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Comparison of guidelines for diabetes diagnostics in 2019 and 2024 in Poland and the rights of insured persons to health services, including access to psychological care

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Abstract

This article compares diabetes diagnostics and treatment reimbursement in Poland between 2019 and 2024, highlighting the changes that occurred over these years. The review is based on an analysis of literature covering diabetes classification, diagnosis, complications, and current guidelines. Scientific articles, reviews, and relevant legislation were analyzed. Diagnostic guidelines highlight the use of glycated haemoglobin (HbA1c) and recommend genetic testing for neonatal diabetes. Reimbursements for diabetes treatment, particularly for modern devices and insulin pen needles, have improved. The 2024 guidelines highlight the importance of mental health, recommending regular psychological assessments. Guidelines have become more comprehensive, and reimbursement policies are more extensive, making access to essential therapies easier for patients. These changes aim at improving treatment outcomes and enhancing the quality of life.

Keywords: **diabetes, diagnostics, insulin therapy, metformin, recommendations, vildagliptin**

Słowa klucze: **cukrzyca, diagnostyka, metformina, rekomendacje, terapia insulinowa, wildagliptyna**

Introduction

Diabetes is a disease belonging to the group of metabolic diseases characterized by hyperglycemia, which is the result of abnormalities in its secretion or action [1]. There are types of diabetes: type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), diabetes of known etiology (resulting from genetic defects in insulin action, diseases of the exocrine part of the pancreas, endocrinopathies, diabetes induced by drugs, chemicals, infection, immunological process and coexisting with genetic syndromes), gestational diabetes, diabetes in pregnancy [1, 2]. In 2019, changes were introduced to distinguish 2 additional groups of diabetes – unclassified diabetes and hybrid forms of diabetes (T2DM with a tendency to ketosis and LADA diabetes – slowly developing diabetes of autoimmune origin in adults) [3].

The constantly growing number of patients affected by this disease draws attention to their needs, which means constant medical care. Progress in the treatment of diabetics has increased rapidly in recent years and modern medical devices have been used, which facilitate, among other things, self-monitoring of glycemia. An important aspect is the cost of diabetes treatment, because without appropriate reimbursement, patients may have difficulty paying for, among other things, medications or devices for measuring glycemia, which may result in poor health and reduced quality of life. In addition, early diagnosis, appropriate treatment and monitoring of the disease allow for minimizing the risk of complications, the treatment of which generates high costs [4–7].

This paper compares data on the diagnosis and reimbursement of diabetes treatment in Poland in 2019 and 2024, taking into account the period of the Coronavirus disease 2019 (COVID-19) pandemic included in this period. This was a time when contact with the health service was limited, and as a result, medical check-ups were less frequent and monitoring of the course of diabetes was more difficult. In addition, the development of medical technology over recent years has been a motivator for the introduction of reimbursement so that the financial situation of patients can allow them to purchase medicines and the most modern medical equipment enabling effective control and treatment of diabetes, even during periods of less frequent doctor visits.

Insurance

The National Health Fund (Polish: Narodowy Fundusz Zdrowia, NFZ) manages health insurance in Poland, covering services such as medical consultations, prescription reimbursements, and hospital stays. Health insurance contributions are 9% of declared monthly income, but not less than the average monthly salary. Compulsory and voluntary insured individuals, as well as others meeting specific criteria, are eligible for NFZ benefits.

Private health insurance is growing in popularity, with 4.8 million people opting for it by the end of 2023 – a 14% increase from 2022 – primarily due to faster access to specialist consultations.

Another important body is the Ministry of Health, which publishes reimbursement lists that often include significant changes in the principles of reimbursement of drugs used by diabetics. It is important to note that Poland lacks a uniform legal framework for individuals with diabetes, and obtaining a diagnosis alone does not automatically qualify patients for public support. Diabetics can apply for a disability certificate based on the severity of their condition, which may qualify them for various rehabilitation benefits and partial expense coverage. Those insured with the Social Insurance Institution (Polish: Zakład Ubezpieczeń Społecznych, ZUS) may be eligible for a disability pension if the disease prevents them from working. Additionally, diabetics can apply for medication and medical device reimbursements according to limits set by the Minister of Health [8].

