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Standards of Care in Diabetes. The position of Diabetes Poland – 2025

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Standards of Care in Diabetes – 2025. Diabetes Poland: Summary of Revisions

Dear Readers,

Time passes inexorably, and in keeping with a long-standing tradition, we once again present to you the latest edition of the Clinical Guidelines of Diabetes Poland (PTD). The team responsible for preparing the 2025 Guidelines deeply hopes that, like previous editions, they will contribute to the continued improvement of diabetes care in our country.

We are all aware that diabetes is a significant public health issue. Despite increasingly widespread preventive measures, its epidemiological and clinical importance continues to grow.

Our understanding of diabetes is constantly evolving, and we are witnessing continuous advancements in its diagnosis, monitoring, and treatment. However, the more we learn, the more we realize how far we are from achieving comprehensive knowledge and fully replicating physiological ideals.

Since 2005, Diabetes Poland (PTD) has been developing and publishing clinical guidelines for managing diabetes. The concept and initiative for creating these guidelines originated in 2004 with Professor Jacek Sieradzki, then President of Diabetes Poland. The first Chair of the PTD Guidelines Team for 2005 was the late Professor Władysław Grzeszczak, who held this role until 2011. Subsequent PTD Clinical Guidelines Coordinators were Professor Leszek Czupryniak (2011–2015), Professor Dorota Zozulińska-Ziółkiewicz (2015–2019), and Professor Irina Kowalska (2019–2023).

The current guidelines, like previous editions, are the result of intensive teamwork involving numerous experts from various medical disciplines. It is also important to acknowledge the contributions of those who have helped shape these clinical guidelines over the years.

These annually updated recommendations are designed to keep pace with the latest clinical research, provide guidance on best practices, and support healthcare professionals in their daily practice.

Summary of the most important changes in the Diabetes Poland (PTD) Guidelines for 2025

In **CHAPTER 2**, in the section on screening for type 2 diabetes, it is stated that the oral glucose tolerance test remains the most sensitive method for detecting prediabetes. HbA_{1c} in the range of 5.7–6.4% may indicate prediabetes, so fasting glucose should be measured, and ideally, an oral glucose tolerance test should be performed to diagnose prediabetes/diabetes. The chapter also includes a recommendation that in the case of BMI ≥ 27 kg/m² and the presence of prediabetes, in addition to behavioural therapy, pharmacotherapy should be considered using GLP-1 receptor agonists or dual GIP/GLP-1 receptor agonists with proven efficacy in reducing the risk of developing type 2 diabetes in this group (liraglutide, semaglutide, tirzepatide).It is also emphasized that for obese individuals, metabolic surgery is effective in preventing type 2 diabetes, particularly in cases of coexisting prediabetes. Additionally, it is noted that due to the shared pathogenesis of obesity, type 2 diabetes, and cardiovascular diseases, in obese individuals who do not yet have a diabetes diagnosis but have cardiovascular disease or cardiovascular risk factors, including prediabetes, anti-obesity pharmacotherapy should be considered using a GLP-1 receptor agonist with proven cardiovascular risk reduction in this group.

In **CHAPTER 3**, the necessity of recommending CGM systems for individuals using multiple daily insulin injections is emphasized. Information on substances that may interfere with glucose meter readings has been updated based on available knowledge.

In **CHAPTER 4**, target blood pressure values have been modified in accordance with the latest ESC and PTNT guidelines.

In **CHAPTER 5**, recommendations for monitoring adult patients with diabetes have been updated.

In **CHAPTER 6**, the section on sweeteners has been expanded with information previously contained in the former Annex 5, which has consequently been removed, and the subsequent annexes have been renumbered.

In **CHAPTER 7**, in the section on the principles of engaging in physical activity for individuals treated with insulin, a paragraph has been added emphasizing that regardless

of the type of exercise, the target blood glucose range should be 126–180 mg/dl or slightly higher for individuals with an increased risk of hypoglycaemia and/or reduced hypoglycaemia awareness. It is not recommended to start physical activity with blood glucose < 90 mg/dl. For strength training and expected hyperglycaemia, there are no contraindications to starting activity with blood glucose at 90 mg/dl. The table on types of physical activity and their impact on blood glucose levels has been expanded to include the range of prandial bolus reduction for activity lasting > 30 min.

CHAPTER 8 has been developed in a new format and structure.

In **CHAPTER 10**, among the most important recommendations, it has been emphasized that CGM systems should be a key element of blood glucose self-monitoring in type 1 diabetes. Furthermore, it has been indicated that in cases where SGLT-2 inhibitors and GLP-1 receptor agonists are necessary for patients with type 1 diabetes for indications other than direct anti-hyperglycaemic effects (cardiological, nephrological, obesity treatment indications), strict, ongoing adaptation of insulin therapy is required, preferably based on CGM or using automated insulin pumps. At the same time, the importance of monitoring ketonuria/ketonemia to prevent euglycemic diabetic ketoacidosis when using SGLT-2 inhibitors, especially in individuals using automated insulin delivery (AID) systems, has been emphasized. In the subsection on the organization of care for individuals with type 1 diabetes, a recommendation has been added that insulin pump therapy should optimally take place in centres where at least one team member holds a current Diabetes Poland Insulin Pump School certificate or is undergoing training. It has also been highlighted that in selected individuals, therapeutic goals can be defined based on time spent in a narrow therapeutic range (time in tight range – TITR) of 70–140 mg/dl. The decision to assess glycemic control based on TITR as a supplement to TIR should be made cautiously, considering the patient's level of education, engagement in treatment, available technology, and psychological profile.

In **CHAPTER 11**, it has been added that some GLP-1 receptor agonists in individuals with type 2 diabetes and chronic kidney disease may be used to reduce the risk of renal events. Additionally, the table listing drugs used in type 2 diabetes therapy has been modified by adding a row on the renal benefits of these drug classes. It has also been noted that contraindications to specific drug therapies should consider information from the latest summary of product characteristics.

In **CHAPTER 12**, the guidelines for type 2 diabetes therapy have been modified, incorporating weekly long-acting insulin analogues into the treatment algorithm.

In **CHAPTER 13**, key recommendations and target blood pressure values have been updated according to the latest ESC and PTNT guidelines, and the diagram illustrating the management of hypertension in individuals with type 2 diabetes has been adjusted accordingly.

In **CHAPTER 14**, the subsection on hypertriglyceridemia has been modified in terms of classification and target values.

In **CHAPTER 15**, in the recommendation concerning the treatment of hypoglycaemia in conscious individuals (with blood glucose ≤ 70 mg/dl; 3.9 mmol/l), the level of scientific evidence has been updated from expert opinion to level C. Meanwhile, in the recommendation for the use of CGM systems in individuals with diabetes and hypoglycaemia unawareness treated with intensive insulin therapy, their absolute indication in such cases has been recommended, extending this recommendation to individuals with diabetes and frequent hypoglycaemic episodes. In the subsection on emergency management of hypoglycaemia, it has been added that in individuals using HCL, in case of hypoglycaemia or the risk of hypoglycaemia, 5–8 mg of glucose may be administered orally, and blood glucose should be rechecked after 15 minutes.

