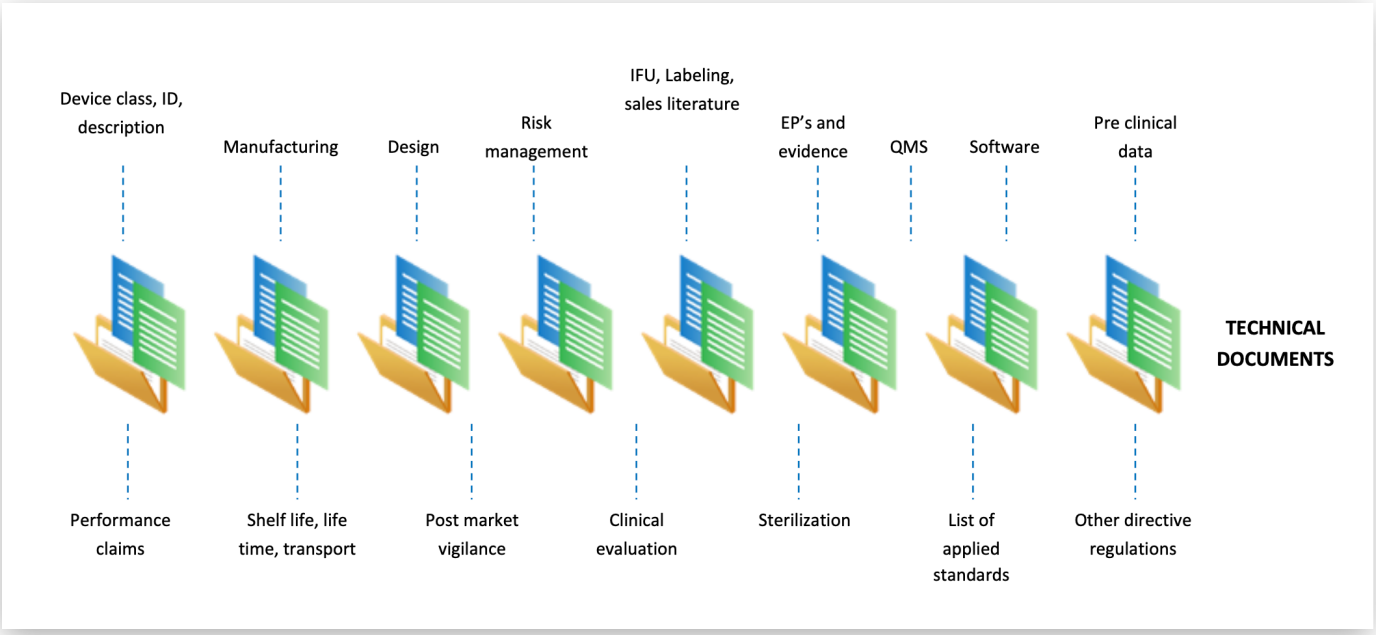


Figure 3: Patients' journey to insulin pump therapy in Saudi Arabia at the moment