Diagnostics

Most often, patients with undiagnosed diabetes are concerned about their general health, primarily mentioning weakness, drowsiness, increased thirst, polyuria, weight loss not explained by intentional weight loss and skin lesions [9, 10]. The Polish Diabetes Association (PDA) in its 2024 recommendations indicates the need to perform a random blood glucose test – a result of ≥ 200 mg/dl (≥ 11.1 mmol/l) is the basis for diagnosing diabetes in the patient. If the patient does not report characteristic symptoms or when the symptoms coexist with random blood glucose < 200 mg/dl (< 11.1 mmol/l), diabetes can be diagnosed based on: two fasting blood glucose tests in the morning. If two results are ≥ 126 mg/dl (≥ 7.0 mmol/l), they are the basis for diagnosing diabetes. Diabetes can also be diagnosed by a single test of glycated hemoglobin (HbA1c), its value must be ≥ 6.5% (≥ 48 mmol/l).

Screening tests for early diagnosis of T2DM, the PDA in its 2024 recommendations recommend that they be performed every 3 years in all people over 45 years of age, and regardless of age, tests should also be performed in people at risk. These include women with a history of gestational diabetes, with polycystic ovary syndrome, overweight or obese patients, or patients with cardiovascular diseases. The recommendations also indicate the need to perform an oral glucose tolerance test (OGTT) to diagnose diabetes in patients with cystic fibrosis, annually after the age of 10. Diagnosis of diabetes in children in the first 9 months of life requires genetic testing for neonatal diabetes.

Changes in the above diagnostic guidelines compared to the 2019 data include taking into account the HbA1c value and the recommendation to perform genetic testing for neonatal diabetes in the case of diabetes diagnosed in children (in the case of the 2019 recommendations, these were the first 6 months of life).

Hyperglycemia first diagnosed during pregnancy

The most common metabolic complication complicating pregnancy is diabetes, which is why it is so important that patients are informed about the risk of complications with poorly controlled glycemia when planning a pregnancy, especially if they are affected by carbohydrate metabolism disorders [11]. A distinction is made between pregestational diabetes (when a woman already suffering from diabetes becomes pregnant, regardless of its type) and hyperglycemia first diagnosed during pregnancy.

According to the guidelines of the PDA from 2019 and 2024, it is recommended to perform a 75 g OGTT to diagnose gestational diabetes between the 24th and 28th week of pregnancy (in women without risk factors and with normal glycemia in the first test during pregnancy, which should be performed as soon as possible after the diagnosis of pregnancy). To diagnose diabetes in pregnancy, one of the following conditions must be met: fasting glucose ≥ 126 mg/dl (7.0 mmol/l), glucose in the 2nd hour of OGTT ≥ 200 mg/dl (11.1 mmol/l), or random glucose ≥ 200 mg/dl (11.1 mmol/l), when accompanied by clinical symptoms of hyperglycemia. The diagnosis of gestational diabetes is made based on OGTT results and requires meeting one of the following criteria: fasting glucose 92–125 mg/dl (5.1–6.9 mmol/l), in the 60th minute ≥ 180 mg/dl (≥ 10.0 mmol/l), in the 120th minute 153–199 mg/dl (8.5–11 mmol/l). The guidelines from both years maintained the recommendation that in the event of failure of dietary treatment, insulin remains the pharmacological treatment of choice for the treatment of hyperglycemia in pregnancy, and also drew attention to the risk of adverse effects of metformin on the fetus. The development of medical technology prompted the inclusion in the guidelines of the PDA from 2024 of the recommendation to use a continuous glucose monitoring (CGM) system in all pregnant women with pregestational diabetes, as well as its consideration in all pregnant women and the recommendation of systems integrated with pump therapy in women with T1DM. This may help to treat and monitor the disease more effectively, and thus reduce complications for both the woman and her offspring, which in turn will contribute to reducing the costs of treating these implications.