In **CHAPTER 16**, information regarding mortality due to CKK has been modified, indicating that in cases of standard-compliant treatment, it remains < 1%, while the risk of death is increased in individuals with recurrent episodes and coexisting hyperosmolarity. In cases of hyperglycaemic hyperosmolar state, mortality ranges from 5–10%. Among the causes of CKK, the use of SGLT-2 inhibitors has been added for individuals with diabetes requiring insulin therapy and an increased risk of CKK. In the section on hydration in patients with CKK, a recommendation has been added stating that in euglycemic CKK (blood glucose <200 mg/dl; 11.1 mmol/l), from the beginning of treatment, in addition to a 0.9% NaCl solution, a 5% glucose solution should be administered at a rate of 100 ml/hour, or in cases of increased energy demand, a 10% glucose solution infusion at a rate of 70 ml/hour should be used.

In **CHAPTER 17**, the title of the entire chapter has been changed to **"Principles of Diagnosis and**

Treatment of Patients with Chronic Coronary Syndrome and Heart Failure with Coexisting Diabetes". The contents of the subsection on chronic coronary syndrome management have been updated according to current knowledge and applicable guidelines.

In **CHAPTER 19**, the term glomerular filtration has been replaced with estimated glomerular filtration rate (eGFR). In the treatment section, an additional recommendation states that in cases of albuminuria, therapy with ACE inhibitors or angiotensin II receptor antagonists (AT1 blockers) should be administered at maximum tolerated doses. Additionally, to continue therapy with ACE inhibitors, AT1 receptor antagonists, or mineralocorticoid receptor antagonists or to maintain appropriate dosing in patients with elevated potassium levels, the use of potassium-binding agents in the gastrointestinal tract (patiromer, sodium zirconium cyclosilicate) may be considered. In the section on the use of GLP-1 receptor agonists in individuals with type 2 diabetes and chronic kidney disease, it has been added that semaglutide is the first GLP-1 receptor agonist (FLOW study) proven to slow the decline of GFR and reduce the risk of kidney-related mortality, as well as all-cause mortality across a wide range of eGFR values (25–75 ml/in/1.73 m^2).

In **CHAPTER 20**, in accordance with current knowledge and existing guidelines, the subsection on diabetic retinopathy treatment has been modified.

In **CHAPTER 21**, in the section on the diagnostic principles of distal symmetric polyneuropathy, information has been added that standardized questionnaires can be used to assess both subjective and objective neuropathy symptoms. For the assessment of subjective symptoms, the Neuropathy Symptom Score (NSS) can be applied, along with the Diabetic Neuropathy Symptom (DNS) scale, which correlates well with NSS. To evaluate both subjective and objective symptoms, the Michigan Neuropathy Screening Instrument (MNSI) can be used, given its documented accuracy and established cutoff points for the Polish population. The painful form of polyneuropathy is diagnosed when clinical symptoms indicative of neuropathy and pain are localized in the same area. For screening neuropathic pain, the Douleur Neuropathique en 4 Questions (DN4) questionnaire can be used, with a score ≥ 4 on a 0–10 scale suggesting neuropathic pain. To assess pain intensity, the Visual Analog Scale (VAS) 0–10 can be applied. In the painful form of polyneuropathy, characteristic physical examination findings may be normal, meaning that neuropathy can still be diagnosed based on typical symptoms, even if physical abnormalities are absent. In the section on the pharmacological treatment of neuropathic pain in diabetic peripheral neuropathy, neuromodulation methods such as Frequency Rhythmic Electrical Modulation System (FREMS), Dorsal Root Ganglion Stimulation (DRGS), and Spinal Cord Stimulation (SCS) may play a role.

In **CHAPTER 22**, the title has been changed to **"Diabetic Foot Disease"**. In accordance with current knowledge and applicable guidelines, the content related to the management of infections in diabetic foot disease, antibiotic therapy principles, and the approach when amputation is required has been modified.

In **CHAPTER 23**, the section on the preclinical phase of type 1 diabetes in children has been expanded to include diagnostic and therapeutic procedures. It has been emphasized that for children with type 1 diabetes requiring intensive insulin therapy, the standard should be the use of Automated Insulin Delivery (AID) systems. The guidelines for managing CKK have been modified, and it has been added that when using AID systems, hypoglycaemia treatment should involve smaller amounts of glucose. The rules for using CGM systems during surgical procedures have been specified. It has also been clarified that for children with type 2 diabetes, if HbA_{1c} ≥ 6.5%, therapy should be intensified.

In **CHAPTER 24**, a statement has been added recommending early detection of glucose tolerance disorders in women with obesity of reproductive age. It is recommended to perform a 75 g OGTT test before a planned pregnancy. Pregnancy should be planned in women with obesity.

In **CHAPTER 25**, a recommendation has been introduced that for people over 65 years old, both with type 1 and type 2 diabetes, who use insulin, the preferred method of blood glucose monitoring should be CGM systems. In the subsection on antihyperglycemic medications, it has been stated that the use of sulfonylureas should be particularly cautious in elderly individuals with diabetes due to the risk of hypoglycaemia. These drugs should not be used in individuals with frailty syndrome.

In **CHAPTER 26**, a table has been added presenting recommendations for the administration of non-insulin antihyperglycemic drugs in the perioperative period.

In **CHAPTER 27**, both the key recommendations and the entire content of the chapter have

been modified and expanded, enriching it with a table containing a vaccination schedule for adults (based on the latest recommendations of the Ministry of Health).

CHAPTER 30 has been completely restructured, and its title has been changed to "Obesity Treatment in People with Diabetes".

In **CHAPTER 31**, recommendations regarding insulin therapy in cases of time zone changes have been significantly modified. Additionally, a new subsection has been added, dedicated to metabolic dysfunction-associated steatotic liver disease (MASLD).

In all chapters, the referenced literature has been updated.

In **ANNEX 1**, the Diabetes Care Information Card has been modified.

In **ANNEX 2**, the section on driver examinations has been updated and modified, specifically the paragraph on insufficient hypoglycaemia awareness in the context of contraindications to driving, as well as the section on blood glucose control while driving, specifying the conditions that must be met for continued driving.

ANNEX 4 has also been updated and modified, introducing a paragraph listing additional risk factors for thyroid cancer, in which thyroid ultrasound screening is recommended for patients with type 2 diabetes treated with GLP-1 receptor agonists.

In **ANNEX 5**, recommendations have been expanded to include the principles of diabetes treatment using AID systems. It has been emphasized that the currently preferred therapy in the use of OPI (personal insulin pumps) is AID systems – hybrid closed-loop (HCL) technology.

ANNEX 7 has been updated and modified, summarizing and compiling the organizational requirements for diabetes care.

We extend our heartfelt thanks to everyone who contributed to the development of this latest edition of the Diabetes Poland (PTD) Guidelines.