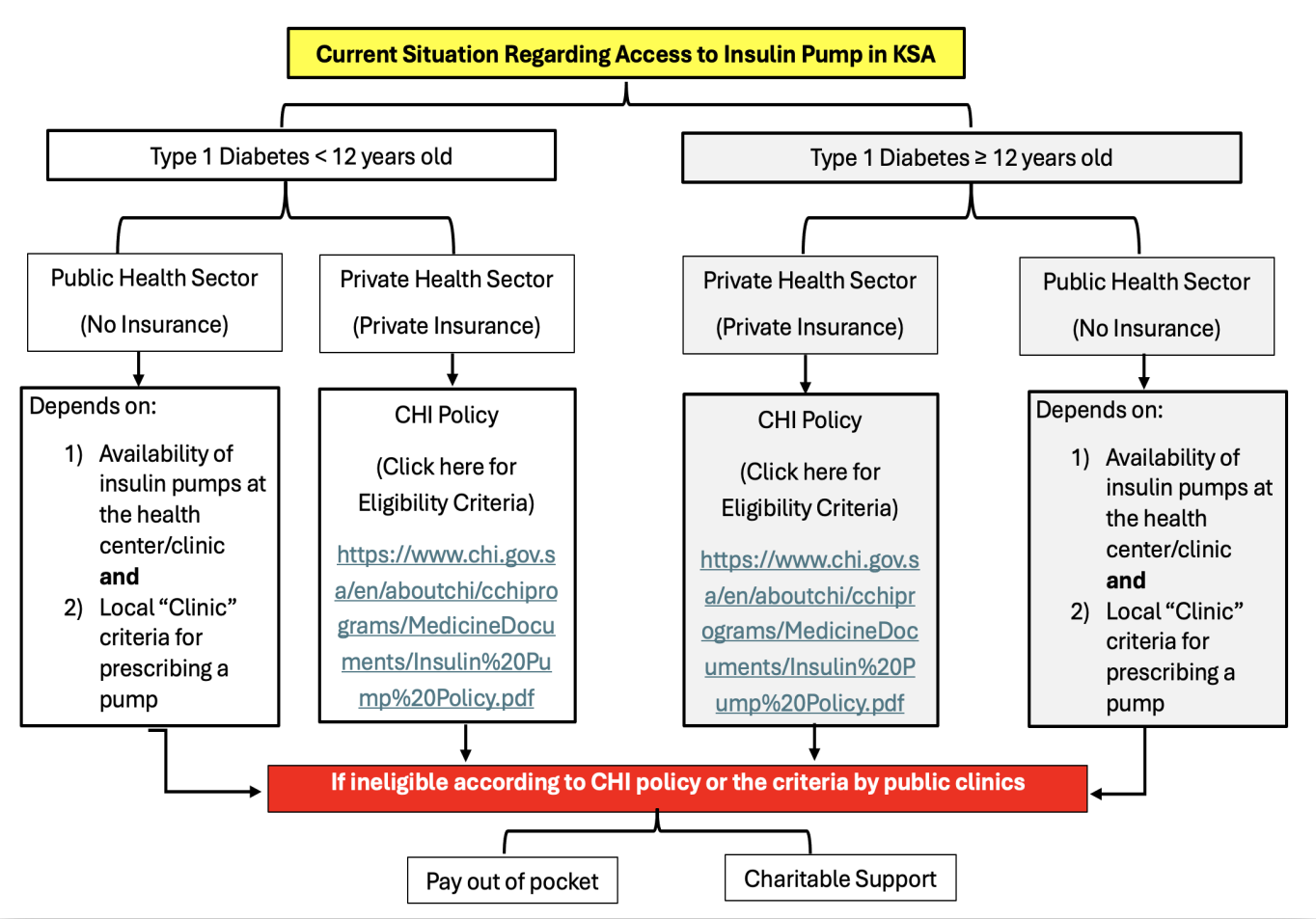


Figure 4: CHI policy used by insurance companies to reimburse insulin pumps in the private sector

INSULINE PUMP POLICY

Policy Outcomes:

The following policy of continuous sub-cutaneous insulin infusion (CSII) therapy are:

1. Improved glycemic control (reduced hemoglobin A1c "HbA1c");
2. Reduced rate of hypoglycemia; and
3. Reduced rate of diabetic ketoacidosis.

1. Purpose:

1.1 Aims and Objectives

An insulin pump therapy needs to:

- Be effective and efficient.
- Be responsive to the needs of patients with type 1 diabetes mellitus (T1DM), their parents and caregivers.
- Provide treatment and care based on best practice, as defined in policy eligibility criteria for T1DM.
- Deliver the required capacity by providing insulin pump therapy for appropriate patients who meet the criteria in this policy.
- Be integrated with other elements of care and services for patients with T1DM.
- Define agreed criteria for referral, and follow local protocols and care pathways for patients with T1DM.
- Be patient-centered and provide equitable access, ensuring that patients are treated with dignity and respect, are fully informed about their care and are able to make decisions about their care in partnership with healthcare professionals.
- Audit the provision of insulin pumps.
- Monitor the number of patients on insulin pump therapy.

2. Policy Scope

2.1 Policy Description:

This policy provides a high-quality insulin pump therapy. CHI defines the key components of a high-quality insulin pump therapy as:

- Identifying patients suitable for insulin pump therapy; and
- Ensuring appropriate composition of the healthcare professional team.

