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Who Gets Access to Diabetes Technology? – A Quick View on Reimbursement in Selected CEDA Countries

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Modern technologies such as continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) can consistently improve glycaemic control in patients with type 1 and type 2 diabetes. Both technology families have been rapidly developed and still will be in order to enhance accuracy, reliability, comfort and safety of the devices. CGM reduces the risk of hypoglycaemia and facilitates detection of new parameters of glycaemic control such as time in range (TIR), which have shown to improve outcomes in addition to HbA_{1c}. Increasingly insulin pumps have been directly linked to glucose sensors. This development has started with sensor-augmented pumps that interrupt insulin application in (imminent) hypoglycaemia, but are now tightly interlinked in so-called hybrid closed loop systems [McGill 2017, McKnight 2015, Peters 2016, Runge 2018]. Moreover, modern diabetes technology may improve quality of life and reduce the burden of diabetes management [Smith-Palmer 2016].

While medical indications for wide usage of those technologies particularly in the management of insulin-treated patients are quite clear especially in individuals with type 1 diabetes, the reimbursement of those technologies is confined to certain indications mainly due to limited ressources and cost considerations. Hence regulations of payers intend to make diabetes technology available to those in highest need and/or highest benefit by the technology. Reimbursement may hence require specific medical reasons, but may even exclude latest developments at all, if their technological advancement is not considered significant and/or expected cost increase is not considered appropriate.

CEDA Science

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Reimbursement regulations strongly differ by country and health insurance system involved. Here we will provide a quick look into three randomly selected CEDA countries and their regulations to reimburse diabetes technology, for real-time (rtCGM) and intermittent-scanning CGM (isCGM, flash glucose monitoring) as well as insulin pumps.

Poland

The reimbursement system is driven by National Health Fund, however medical indications and contraindications for reimbursement of modern, diabetes-related technologies are listed in guidelines of Diabetes Poland [Araszkiewicz 2021].

CGM

Sensors for rtCGM (up to 4 each month) and transmitters are covered by 70 % of their value and reimbursed for individuals under the age of 26 years with type 1 diabetes and hypoglycaemia unawareness using insulinpumps.

Sensors for isCGM (FreeStyle Libre) are reimbursed for individuals at the age 4–18 years, who measured blood glucose at least 8 times per day and who are willing to scan at least 8 times per day.

Insulin pumps

Indications for insulin pump reimbursement are regulated in detail and limited for patients with type 1 diabetes < 26 years of age for full coverage, whereas 70 % coverage applies for older patients:

1. Early morning hyperglycaemia;
2. Frequent hypoglycaemia episodes including severe hypoglycaemia episodes > 1 per year; hypoglycaemia < 70 mg/dl not requiring help of others ≥ 4 times a week; inability to achieve target HbA_{1c} level without frequent hypoglycaemia episodes, i.e. ≥ 4 times a week, and impaired

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awareness of typical hypoglycaemia symptoms;
3. Persistently elevated HbA_{1c} level > 6.5 % but < 9.0 % despite treatment intensification in a well-educated and adherent patient;
4. Subjects engaged in shift work, with irregular professional activity, or traveling frequently to other time zones, with HbA_{1c} level < 9.0 %;
5. Subjects engaged in competitive sport or undertaking regular intensive physical activity, with HbA_{1c} level < 8.5 %;
6. Children and/or their parents accepting this form of insulin therapy;
7. Continuation of previous treatment with personal insulin pump if no contraindications exist.

In selected cases, the decision on insulin pump purchase reimbursement may be made by the voivodship of the diabetes consultant or the voivodship of the pediatric endocrinology and diabetes consultant after reviewing the patient's medical records and obtaining an opinion of the treating diabetes specialist.

Contraindications for reimbursement of insulin pumps in type 1 diabetes patients include: HbA_{1c} level ≥ 9.0 % on average during the last year, mental and intellectual disorders, eating disorders, addiction to alcohol and psychoactive substances, non-adherence to clinic visits and intensive insulin therapy, more than one episode of ketoacidosis during a year, severe, rapidly progressing proliferative retinopathy, lack of disease acceptance despite full diabetes care and psychologic support, poor personal hygiene, and regular exposure to strong magnetic fields.

Switzerland

In Switzerland there are two important organisations that define recommendations and regulate reimbursement. The Swiss Society for Endocrinology and Diabetes (SGED/SSED) formulates recommendations for the use of new devices [Lehmann 2018], whereas the health authorities of Switzerland (Bundesamt für Gesundheit; BAG) define the limitations for their use and indicate the exact amount of the reimbursement. These limitations for new devices are updated annually or bi-annually in the so called MiGeL (Mittel- und Gegenstandsliste).

CGM

All CGM systems must be prescribed by endocrinologists/diabetologists and reimbursement is to be renewed every 12 months.