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List of abbreviations:

ABI – Ankle-Brachial Index
ABPM – Ambulatory Blood Pressure Monitoring
ACE – Angiotensin-Converting Enzyme
ACEI – Angiotensin-Converting Enzyme Inhibitors
ACS – Acute Coronary Syndrome
ACR – Albumin-to-Creatinine Ratio
ACS – Acute Coronary Syndrome
ADA – American Diabetes Association
ADI – Acceptable Daily Intake
AER – Albumin Excretion Rate
AF – Atrial Fibrillation
AID – Automated Insulin Delivery
ALT – Alanine Aminotransferase
anti-GAD – Glutamic Acid Decarboxylase Antibodies
Anti-HBs – Hepatitis B Surface Antibody
apo-B – Apolipoprotein B
APS – Artificial Pancreas System
APTT – Activated Partial Thromboplastin Time
ARB – Angiotensin Receptor Blockers
ARNI – Angiotensin Receptor Neprilysin Inhibitors
ASA – Acetylsalicylic Acid
ASCVD – Atherosclerotic Cardiovascular Disease
AST – Aspartate Aminotransferase
AT-1 – Angiotensin 1
ATP – Adenosine Triphosphate
BCVA – Best Corrected Visual Acuity
BE – Base Excess
BGM – Blood Glucose Monitoring
BMI – Body Mass Index
BP – Blood Pressure
CAD – Coronary Artery Disease
CCB – Calcium Channel Blockers
CCS – Chronic Coronary Syndrome
CDC – Centers for Disease Control and Prevention
CFRD – Cystic Fibrosis-Related Diabetes
CGM – Continuous Glucose Monitoring
CK – Creatine Kinase
DKA – Diabetic Ketoacidosis
CHO Exchange – Carbohydrate Exchange
CME – Diabetic Macular Edema, Cystoid Form
CKD – Chronic Kidney Disease
CRT – Cardiac Resynchronization Therapy
CSII – Continuous Subcutaneous Insulin Infusion (often referred to as an "insulin pump")
CV – Coefficient of Variation
CVOT – Cardiovascular Outcome Trial
DAPT – Dual Antiplatelet Therapy
DASH – Dietary Approaches to Stop Hypertension
DBP – Diastolic Blood Pressure
DFS – Diabetic Foot Syndrome
DIY Pump – Do It Yourself Insulin Pump
DLCN – Dutch Lipid Clinic Network
DME – Diabetic Macular Edema
DPP-4 – Dipeptidyl Peptidase-4
DPP-4i – Dipeptidyl Peptidase-4 Inhibitor
DRIL – Disorganization of the Retinal Inner Layers
DRT – Diabetic Macular Edema, Diffuse Form
DSMES – Diabetes Self-Management Education and Support
EASD – European Association for the Study of Diabetes
ED-NOS – Eating Disorders Not Otherwise Specified
eGFR – Estimated Glomerular Filtration Rate
EKG – Electrocardiography
EPA – Eicosapentaenoic Acid
ESC – European Society of Cardiology
ESH – European Society of Hypertension
ETDRS – Early Treatment Diabetic Retinopathy Study
FGM – Flash Glucose Monitoring
FH – Familial Hipercholesterolemia
Frailty – Frailty Syndrome
FRC – Fixed Ratio Combination Therapy
GDM – Gestational Diabetes Mellitus
GI – Glycemic Index
GIP – Glucose-Dependent Insulinotropic Polypeptide
GL – Glycemic Load
GLP-1 – Glucagon-Like Peptide-1
GLP-1 RA – Glucagon-Like Peptide-1 Receptor Agonist
GMI – Glucose Management Indicator
HAV – Hepatitis A Virus
HbA1c – Glycated Hemoglobin
HCL – Hybrid Closed Loop
HDL-C – High-Density Lipoprotein Cholesterol
HF – Heart Failure
HFmEF – Heart Failure with Mildly Reduced Ejection Fraction
HFpEF – Heart Failure with Preserved Ejection Fraction
HFrEF – Heart Failure with Reduced Ejection Fraction
HTG – Hypertriglyceridemia
HTN – Hypertension
Hz – Hertz
IA-2 – Insulinoma-Associated-2 Autoantibodies
IAA – Insulin Autoantibodies
ICA – Islet Cell Autoantibodies
ICD – Implantable Cardioverter-Defibrillator
IFG – Impaired Fasting Glucose

IgA – Immunoglobulin A
IGT – Impaired Glucose Tolerance
IIEF – International Index of Erectile Dysfunction
IIT – Intensive Insulin Therapy
Immunization Program – Vaccination Program
INR – International Normalized Ratio
iPCSK9 – PCSK9 Inhibitors
KCl – Potassium Chloride
KDIGO – Kidney Disease: Improving Global Outcomes
LADA – Latent Autoimmune Diabetes in Adults
LDL-C – Low-Density Lipoprotein Cholesterol
L-DOPA – Levodopa, L-3,4-Dihydroxyphenylalanine
Lp(a) – Lipoprotein(a)
LVEF – Left Ventricular Ejection Fraction
LVH – Left Ventricular Hypertrophy
MASLD – Metabolic Dysfunction-Associated Steatotic Liver Disease
MDCT – Multi-Detector Computed Tomography
MDI – Multiple Daily Injections
MNSI – Michigan Neuropathy Screening Instrument
MODY – Maturity Onset Diabetes of the Young
MRA – Mineralocorticoid Receptor Antagonists
MRI – Magnetic Resonance Imaging
MRSA – Methicillin-Resistant *Staphylococcus aureus*
Na – Sodium
NaCl – Sodium Chloride
NaHCO3 – Sodium Bicarbonate
NFG – Normal Fasting Glucose
NGSP – National Glycohemoglobin Standardization Program
non-HDL-C – Non-High-Density Lipoprotein Cholesterol
NPDR – Nonproliferative Diabetic Retinopathy
ns-MRA – Non-Steroidal Mineralocorticoid Receptor Antagonist
OCT – Optical Coherence Tomography
OGTT – Oral Glucose Tolerance Test
PAD – Peripheral Arterial Disease
PCI – Percutaneous Coronary Intervention
PCOS – Polycystic Ovary Syndrome
PDR – Proliferative Diabetic Retinopathy
PDS – Polish Diabetes Society
PET – Positron Emission Tomography
PGDM – Pregestational Diabetes Mellitus
PHQ-9 – Patient Health Questionnaire-9
POCT – Point-Of-Care Testing
PPAR-g Agonist – Peroxisome Proliferator-Activated Receptor Gamma Agonist
RAA System – Renin-Angiotensin-Aldosterone System
SADI – Single Anastomosis Duodeno-Ileal Bypass
SBP – Systolic Blood Pressure
SGLT-2 – Sodium-Glucose Co-Transporter 2
SGLT-2i – Sodium-Glucose Cotransporter 2 Inhibitor
SI – International System of Units
siRNA – Small Interfering RNA
SMBG – Self-Monitoring of Blood Glucose
SNRI – Serotonin-Norepinephrine Reuptake Inhibitor
SPC- Single Pill Compilation
SPECT – Single Photon Emission Computed Tomography
SU – Sulfonylureas
T1DM – Type 1 Diabetes Mellitus
T2DM – Type 2 Diabetes Mellitus
TAR – Time Above Range
TBR – Time Below Range
TCA – Tricyclic Antidepressants
TcPO2 – Transcutaneous Partial Pressure of Oxygen
TG – Triglycerides
TIR – Time in Range
TOD – Target Organ Damage
UACR – Urine Albumin-Creatinine Ratio
ULN – Upper Limit of Normal
USG – Ultrasonography
VAS – Visual Analog Scale
VEGF – Vascular Endothelial Growth Factor
WHO – World Health Organization
ZnT8 – Zinc Transporter 8 Autoantibodies