Diabetes Management Medical Equipment

Access to reimbursed medical devices is essential for effective diabetes management in Poland. Reimbursement is granted based on prescriptions from authorized specialists. Often, during the first consultation confirming the diagnosis of diabetes, patients are provided with a free glucometer. Test strips are available without quantity restrictions, though co-payment varies with insulin therapy type. Since 2022, needles for insulin pens are reimbursed for patients with diabetes requiring insulin administration, with a limitation of up to 400 units per year [12]. Insulin pumps are reimbursed for patients under 26 years, and since 2023, pump accessories are also covered for individuals with type 3 diabetes mellitus (T3DM) [13]. Another category of reimbursed medical devices includes glucose monitoring systems, specifically continuous glucose monitoring systems with real-time capabilities (CGM-RT) and flash glucose monitoring (FGM) systems. Since 2019, FGM systems have been eligible for reimbursement in Poland. Starting in 2023, reimbursement is extended to all patients with T1DM, T3DM, and those with "other types of diabetes," including T2DM patients who require more than three insulin injections daily. Doctor can prescribe the medical device using code R.05.02 (formerly code 137.1) for a maximum period of 6 months, enabling the patient to receive up to 13 sensors. Eligibility for reimbursement of FGM under code R.05.01 (formerly code 137) extends to children aged 4–18 with type 1 or T3DM with well-controlled glycemia, women with diabetes during pregnancy and the postpartum period, patients with congenital hyperinsulinemia, and adults with diabetes on insulin therapy who possess a significant disability certificate due to visual impairment [13, 14]. As of January 2024, patients with glycogen storage disorders are eligible for FGM reimbursement, and prior insulin therapy is no longer required for pregnant women and those postpartum [13].

CGM-RT have been reimbursed in Poland since 2018 [12]. As of January 1, 2024, the reimbursement regulations for CGM systems have been revised. The updated criteria for reimbursement now include patients with type 1 or T3DM who require intensive insulin therapy and experience asymptomatic hypoglycemia. Reimbursement is tailored based on patient age and device type, with different intervals for sensors and transmitters. These modifications primarily impact patients over the age of 18, who are now eligible for reimbursement even if they use insulin injection devices; previously, reimbursement was restricted to patients utilizing insulin pumps [13, 15].

In summary of the above information, it is noteworthy that significant changes in the reimbursement policies for medical devices have occurred between 2019 and 2024. For example, insulin pen needles, which were not reimbursed in 2019, are now included under reimbursement [12]. The availability of various medical devices has significantly increased. Additionally, the patient populations eligible for reimbursement for diabetes management have been substantially expanded. An example is the inclusion of patients with glycogen storage diseases, who have been eligible for reimbursement of flash glucose monitoring (FGM) sensors since January 1, 2024 [13, 16]. In 2019, only specialists in diabetology and endocrinology, as well as doctors working in diabetes departments and clinics, could issue prescriptions for reimbursed glucose monitoring devices. As of January 1, 2024, the list of authorized prescribers for reimbursed sensors and transmitters has expanded to include specialists in internal medicine, geriatrics, cardiology, family medicine, pediatrics, perinatology, obstetrics and gynecology, as well as primary care physicians. Additionally, nurses and midwives are now permitted to continue prescriptions [13, 16, 17]. Another significant change between 2019 and 2024 is the revision of the medical device coding system (Table 1) [13, 16, 17].

A medical device intended for patients with diabetes	Code in effect in 2019	Code effective from January 1, 2024
Infusion sets for personal insulin pumps or modules for patch pumps include cannulas, connectors, and tubing or an integrated inserter.	91	R.01.01
Insulin reservoirs intended for personal insulin pumps.	134	R.02.1
CGM-RT that require replacement every 10 or 14 days, or every 6–7 days.	135	R.03.01
CGM-RT are available to diabetics over the age of 26.	135A	R.03.02
CGM sensors, categorized by age groups 18–26 and over 26, are designated for individuals requiring intensive insulin therapy and experiencing hypoglycemia unawareness.	135B	R.03.03
Transmitters for CGM that require replacement every three months.	136	R.04.01
Transmitters that require replacement less frequently than every three months.	136A	R.04.02
Glucose monitoring system sensors (FGM) that provide measurements with an accuracy of ≤10% Mean Absolute Relative Difference (MARD).	137	R.05.01
FGM sensors that effectively replace measurements taken with a glucometer.	137A	R.05.02

Table 1. Comparison of Medical Device Codes for Diabetes in 2019 and 2024

Source: [13, 16].

Insulin Therapy

When considering the changes in the reimbursement of insulin in 2019 and 2024, it is noteworthy that the number of available preparations for patients managing diabetes has been steadily increasing. In January 2019, a new preparation containing insulin glargine – Semglee – was introduced with a 30% reimbursement level, provided that strictly defined indications were met [18].

On May 1, 2019, another long-acting human insulin analogue, Tresiba FlexTouch (insulin degludec), was added to the reimbursement list. This preparation was covered for use in the following cases:

- In the treatment of T1DM in adults
- In T2DM in adult patients treated with Neutral Protamine Hagedorn (NPH) insulin for at least 6 months and with HbA1c levels greater than or equal to 8%.
- In T2DM in adult patients treated with NPH insulin for at least 6 months with documented recurrent episodes of severe or nocturnal hypoglycemia, or for diabetes of known cause.