The reimbursement of isCGM (Position 21.06 in the MiGeL) is open to all patients with diabetes mellitus (irrespective of type) with intensified insulin treatment. The latter is defined by application of a basal bolus system or insulin pump where the amount of the bolus depends on glucose measurement, carbohydrate ingestion or the physical activity. One glucose reader is reimbursed every 3 years and 27 sensors per year.

rtCGM with alarm function (Position 21.05 in the MiGeL) is indicated when one or more of three conditions are met in insulin-treated patients: HbA_{1c} ≥ 8.0 %, severe hypoglycaemia grade II or III, severe form of brittle diabetes with emergency consultations or hospitalizations. The indications comply roughly with the recommendations of the SGED/SSED, which in additions recommends rtCGM use for diagnostic purpose, and recommends rtCGM use applying personalised HbA_{1c} targets and in situations with very low insulin requirement and huge variations in glucose control, particularly during sleep (e.g. small children).

Insulin pumps

Insulin pump systems (MiGeL position 0.3.02.01.00.2) are indicated for patients with a labile diabetes and/or if an optimal glucose management cannot be achieved with a basal bolus therapy. The indication for this treatment as well as patient care and support must be performed by an endocrinologist/diabetologist or a specialised and qualified center with at least one certified endocrinologist/diabetologist.

The rental fee is generally reimbursed by the health care insurance. However, the most advanced hybrid closed loop systems with a daily amount of 1.13 to 1.56 CHF (1.03 to 1.42 €; MiniMed 780G, Medtronic) or 1.65 CHF (1.51 €; t:slim X2) has to be paid by the patient.

The recommendations of the SGED/SSED for the use of insulin pumps are specified in more detail:
1. HbA_{1c} above the individual target range;
2. High risk for severe hypoglycaemia or hypoglycaemia unawareness;
3. During pregnancy to achieve an optimal HbA_{1c} and optimal glucose levels;
4. In persons with an aversion against daily multiple injections or glucose measurements, in whom despite counseling and education this aversion cannot be overcome.

Austria

Health care is based on a compulsory social insurance including health, which is solidary funded and guarantees the security of care for all people in Austria. Patients fulfilling standardised (not personal) requirements have the right to receive contracted benefits.

CGM

An isCGM system can be prescribed for all people performing basis bolus therapy. The prerequisite is that > 6 glucose measurements are performed daily. For rtCGM systems, there must be an indication and a written application made by a specialist or by a diabetes centre, which has to be approved by a chief physician of the compulsory health insurance. Typical indications are high risk for severe or nocturnal hypoglycaemia, hypoglycaemia unawareness, pregnancy and diabetes complications. The chief physicians of the payers usually accept justifications according to the guidelines of the Austrian Diabetes Association [Schütz-Fuhrmann 2019].

The following products are available in Austria: Dexcom 6 sensors, FreeStyle Libre 1 and 2 sensors, and Enlite sensors.

Insulin pumps

Historically grown and supported by national opinion leaders in diabetology, the right to an insulin pump is given to all people with diabetes who require insulin by basis bolus therapy regardless of the type of diabetes. In principle, this option is primarily used by subjects with type 1 diabetes. The proportion of subjects with diabetes mellitus type 2 and type 3 (mostly cystic fibrosis-related diabetes) is small. The consultation, product selection as well as the prescription must be done by a diabetes centre or a diabetes specialist. The providing company guarantees a functioning product for four years. Thereafter, a new product can be applied for.

Indication for insulin pump reimbursement is not limited to patients with prior daily multiple injections. Similar to CGM, justifications according to the guidelines of the Austrian Diabetes Association are accepted. Classic indications are early morning hyperglycaemia, frequent hypoglycaemia episodes including severe hypoglycaemia episodes > 1 per year, persistently elevated HbA_{1c} level > 6.5 %, shift work, intensive physical activity and children.

In Austria, the following products can be prescribed: Medtronic – MiniMed 640G and 670G; Roche – Accu-Chek Insight, Accu-Chek Combo, Accu-Chek Solo; Omnipod Diabetes Management System; YpsoPump.

In summary, the range of products available in Austria has become smaller. It seems difficult to establish new products through the mandatory insurance processes. In addition, unfortunate company decisions have occurred, such as the recent removal of the Eversense sensor from the Austrian market after a change of the vendor.

Conclusions

Regulations on the access, i.e. reimbursement, of advanced diabetes technology differ considerably in CEDA countries. In addition, there are differences in the percentage of patients' contribution. More importantly, not all breakthrough technologies are available in every CEDA country. E.g., even a „rich" country such as Austria does currently not provide access to the significantly advanced hybrid closed loop system MiniMed 780G. In this regard, small markets as many individual CEDA countries have considerable disadvantages in cost negotiations with worldwide marketing companies. Therefore, we as diabetes specialists have to demonstrate the added value of up-to-date diabetes technology before regulatory authorities and payers based on scientific data in order to make these advancements available to the subjects with diabetes we care for. Discussions to expand reimbursement for both CGM and insulin pumps for indications and/or devices not covered yet may have been compromised during the COVID-19 pandemic, but we keep being ready to stand up for our patients.

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