1. Diagnosing Glucose Tolerance Disorders

CHAPTER HIGHLIGHTS
• Glucose tolerance disorders are identified based on random glycaemia, fasting glycaemia, the 120-minute oral glucose tolerance test (OGTT) as well as glycated haemoglobin (HbA_{1c}) results. [**A**]
• Screening for early diagnosis of pre-diabetes/type 2 diabetes should be undertaken in all individuals over the age of 45 and, regardless of age, in all individuals with at least one risk factor of diabetes. [**B**]
• In women who have not previously been diagnosed with diabetes, an oral glucose tolerance test should be performed between the 24th and 28th week of pregnancy for gestational diabetes diagnosis. [**A**]
• The diagnosis of diabetes in children within first 9 months of life requires genetic testing for permanent neonatal diabetes. [**A**]
• In individuals with cystic fibrosis, an annual oral glucose tolerance test should be conducted after the age of 10 for diabetes diagnosis [**A**]

Diabetes describes a complex metabolic disorder characterized by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action and both. Chronic hyperglycaemia leads to damage, dysfunction, and failure of various organs, notably the eyes, kidneys, nerves, heart, and blood vessels.

I. Symptoms indicating the possibility of diabetes with significant hyperglycaemia:

- polyuria,
- excessive thirst,
- unexplained weight loss,
- other, less common symptoms like fatigue, increased sleepiness, skin infections and genitourinary organs inflammation.

II. Diagnostic criteria of glucose tolerance disorder:

- if diabetes symptoms are present, a random venous plasma glucose measurement is required – a result of ≥ 200 mg/dl (≥ 11.1 mmol/l) is a basis for diabetes diagnosis;
- in the absence of symptoms or with coexisting symptoms with random glycaemia < 200 mg/dl (< 11.1 mmol/l) diabetes can be diagnosed based on:
  - » two fasting glycaemia measurements in the morning (each test performed on a different day) – two results ≥ 126 mg/dl (≥ 7.0 mmol/l);
  - » a single measurement of glycated haemoglobin (HbA_{1c}) – level ≥ 6.5% (≥ 48 mmol/mol),
  - » if the result of one or two fasting glycaemia measurements is 100–125 mg/dl (5.6–6.9 mmol/l) or HbA_{1c} is 5.7–6.4% (39–46 mmol/mol) in a person with a reasonable suspicion of impaired glucose tolerance or diabetes, a glucose tolerance test (OGTT) should be performed – a glycaemia at the 120th minute of OGTT ≥ 200 mg/dl (≥ 11.1 mmol/l) is a basis for diabetes diagnosis, and 140–199 mg/dl (7.8–11.0 mmol/l) – indicates impaired glucose tolerance (IGT).

Fasting blood glucose measurements, 120th minute OGTT blood glucose test and HbA_{1c} measurement can be considered equally diagnostic, even though they diagnose diabetes in different individuals. Compared with fasting blood glucose and HbA_{1c}, the 120th minute OGTT blood glucose test has a greater rate of diagnosing diabetes and pre-diabetic conditions (Table 1.1).

III Diagnostic tests performance:

- the oral glucose tolerance test (OGTT) should be performed without restricting carbohydrate intake prior to the test, during morning hours, on a fasting and well-rested individual after an overnight sleep. The test person should remain at rest for 2 hours at the testing site after drinking a solution containing 75 g of glucose; all glucose levels measurements must be performed on venous plasma in a laboratory;
- if an OGTT needs to be performed in a person with glucose intolerance (i.e., a pre-diabetic state) who is therefore using metformin, the medication should be discontinued at least one week prior to the test:
  - » glycaemia measurements for diagnostic purposes should be conducted in a laboratory; using glucometers for this purpose is not permitted;
  - » HbA_{1c} measurements should be performed in the laboratory using methods certified by the National Glycohemoglobin Standardization Program (NGSP); HbA_{1c} measurements should not be performed for diag-

Table 1.1. Guidelines of diagnosing glucose tolerance disorders

Venous plasma glucose level measured in the laboratory			HbA_{1c} level measured in a laboratory using a NSGP-certified method
Random blood glucose – measured in blood sample collected at any time during the day, regardless of the timing of the last meal	Fasting blood glucose – measured in a blood sample collected 8–14 hours after the last meal	Blood glucose at 120 minutes during an oral glucose tolerance test (OGTT) according to WHO	
≥ 200 mg/dl (11.1 mmol/l) → diabetes (if symptoms of hyperglycaemia are present, such as excessive thirst, polyuria, fatigue)*	70–99 mg/dl (3.9–5.5 mmol/l) → NFG	< 140 mg/dl (7.8 mmol/l) → NGT	
	100–125 mg/dl (5.6–6.9 mmol/l) → IFG	140–199 mg/dl (7.8–11.1 mmol/l) → IGT	
	≥ 126 mg/dl (≥ 7,0 mmol/l) → diabetes*	≥ 200 mg/dl (11.1 mmol/l) → diabetes*	≥ 6.5% (48 mmol/mol) → diabetes*

IFG – impaired fasting glucose, IGT – impaired glucose tolerance, NFG – normal fasting glucose, NGT – normal glucose tolerance, NGSP — National Glycohemoglobin Standardization Program, WHO – World Health Organization

**To diagnose diabetes, it is necessary to find abnormalities as described in the text.*

To diagnose diabetes, it is necessary to find one of the abnormalities, except for fasting blood glucose, when double confirmation of the abnormality is required; when determining blood glucose, it is necessary to consider the possible influence of factors unrelated to the test (time of the last meal consumed, exercise, time of day).

nostic purposes using point-of-care testing analysers (POCT), even those certified by the NGSP;

- HbA_{1c} measurements should not be performed for diabetes diagnosis in individuals with conditions/diseases that affect the correlation between the HbA_{1c} value and average blood glucose level, such as anaemia, certain hemoglobinopathies, pregnancy and postpartum period, haemodialysis treatment, use of erythropoietin, HIV infection and use of antiretroviral drugs. In such cases, diagnostic criteria based on plasma glucose levels should be used.

IV. World Health Organization (WHO) classification of hyperglycaemic states:

- normal fasting glucose: 70–99 mg/dl (3.9–5.5 mmol/l);
- impaired fasting glucose (IFG): 100–125 mg/dl (5.6–6.9 mmol/l);
- normal glucose tolerance: OGGT 120-minute glucose < 140 mg/dl (< 7.8 mmol/l);
- impaired glucose tolerance (IGT): OGTT 120-minute glucose 140–199 mg/dl (7.8–11.0 mmol/l);
- irediabetes – IFG and/or IGT;
- diabetes – one of the following criteria:
  - » symptoms of hyperglycaemia and random glucose ≥ 200 mg/dl (≥ 11.1 mmol/l),
  - » fasting glucose ≥ 126 mg/dl (≥ 7.0 mmol/l) (twice-each test performed on a different day);
  - » OGTT 120-minute glucose ≥ 200 mg/dl (≥ 11.1 mmol/l);
  - » HbA_{1c} ≥ 6.5% (≥ 48 mmol/mol).