Another new preparation added to the reimbursement list was Tresiba Penfill (insulin degludec), with the same reimbursement criteria as Tresiba FlexTouch. The reimbursement level for both preparations was set at 30% [19].

In November 2019, two new preparations, Liprolog and Liprolog KwikPen (both containing insulin lispro), were included in the reimbursement list. These preparations were made available at a flat-rate cost for all diabetes patients [20].

In January 2024, the prices of all insulin products remained unchanged. However, Insuman Basal, a suspension for injection (100 IU/ml, 5 SoloStar pens of 3 ml), was removed from the reimbursement list and became available only at full cost after January 1, 2024 [21].

Until the end of June 2024, there were no major changes to the reimbursement list. However, starting July 1, 2024, the Ministry of Health standardized and simplified the existing reimbursement criteria for long-acting insulins. The updated guidelines were less restrictive, removing conditions related to the use of NPH insulin, the presence of hypoglycemia, and strict classification of diabetes types. Additionally, for insulin Levemir, the lower age limit for treatment coverage in children was reduced to 1 year (previously 2 years) [22].

Metformin

The year 2019 did not bring significant changes in the availability of new preparations containing metformin, and their prices remained relatively stable. As of January 2019, no new metformin preparations were added to the reimbursement list, and the existing ones were reimbursed at a flat rate for diabetes treatment [18].

In May 2019, there was a slight increase in patient copayments for metformin-containing drugs such as Siofor, Glucophage, Symformin XR, and Formetic [19].

Similarly, in January 2024, no new metformin preparations were introduced, and the reimbursement levels for the existing ones remained consistent with previous lists [21].

Mental health

Diabetes brings complex physical and psychological challenges to an individuals' life. It is important to remember

Domain / Year	2019	2024	Key change
Diabetes diagnosis	• No HbA1c criterion as a basis for diagnosing diabetes. • Diagnostics of infants up to 6 months of age. • No specific indications for screening. • OGTT used only in specific cases.	• Adding HbA1c ≥ 6.5% as a criterion for diagnosing diabetes. • Diagnosis of infants up to 9 months of age using mandatory genetic tests. • Specific risk groups for whom screening is recommended are highlighted: gestational diabetes, polycystic ovary syndrome (PCOS), obesity, cardiovascular diseases, etc. • OGTT as an annual test in patients with cystic fibrosis over 10 years of age.	• Introduction of new criteria for diagnosing diabetes. • Expanding diagnostics in pediatrics. • Expanding and clarifying the indications for screening tests. • New recommendations for patients with cystic fibrosis.
Diabetes first diagnosed during pregnancy	• CGM and pump-integrated systems are not routinely recommended.	• CGM recommended for all women with diabetes diagnosed before pregnancy and to be considered in other cases. • Recommendation for the use of pump-integrated systems in women with T1DM.	• Expanding diabetes monitoring methods in pregnant women to include continuous glucose monitoring systems and systems integrated with pump therapy.
Reimbursement of medical devices	• FGM system (FreeStyle Libre) is reimbursed for pediatric patients aged 4 to 18 years with T1DM, as well as for selected individuals with disabilities. • CGM-RT are reimbursed for patients using insulin pump therapy. • There is currently no reimbursement for disposable insulin pen needles. • Accessories and consumables for insulin pumps are not covered by reimbursement.	• FGM system is reimbursed for patients with T1DM, T3DM, and selected cases of T2DM. • CGM-RT are reimbursed for adult patients administering insulin injections, with T1DM or T3DM diabetes, and with asymptomatic hypoglycemia. • In 2022, reimbursement for disposable insulin pen needles was introduced, with a limit of 400 needles per year for patients requiring insulin therapy. • In 2023, reimbursement for insulin pump accessories was introduced for patients with T3DM.	• Expansion of reimbursement indications. • Introduction of new reimbursement technology elements.
Healthcare workers authorized to issue equipment reimbursements	• Diabetologists and endocrinologists	• Reimbursement prescriptions may be initiated by diabetologists, endocrinologists, general practitioners, internists, gynecologists, pediatricians, and geriatricians. • Continuation of therapy may be managed by nurses and midwives.	• Widening the scope of authority to prescribe medications covered by reimbursement.
Medical Equipment Coding System	• Older coding system (e.g., 91).	• New systems of codes (e.g. R.01.01).	• A more understandable and standardized approach to coding.
Insulin therapy	• Semglee (insulin glargine) and Tresiba Penfill (insulin degludec) have been included on the list of drugs with a 30% reimbursement rate, provided specific conditions are met. • Liprolog and Liprolog KwikPen (insulin lispro) are now covered under a flat-rate reimbursement scheme for all patients diagnosed with diabetes.	• Insuman Basal (isophane insulin) has been removed from the list of reimbursed medications. • Reimbursement criteria for long-acting insulins have been standardized and simplified. • The minimum age for reimbursement of Levemir (insulin detemir) has been lowered to 1 year of age (previously available from age 2).	• Expansion of the list of reimbursed medicinal products. • Reduction in the restrictiveness of reimbursement indications. • The focus was placed on improving access, with only marginal price changes.

