

Supplementary Materials (I)

Cost-effectiveness analysis of CGM systems

In comparison with glucometers, rtCGM systems are a more expensive solution for patients. Currently, they are partially reimbursed in Poland [1]. Different reimbursement criteria apply to the FreeStyle Libre 2 system and other systems. The FreeStyle Libre 2 for children with type 1 or type 3 diabetes, aged 4 to 18 years, is subject to an 80% reimbursement. This level of refund also applies to patients with diabetes who are blind or visually impaired and are treated with insulin. For other patient groups, the reimbursement is 70%. This reimbursement is available to patients with type 1 or type 3 diabetes from the age of 18, patients with type 2 diabetes treated with at least 3 insulin injections per day, women with diabetes during pregnancy and the postpartum period and patients with congenital hyperinsulinism or glycogenosis. The national insurer has introduced limits on reimbursement for strips for patients using the FreeStyle Libre 2 system (25 or 50/month). Once the limit is exceeded, patients temporarily lose coverage for the sensor.

To continue reimbursement the FreeStyle Libre 2 for an adult patient treated with three insulin injections per day, the established requirements must be met at a follow-up visit within 4-6 months. Patient needs to meet the following conditions: sensor activity for at least 75% of the time of use, reimbursement of glucometer strips in a number of no more than 25 pieces on average per month in the period preceding the subsequent order, and metabolic criteria: TIR in the range of 70-180 mg/dl > 70% of the time of use or HbA1c below 7.5% or other therapeutic goals individually determined in cooperation with a doctor. Different groups of patients may have their sensor order extended if they have not exceeded the monthly limit of 50 strips.

Reimbursement for other rtCGM systems is available to a smaller group of patients. Patients with type 1 or 3 diabetes with hypoglycemia unawareness and treated with intensive insulin therapy, patients with congenital hyperinsulinism, or glycogenosis are eligible for reimbursement. Patients receive a 70% reimbursement, but for individuals over 26 years of age, a monthly sensor limit of PLN 510 has been introduced. Strip limits have also been introduced. For 10-day sensors, the limit is 50 strips per month. For 7- or 14-day sensors, the limit is 100 strips per month. For 180-day sensors, the limit is 400 strips per 6 months. Renewal of the order does not require an assessment of metabolic control, as long as compliance with the strip limit is met.

Access to CGM systems varies across Europe. The following describes the reimbursement criteria and availability of FreeStyle Libre sensors for several European countries.

In Slovakia, reimbursement limits apply to various patient groups [2]. The FreeStyle Libre 2 sensor is available for patients. Patients with type 1 diabetes up to 19 years of age are eligible for reimbursement up to a limit of €1,947.50 per year. Patients with type 1 diabetes and hypoglycemia unawareness are eligible for reimbursement of €1,281.25 per year. Adults aged 19 and over with type 1 diabetes treated with MDI or CSII are eligible for reimbursement of €871.25 per year. Pregnant women with type 1 diabetes are eligible for reimbursement of €1,824.50 per year.

Different conditions apply in the neighboring Czech Republic [3]. The FreeStyle Libre 2 system is fully reimbursed for patients with type 1 diabetes. Patients are eligible for reimbursement for 26 sensors per year and one reader every four years. However, patients with type 2 diabetes do not have access to reimbursement. The FreeStyle Libre 2 and FreeStyle Libre 2 Plus sensor versions are available for distribution.

The latest versions of the FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors are available in Germany. Patients with type 1 and type 2 diabetes who use intensive insulin therapy receive reimbursement for the sensors [4]. The patient co-payment is €10 per month for the sensor and €5.99 per month for the reader.

In Austria, patients can use the FreeStyle Libre 2 and FreeStyle Libre 3 sensors [5]. Both sensor versions are reimbursed. The reimbursement criteria that the patient must meet are: intensive insulin therapy using MDI or CSII.

In Italy, FreeStyle Libre 2 and FreeStyle Libre 3 sensors are available for patients [6]. Patients with type 1 or type 2 diabetes treated with insulin are eligible for reimbursement. Reimbursement criteria vary slightly between regions. Some regions assess the occurrence of hypoglycemia episodes or hypoglycemia unawareness, as well as concomitant illnesses. Some regions also allow reimbursement for patients taking oral medications that can cause hypoglycemia. However, patients who do not meet reimbursement criteria can purchase the sensor online and claim a 19% tax refund.