V. Screening for type 2 diabetes

Screening for type 2 diabetes is necessary in at-risk groups, as most patients do not have symptoms of hyperglycaemia. Diabetes screening should be carried out once every three years in every person over the age of 45. In addition, regardless of age, this test should be performed annually in people in the following risk groups:

- overweight or obese (BMI ≥ 25 kg/m^2 and/or waist circumference ≥ 80 cm in women or ≥ 94 cm in men);
- with a family history of diabetes (parents or siblings);
- physically inactive individuals;
- from an environmental or ethnic group characterized by increased diabetes incidence;
- with a previous diagnosis of prediabetes;
- in women with a history of gestational diabetes;
- in women who have given birth to a child weighing > 4000 g;
- with hypertension;
- with dyslipidemia,

- in women with polycystic ovary syndrome;
- with cardiovascular disease.

In those taking antihyperglycemic drugs for reasons other than type 2 diabetes, the basis for the diagnosis of the disease is an HbA_{1c} ≥ 6.5% (≥ 48 mmol/mol).

VI. Etiological classification of diabetes:

- type 1 diabetes – autoimmune destruction of pancreatic β cells, usually leading to absolute insulin deficiency;
- type 2 diabetes – progressive loss of β cells leading to relative insulin deficiency with accompanying insulin resistance;
- other specific types of diabetes including:
  - genetic defects in β cells function;
  - genetic defects in insulin action;
  - diseases of the exocrine pancreas;
  - endocrinopathies;
  - drug- or chemical-induced;
  - infections;
  - uncommon forms of immune-mediated diabetes;
  - other genetic syndromes sometimes associated with diabetes;
- hyperglycaemia first identified during pregnancy:
  - diabetes in pregnancy;
  - gestational diabetes mellitus (GDM).

The current classification of diabetes does not distinguish type LADA, which is one of clinical forms of type 1 diabetes.

Since the differential diagnosis of type 1 diabetes, especially when diagnosed in adults, can be challenging, a standardized diagnostic algorithm has been proposed in the recent ADA/EASD consensus.

If the diagnosis in an adult is in doubt, it is necessary to determine the presence of autoantibodies and/or low C-peptide levels. Antibodies to glutamic acid decarboxylase (anti-GAD) should be measured first. If negative, antibodies to tyrosine phosphatase 2 (anti-IA2) and/or zinc transporter 8 (anti-ZnT8) should be measured next if these tests are available.

Monogenic diabetes

Monogenic diabetes is 1–2% of all diabetes cases and it results from mutations in a single gene. Most of its forms are related to insulin secretion defects. The most common types include:

- MODY (maturity onset diabetes of the young);
- mitochondrial diabetes;
- permanent neonatal diabetes.

Including monogenic forms in the differential diagnosis of diabetes can help optimize treatment and provide accurate prognoses for patients and their families. A definitive diagnosis of monogenic diabetes is established through genetic testing. Centres with extensive experience in this area should handle qualification for genetic testing and make any subsequent therapeutic decisions based on the diagnosis.

Permanent neonatal diabetes mellitus is defined as having developed before the age of 9 months. Genetic testing is recommended for all patients with this condition to identify mutations particularly in the *KCNJ11* gene, which encodes the Kir6.2 protein. Such mutations are commonly associated with permanent neonatal diabetes. Most patients with *KCNJ11* gene mutations can be effectively and safely treated with sulfonylurea drugs. Further genetic analysis may involve looking for mutations in insulin genes, the *ABCC8* that encodes the SUR1 protein and the glucokinase gene. The identification of a mutation in the *ABCC8* gene allows for therapy with sulfonylurea derivatives. Insulin treatment is necessary for carriers' insulin gene mutations or double mutations in the glucokinase gene. Decisions on searching for mutations in other genes related to diabetes should be made by diabetologists with extensive experience in the genetics of diabetes.

In families with autosomal dominant early-onset diabetes resulting from impaired insulin secretion, which in most cases is not accompanied by obesity, MODY diabetes and the search for mutations in the genes responsible for its formation should be considered in the differential diagnosis. The most common form of MODY is associated with mutations in the *HNF1A* and glucokinase genes.

The typical clinical profile of diabetic MODY patients due to ***HNF1A* gene mutations** includes:

- early onset of diabetes (typically before age 25);
- independence from insulin and a low tendency towards ketoacidosis, with minimal insulin requirements and detectable C-peptide levels even after several years of the disease;
- a family history of diabetes spanning at least 2 generations, with at least two family members experiencing early-onset diabetes; an OGTT performed at an early stage of diabetes often shows a significant increase in postprandial glycaemia, sometimes with normal fasting values;
- absence of autoantibodies typically associated with type 1 diabetes;
- glycosuria higher than would be expected based on glycemic levels.

A significant proportion of patients with *HNF1A* MODY develop chronic diabetes complications, hence it is crucial to strive for optimal disease management from the onset. The preferred treatment, except during pregnancy or the presence of typical contraindications, is the implementation of sulfonylurea derivatives. Once their efficacy is exhausted, a combination therapy with insulin, metformin or DPP-4 inhibitors or insulin monotherapy may be considered.

Searching for **mutations in the glucokinase gene** is indicated in the following cases:

- persistently elevated fasting glycaemia in the range of 99–144 mg/dl (5.5–8.0 mmol/l);
- glycemic increase during OGTT less than 83 mg/dl (4.6 mmol/l), and in most cases less than 54 mg/dl (3 mmol/l);
- one parent with diagnosed diabetes; however, the absence of a family history does not rule out this condition.

The approach for a glucokinase defect caused by a single mutation is a healthy dietary management excluding simple sugars as pharmacotherapy is usually ineffective. The characteristic HbA_{1c} value of a glucokinase defect does not exceed 7.5% (59 mmol/mol).

Decisions regarding the search for mutations in other MODY genes should be made on a case-by-case basis at centres experienced in performing such tests.

The most common cause of **mitochondrial diabetes** is the *A3243G* mutation in the leucine tRNA gene. This mutation should be investigated in cases of maternal inheritance of early-onset diabetes within a family, particularly if some members also suffer from deafness. Therapeutic approaches for mitochondrial diabetes may include dietary changes and the use of sulfonylurea derivatives or insulin, tailored to the level of insulin secretion impairment. Metformin therapy is typically avoided in mitochondrial diabetes.

Cystic fibrosis-related diabetes (CFRD)

Diabetes in individuals with cystic fibrosis (CFRD) affects approximately 20% of adolescents and 40–50% of adults, representing the most common comorbidity. CFRD is, among other specific types of diabetes, associated with diseases of the exocrine pancreas and typically develops slowly and asymptomatically over many years. Diabetic ketoacidosis is rare, most likely due to preserved endogenous insulin secretion or concomitant impaired glucagon secretion. Hyperglycaemia initially occurs in situations that exacerbate insulin resistance, such as acute and chronic infections, steroid therapy, or high carbohydrates intake (oral, intravenous, via gastric probe or percutaneous gastrostomy). Insulin therapy is the treatment of choice.