Metformin	• Reimbursement does not cover innovative combination therapies with metformin. • No reimbursement is provided for seniors aged 75 and above. • Reimbursement is granted only in cases of a confirmed diabetes diagnosis.	• Since 2023, the combination product vildagliptin + metformin has been reimbursed. • Metformin is available free of charge for patients over 75 years of age. • Reimbursed with a 30% co-payment, including for patients with PCOS.	• Inclusion of new medicinal products in the reimbursement scheme. • New healthcare benefits introduced for seniors. • Reimbursement has been extended to conditions other than diabetes.
Psychiatric and psychological care	• No recommendations.	• New PDA recommendations for mandatory mental health assessment at the start of diabetes diagnosis and treatment and at each subsequent follow-up visit.	• Introduction of mandatory mental health monitoring.

Table 2. Key systemic changes in the diagnosis, treatment and reimbursement of diabetes in Poland between 2019 and 2024
Source: [9–14, 16–22, 24].

the possibility of psychiatric consultation when a patient develops depressive symptoms. Diabetes and depression occur together approximately twice as frequently as would be predicted by chance alone. Depression is frequently missed in people with diabetes despite effective screening tools being available [23]. The Polish Society of Diabetology, in its 2024 recommendations, points out that the patient's mental state should be assessed at the start of diabetes treatment and during each doctor's visit [24].

The psychological and social stress of living with diabetes, known as diabetes distress, may play a role in the development of eating disorders. Patients with T1DM experience a higher incidence of eating disorders compared to the general population, with 30–40% of young individuals with T1DM affected by an eating disorder, including diabulimia.

These disorders complicate the management of insulin therapy and lead to poorer glycemic control [25]. Diabulimia is a disordered eating behavior in which a person withholds insulin injections to lose weight [25].

Sexual dysfunction in people with diabetes is common too. A global study involving 67,040 diabetic patients found a 61.4% prevalence of sexual dysfunction, with the highest rates in Europe. Males had a 65.91% prevalence, and females 58.81%. Patients with T2DM were at a greater risk of experiencing sexual dysfunction [26].

There is a need to raise awareness of the mental health of patients with diabetes. To provide effective treatment, clinicians should also be aware of the challenges faced by people with diabetes. Psychological support plays a key role here. Any general practitioner can refer a patient to a psychologist. An integrated approach is fundamental and can be a valid strategy to face this growing problem.

Table 2 presents the most important information on systemic changes in the diagnosis, treatment and reimbursement of diabetes in Poland in 2019–2024.

Conclusion

Significant progress has been made in diabetes care in Poland between 2019 and 2024.

The most important changes:

- Reimbursement for FGM has been available since 2019. Starting in 2023, reimbursement is extended to all patients with T1DM, T3DM, and those with "other types of diabetes," including T2DM patients who require more than three insulin injections daily.
- Since 2022, insulin pen needles have been reimbursed for patients with diabetes requiring insulin administration, with a limitation of up to 4 packs of needles.
- Reimbursement for insulin pump accessories is available for individuals with T1DM, and since January 2023, also for individuals with T3DM.
- New list of reimbursed drugs – since 2023, a new combination drug (vildagliptin and metformin hydrochloride) has been reimbursed.
- Since January 2024, patients with glycogen storage disorders have been eligible for reimbursement of FGM, preparations containing metformin have been reimbursed under a flat-rate system, all long-acting insulins have been reimbursed for all patients with diagnosed diabetes, regardless of type.

The findings underline the necessity of a comprehensive approach to diabetes management, combining modern diagnostics, updated reimbursement policies, and mental health support.

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