In Ireland, FreeStyle Libre 2 and FreeStyle Libre 3 sensors, as well as FreeStyle 2 Plus and FreeStyle Libre 3 Plus sensors, are available to patients [7]. FreeStyle Libre 2 sensors are reimbursed. Patients with type 1 diabetes are eligible for reimbursement.

In the Netherlands, three sensor versions are available and fully reimbursed [8]. The FreeStyle Libre 2 sensor is reimbursed for patients with type 1 diabetes, patients with type 2 diabetes treated with intensive insulin therapy, and women with type 1 or 2 diabetes before conception and during pregnancy. The FreeStyle Libre 2 Plus and FreeStyle Libre 3 Plus sensors are reimbursed for children with type 1 diabetes, adults with insufficiently controlled type 1 diabetes ($HbA_{1c} > 8\%$; > 64 mmol/mol), patients with type 1 diabetes with severe hypoglycemia episodes or hypoglycemia unawareness, and women with type 1 or 2 diabetes before conception and during pregnancy.

In Denmark, the FreeStyle Libre 2 and FreeStyle Libre 3 sensors, as well as the FreeStyle 2 Plus and FreeStyle Libre 3 Plus, are available [9]. Twenty-eight sensors are reimbursed annually, thanks to support from municipalities. Patients can also apply for reimbursement through the government portal borger.dk [10]. For patients who do not receive financial support, a subscription to the sensors is offered.

In Croatia, the FreeStyle Libre 2 sensor is available and reimbursed [11]. The following groups of people with diabetes are eligible for reimbursement: children from 4 to 18 years of age (after the age of 18, the indications for further use are assessed), people using intensive insulin therapy (at least 4 injections per day) regardless of when the disease was diagnosed and who perform at least 4 measurements per day (application views), pregnant women using insulin therapy (4 or more injections per day), blind people with type 1 or 2 diabetes using insulin, patients after total or distal pancreatic resection, and patients with cystic fibrosis treated with intensive insulin therapy (4 or more injections per day).

In Greece, the FreeStyle Libre 2 and FreeStyle Libre 2 Plus sensors are available and reimbursed [12]. Eligible for reimbursement of the FreeStyle Libre 2 sensor are individuals with type 1 diabetes from the age of 4. The FreeStyle Libre 2 Plus sensor is available from the age of 2, pregnant women with diabetes from the time of diagnosis until as long as necessary after delivery, and individuals with pancreatic diseases (cystic fibrosis, pancreatic cancer) or after pancreatectomy.

In Switzerland, the FreeStyle Libre 2 Plus and FreeStyle Libre 3 Plus sensors are available and reimbursed [13]. Diabetic patients treated with intensive insulin therapy by injection or using an insulin pump are eligible for reimbursement.

Patients with insurance coverage in Slovenia can benefit from reimbursement for the FreeStyle Libre 2 Plus sensor [14]. Reimbursement criteria include diabetes treated with intensive insulin therapy by injection (minimum 4 injections per day) or with an insulin pump, and pregnant women with diabetes treated with insulin. Criteria for extending reimbursement have also been defined. The patient must achieve specific therapeutic goals: $HbA_{1c} > 7\%$ or TIR $> 70\%$, as well as a TBR reduction of $< 4\%$ and avoidance of severe hypoglycemia. A maximum of 26 sensors are available per year. Patients using CGM sensors are limited to one glucose test strip per day for type 2 diabetes, two for type 1 diabetes, and five for pregnant women with diabetes.

In summary, based on the FreeStyle Libre system, both the availability of sensor versions and reimbursement criteria vary across countries. Furthermore, it's worth noting that public health insurers in some countries are introducing extended reimbursement criteria. This approach may motivate patients to improve their metabolic control, but it also impacts access to this glucose monitoring method. In several countries, patients who choose to monitor glucose using the FreeStyle Libre system are subject to a limit on the number of glucose test strips.

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