For individuals over > 10 years of age with cystic fibrosis, an annual OGTT during periods of good health is recommended for diabetes detection.

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2. Prevention or Delay of Diabetes

CHAPTER HIGHLIGHTS
• In the group of individuals with overweight or obesity, active screening for prediabetes is recommended, particularly in those with other features of metabolic syndrome. This enables earlier implementation of preventive or therapeutic measures aimed at reducing the risk of type 2 diabetes and cardiovascular diseases. [**A**]
• Patients with prediabetes should receive guidance on a healthy lifestyle (at least 150 minutes of physical activity per week, in overweight and obese patients- weight reduction of at least 7% per year and maintenance of that weight loss) and be informed about the effectiveness of such measures in preventing the progression to diabetes. [**A**]
• For those with prediabetes, especially those with both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), and/or a body mass index (BMI) ≥ 35 kg/m^2, and/or under 60 years of age, as well as women with a history of gestational diabetes (GDM), pharmacological prevention of diabetes with metformin should be considered alongside lifestyle modification. [**A**]
• Screening tests are conducted by measuring fasting glycaemia, performing an oral glucose tolerance test, or measuring HbA_{1c}. [**C**]

Type 1 diabetes

Currently, there is not clinically effective method of preventing type 1 diabetes, either in the general population or in people at risk.

Type 2 diabetes

1. Screening tests are carried out by measuring random glucose, fasting glucose, performing an oral glucose tolerance test (OGTT), or measuring HbA_{1c}. The most sensitive method for detecting prediabetes remains the OGTT. HbA_{1c} levels in the range of 5.7–6.4% may indicate the presence of prediabetes; therefore, fasting glucose levels should be measured, and ideally, an OGTT should be performed to diagnose prediabetes or diabetes.
2. For risk factors of type 2 diabetes, refer to Chapter 1.
3. Review of recommendations for preventing or delaying the onset of type 2 diabetes includes:

- individuals at high risk should receive appropriate education on the role of healthy lifestyle principles in the prevention of type 2 diabetes,
- the benefits of increasing physical activity apply to everyone, regardless of age, with the highest effectiveness of such interventions observed in individuals over 60 years of age,
- individuals with prediabetes should receive guidance on a healthy lifestyle – this includes achieving a weight reduction of at least 7% over the course of a year for those who are overweight or obese and maintaining this reduction through patient-appropriate physical activity (at least 150 minutes per week) and adherence to a suitable diet, with information provided on the effectiveness of these measures in reducing the risk of developing diabetes,
- in individuals with prediabetes, particularly those with concurrent impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), and/or a body mass index (BMI) ≥ 35 kg/m², and/or those under 60 years of age, as well as women with a history of gestational diabetes mellitus (GDM), pharmacological prevention of type 2 diabetes with metformin should be considered alongside lifestyle modification,
- in cases of BMI ≥ 27 kg/m² and the presence of prediabetes, in addition to behavioural therapy, pharmacotherapy with GLP-1 receptor agonists or a dual GIP/GLP-1 receptor agonist with proven efficacy in reducing the risk of type 2 diabetes in this group (liraglutide, semaglutide, tirzepatide) should be considered,
- when non-pharmacological treatment for obesity does not result in sufficient weight reduction, pharmacological treatment or qualification for metabolic surgery should not be delayed,
- metabolic surgery is effective in preventing type 2 diabetes, particularly in individuals with prediabetes,
- due to the shared pathogenesis of obesity, type 2 diabetes, and cardiovascular diseases, in individuals with obesity without a current diagnosis of diabetes but with cardiovascular diseases, cardiovascular risk factors, including prediabetes, pharmacological treatment for obesity with a GLP-1 receptor agonist proven to reduce cardiovascular risk in this group (e.g., semaglutide) should be considered,
- repeating lifestyle advice during each patient visit is crucial for effective prevention of glucose metabolism disorders,

- regular screening for other cardiovascular risk factors (e.g., obesity, smoking, hypertension, lipid disorders) is recommended for individuals with prediabetes, and appropriate treatment should be initiated if such factors are present; treatment goals for comorbid conditions in individuals with prediabetes should align with those of the general population.
- diabetogenic medications should be avoided.

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3. Glycemic Monitoring

CHAPTER HIGHLIGHTS
• Most individuals using multiple daily injections (MDI) for insulin therapy should utilize continuous glucose monitoring (CGM) or perform self-monitoring of blood glucose (SMBG) both before and after meals, at bedtime, before planned physical activity, when hypoglycaemia is suspected, and before activities where hypoglycaemia poses a particular risk (e.g., driving a car). [**B**]
• As part of a comprehensive educational program, SMBG can assist individuals on less frequent insulin injection regimens [**B**] and those with diabetes not on insulin therapy in making independent therapeutic decisions. [**E**]
• When recommending SMBG, continuous education of individuals with diabetes is crucial, along with periodic assessment of the correctness of self-monitoring techniques, their results, and their impact on therapeutic decisions. [**E**]
• CGM combined with intensive insulin therapy can be a useful tool for lowering HbA_{1c} in individuals with type 1 diabetes. [**A**]
• CGM may also be beneficial for people with hypoglycaemia unawareness and those experiencing recurrent episodes of hypoglycaemia. [**B**]
• Individuals with diabetes using CGM should also always have access to SMBG. [**A**]

Current monitoring and retrospective assessment of glucose are integral parts of effective diabetes management. Proper self-monitoring of glucose requires systematic education of individuals with diabetes, especially in mastering the use of glucometers and continuous glucose monitoring (CGM) systems, and in interpreting self-monitoring results. This includes using the data to make daily adjustments to diet, physical activity, and doses of anti-hyperglycaemic medications. Another essential element of diabetes treatment monitoring is the regular measurement of glycated haemoglobin (HbA_{1c}), and for those using CGM systems, the analysis of glycemic control reports.

I. Self-monitoring of glucose

Self-monitoring of blood glucose is an integral part of diabetes treatment.

Individuals with diabetes treated with multiple daily insulin injections or via continuous subcutaneous insulin infusion should use CGM systems, which increase the safety and effectiveness of insulin therapy and improve the comfort of life and the quality of care for people with diabetes.

The use of glucose monitoring systems is particularly advisable for individuals with type 1 diabetes with a history of unstable glycaemia levels, with coexisting frequent episodes of hypoglycaemia and lack of awareness of it, as this improves the safety and effectiveness of treatment.

Self-monitoring of blood glucose is also recommended to achieve therapeutic goals in individuals treated with single insulin injections, oral anti-hyperglycaemic drugs, and/or GIP/GLP-1 receptor agonists (Table 3.1). All individuals with diabetes, regardless of the treatment method, should check their glycaemia more frequently in case of ill health or a sudden deterioration in health.

For proper self-monitoring of blood glucose, individuals with diabetes should be trained in the use of a blood glucose meter, CGM system, interpretation of results, and further actions (Figure 3.1).