2.1.1 Identifying patients suitable for insulin pump therapy:

Consultant endocrinologist or consultant diabetologist will prescribe insulin pump therapy in line with the criteria based on this policy.

2. Policy Scope

Insulin pump therapy (CSII) is recommended as a treatment option for **adults and children 12 years and older with T1DM** provided that:

1. Documented attempts of treatment with multiple daily injections (MDIs) of insulin (≥ three injections daily) for at least six months before initiation of the insulin pump; and
2. Follow-up with physician with documented frequent blood glucose monitoring frequency during the last two months before initiation of the insulin pump; and
3. Documented multiple adjustments to insulin administration and self-monitoring regimens; and
4. Frequent self-adjustment of insulin dose; and
5. Completed a satisfactory diabetes education-training program including self-care processes and follow-up; and
6. HbA1c levels have remained high (8.5% (69 mmol/mol)) or above on two consecutive readings that include a test taken in the past three months (patients was on MDI therapy including, if appropriate, the use of long-acting insulin analogues).

in addition to meeting one or more of the following criteria:

- Patients experiencing disabling hypoglycaemia (repeated and unpredictable occurrence of hypoglycaemia is associated with a significant impact on patient quality of life); or
- Documented history of recurring hypoglycaemia or diabetic ketoacidosis (DKA) resulting in patient hospitalization: or
- Documented wide fluctuations in blood glucose before mealtime; or
- Documented dawn phenomenon (frequent early morning blood glucose increases) with fasting blood glucose frequently >200 mg/dL; or
- Documented history of severe glycaemic excursions.

Insulin pump therapy is recommended as a treatment option for **children younger than 12 years with TI DM** provided that:

1. MDI therapy is considered impractical or inappropriate; and
2. Children on insulin pumps would be expected to undergo a trial of MDI therapy.

2.1.2 Ensuring appropriate composition of the healthcare professional team:

Insulin pump therapy can be requested and initiated only by consultant endocrinologist or consultant diabetologist who manages multiple patients using insulin pumps and works closely with a highly trained specialist team, which should normally comprise nurses. diabetic educators, and dietitians who are knowledgeable in the use of insulin pumps.

Figure 5: The evolution and projection of the Essential Benefit Package (EBP) in Saudi Arabia.