For glycemic control, it is recommended to use glucometers that present plasma glucose levels as the test result, and which have a declared determination error of no more than 15% for glucose concentrations ≥ 100 mg/dl (5.6 mmol/l) and 15 mg/dl (0.8 mmol/l) for glucose concentrations < 100 mg/dl (5.6 mmol/l), as confirmed in publi-

Table 3.1. Recommended frequency of self-monitoring of blood glucose using a glucometer

Diabetes treatment	Frequency of glycemic measurements
Multiple (i.e., at least 3 times a day) insulin injections, intensive functional insulin therapy, regardless of diabetes type	Multiple measurements per day (i.e., at least 4 times a day, recommended 8 times a day) according to established treatment regimen and patient needs
People with type 2 diabetes treated with fixed doses of insulin	Daily 1–2 glucose measurements, additionally once a week a shortened glucose profile (fasting and postprandial) and once a month a 24-hour glucose profile
People using non-insulin antihyperglycemic drugs	Once a week a shortened glucose profile or measurements depending on the patient's clinical needs

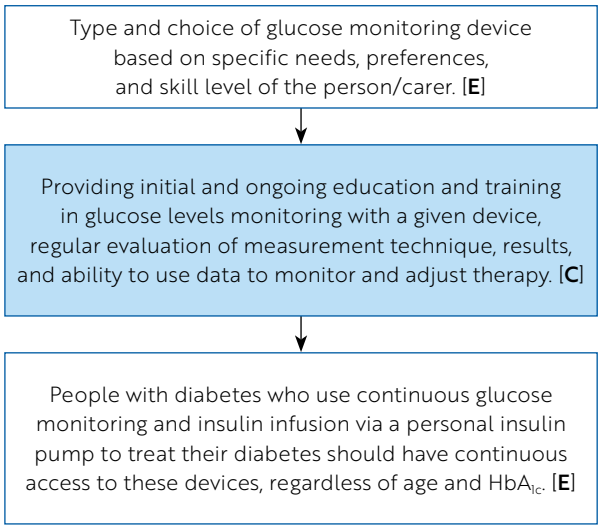

Figure 3.1. Recommendations for individualizing the approach to glucose levels monitoring [10]

cations and manufacturer's materials. In patients taking ≥ 4 measurements per day, it may be helpful to analyse the results using a computer program dedicated to this purpose. Monitoring the accuracy of glucose meter measurements, along with assessing the correctness of their use, should be carried out when abnormalities are suspected and at least once a year at the facility at which the person with diabetes is treated on an outpatient basis. The control should consist of glucose determinations on the same material with a glucometer using a comparative method - laboratory - or point of care testing (POCT) consistent with the laboratory method. The difference in results should not exceed the above-mentioned limits of acceptable error.

Tables 3.2 and 3.3 present examples of substances that can disrupt the reading of glucose concentration using blood glucose meters and CGM systems.

Table 3.2. Examples of substances that can interfere with blood glucose readings using glucometers [1]

Glucose oxidase strips
Uric acid
Galactose
Xylose
Acetaminophen
L-DOPA
Ascorbic acid
Test strips with glucose dehydrogenase (GDH) using pyrroloquinoline quinone (PQQ) as a cofactor
Icodextrin (used in peritoneal dialysis)

II. Haemoglobin A_{1c} (HbA_{1c})

The haemoglobin A_{1c} (HbA_{1c}) reflects the average blood glucose levels over the approximately 3 months preceding the measurement, and approximately 50% of the HbA_{1c} present in the blood is formed in the last month prior to the measurement.

HbA_{1c} should be measured once a year in people with well-managed diabetes achieving treatment goals. HbA_{1c} should be performed at least quarterly in individuals who do not achieve treatment goals, or those in whom a change in treatment has been made.

HbA_{1c} should be measured using analytical methods certified by NGSP (http://www.ngsp.org). It is possible to perform HbA1c measurements outside the laboratory, in POCT mode, provided that the method and analyser certified by NGSP are used. Diagnostic laboratories report the HbA_{1c} result as a percentage (%) and in SI units.

While interpreting the HbA_{1c} levels, interfering factors such as changes in erythrocyte survival time, hemoglobinopathies, chemical haemoglobin modifications, which may hinder or prevent their use, should be considered.

Table 3.3. Examples of substances that can interfere with glucose readings using CGM systems [1]

Substance	System	Result
Acetaminophen > 4 g/day Any dose	Dexcom G6, Dexcom G7 Medtronic Guardian	Higher sensor readings than actual glucose levels Higher sensor readings than actual glucose levels
Ascorbic acid > 500 mg/day (vit. C)	Freestyle Libre	Higher sensor readings than actual glucose levels
Hydroxyurea	Dexcom G6, Dexcom G7 Medtronic Guardian	Higher sensor readings than actual glucose levels
Mannitol	Senseonics Eversense	Higher sensor readings than actual glucose levels
Sorbitol	Senseonics Eversense	Higher sensor readings than actual glucose levels

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4. Therapeutic Diabetes Goals

CHAPTER HIGHLIGHTS
• In individuals with diabetes, the overall goal for glycemic control, expressed as an HbA_{1c} ≤ 7.0% (53 mmol/mol). [**A**]
• Low-density lipoprotein cholesterol (LDL-C) levels < 55 mg/dl (< 1.4 mmol/l) and a reduction of at least 50% from the baseline in individuals with diabetes at very high cardiovascular risk, and as a secondary goal, reducing non-high-density lipoprotein cholesterol (non-HDL-C) levels < 85 mg/dl (< 2.2 mmol/l). [**A**]
• LDL-C levels < 70 mg/dl (1.8 mmol/l) and a reduction of at least 50% from the baseline in individuals with diabetes at high cardiovascular risk, and as a secondary goal, reducing non-HDL-C levels < 100 mg/dl (< 2.6 mmol/l). [**A**]
• LDL-C levels < 100 mg/dl (< 2.6 mmol/l) in individuals with diabetes at moderate cardiovascular risk, and as a secondary goal, reducing non-HDL-C levels < 130 mg/dl (< 3.4 mmol/l). [**A**]
• Recommended blood pressure ≤ 120–129/70–79 mm Hg. [**A**]

I. General remarks

1. Therapeutic goals for diabetes should be understood as the achievement of targets for blood glucose, blood pressure, lipids, and body weight.
2. In the elderly individuals and in the presence of comorbidities, if the life expectancy is less than 10 years, the criteria for glycemic control should be adjusted downwards to a degree that will not impair the patient's quality of life.
3. In modern diabetology, there is a principle of far-reaching individualization of goals and intensification of therapy. In each person with diabetes, especially type 2 diabetes, when setting goals and choosing a therapeutic strategy, one should consider the patient's attitude and expected involvement in treatment (also from their surrounding), the degree of risk of hypoglycaemia and its potential consequences (more serious in the elderly, with impaired cardiovascular and/or nervous systems), the duration of diabetes, life expectancy, the presence of serious vascular complications of diabetes and significant comorbid diseases, the level of education of the person with diabetes, and the benefit-risk ratio of achieving specific therapeutic target values. In some situations (e.g. in the presence of advanced complications, elderly age), the established treatment goals should be achieved gradually, over a period of 2 to 6 months.