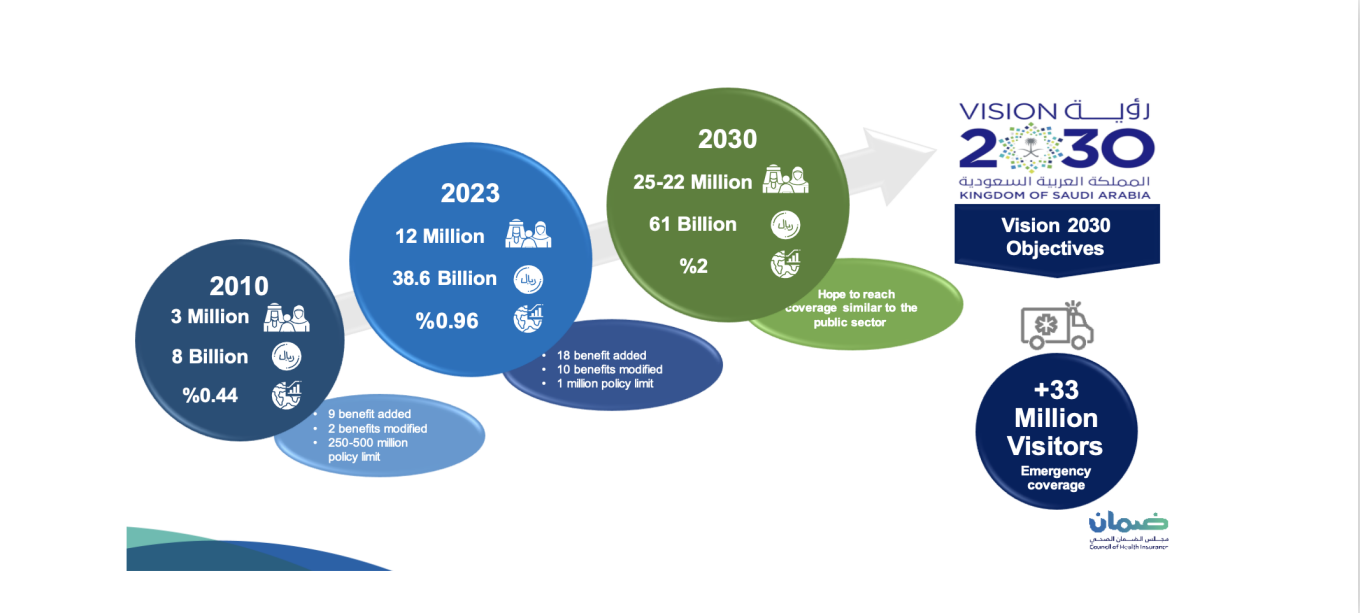
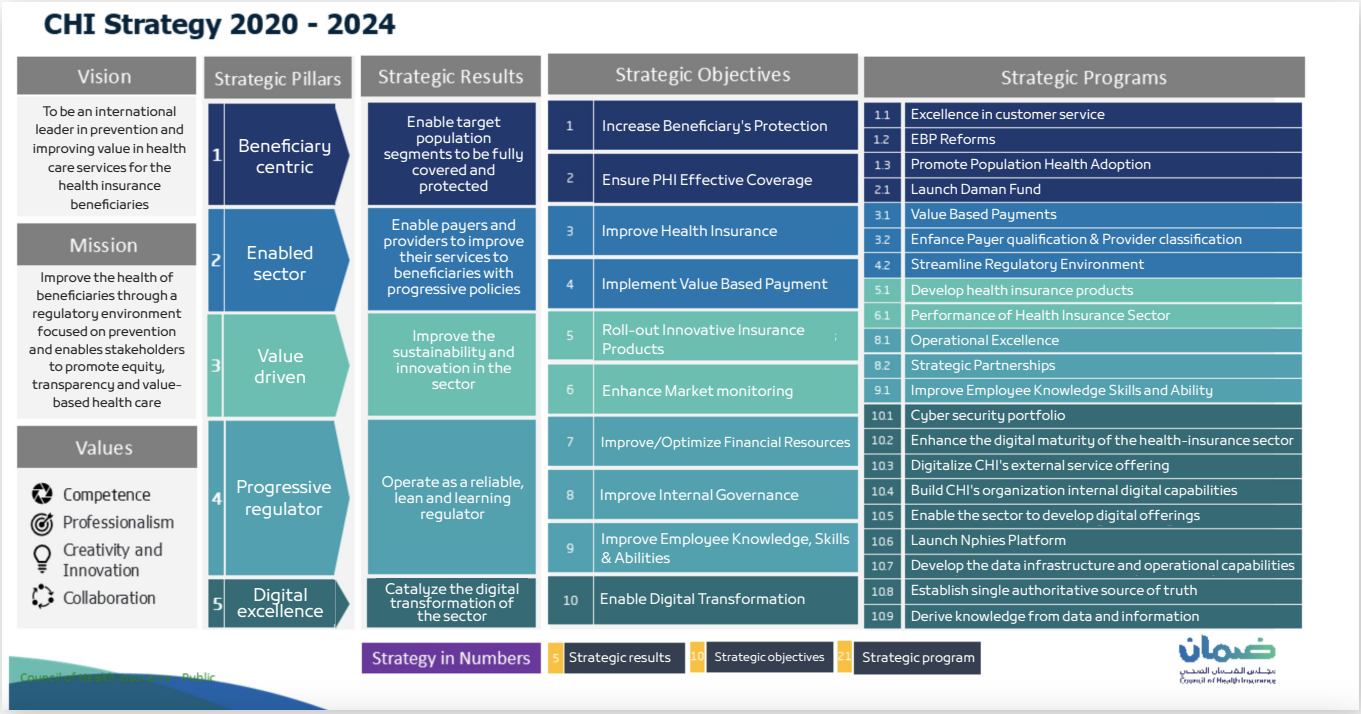


Figure 6: The strategic objectives and programs of the Saudi Counsel of Health Insurance (CHI).



المجلس الصحي السعودي
Saudi Health Council

المركز الوطني للسكري
National Diabetes Canter