II. Glycemic targets

General goals: HbA_{1c} ≤ 7% (≤ 53 mmol/mol).
Individual goals:

1) HbA_{1c} ≤ 6.5% (≤ 48 mmol/mol):
- in relation to type 1 diabetes, when striving for the goal is not associated with an increased risk of hypoglycaemia and a deterioration in quality of life – fasting glycaemia and pre-meal, also in self-monitoring: 70–110 mg/dl (3.9–6.1 mmol/l), and 2 hours after starting a meal in self-monitoring 140 mg/dl (7.8 mmol/l),
- in the case of short-term type 2 diabetes (duration < 5 years),
- in children and adolescents – regardless of the type of disease, when striving for the goal is not associated with an increased risk of hypoglycaemia and a deterioration in quality of life.

When assessing the glycemic profile in relation to the target HbA_{1c}, one should be guided by the converter provided in Table 4.1, relating the HbA_{1c} to the average daily and range of blood glucose levels.

2) HbA_{1c} value 8.0–8.5% (64–69 mmol/mol) – for elderly individuals with long-standing diabetes and significant complications of macroangio-

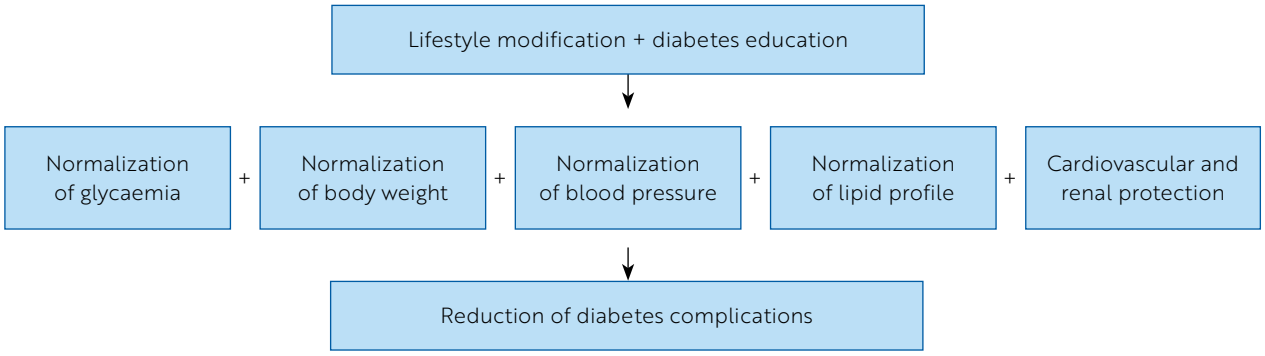

Figure 4.1. A holistic approach to strategies leading to the reduction of the risk of diabetes complications

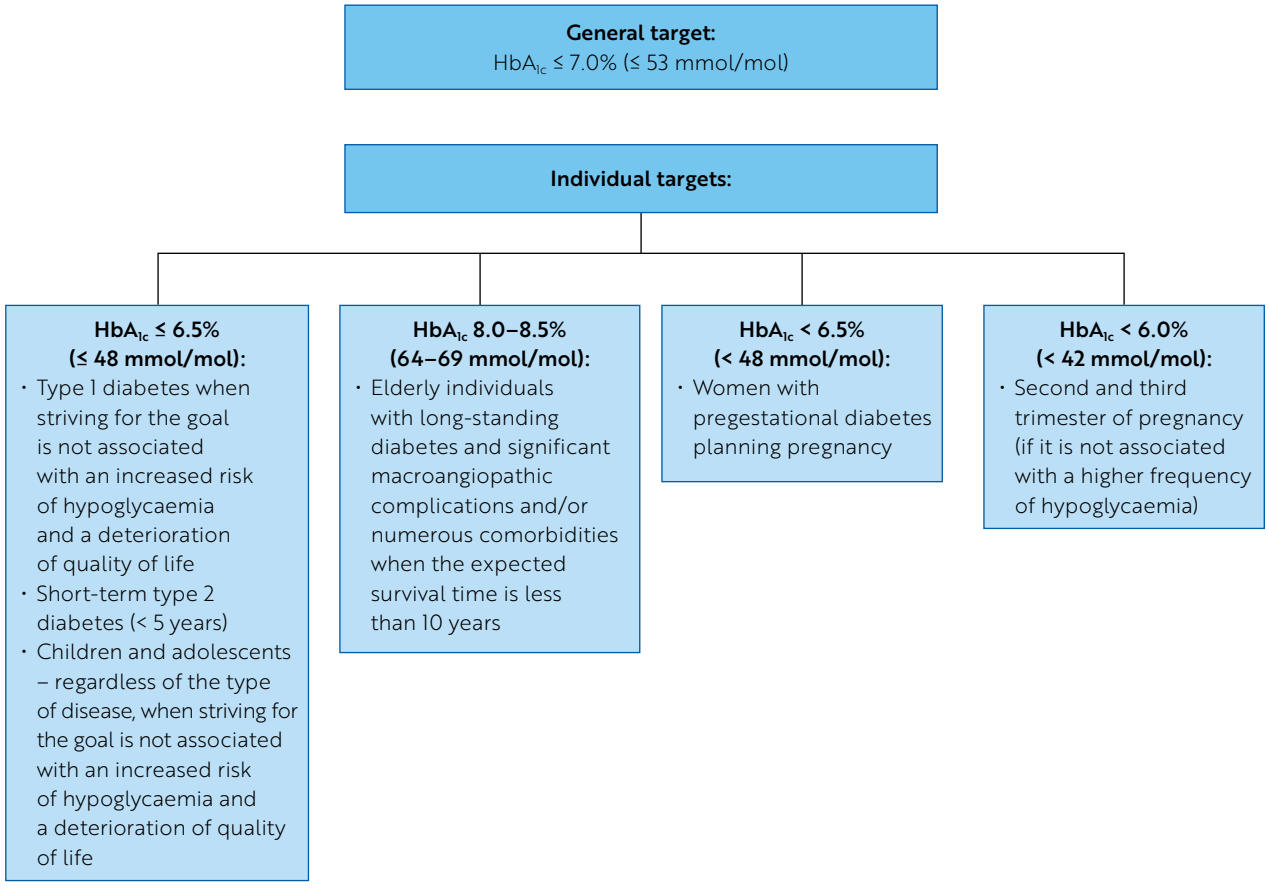

Figure 4.2. Glycemic targets

pathy (a history of heart attack and/or stroke) and/or numerous comorbidities, when the expected survival time is less than 10 years; if a person with diabetes over the age of 65 is expected to live longer than 10 years, while realizing general treatment goals, one should aim for a gradual diabetes management, adopting a target HbA_{1c} value of ≤ 7%;

3) HbA_{1c} value < 6.5% (48 mmol/mol) in women with pregestational diabetes planning pregnancy, and < 6.0% (42 mmol/mol) in the second and third trimesters of pregnancy, if it is not associated with a higher frequency of hypoglycaemia.

In patients using a continuous glucose monitoring (CGM) system, one of the fundamental parameters for assessing diabetes management should be the time in range (TIR). Detailed recommendations regarding TIR depending on the type of diabetes are presented in Table 4.2.

III. Lipid targets

- LDL-C levels < 55 mg/dl (< 1.4 mmol/l) and a reduction of at least 50% from the baseline in people with diabetes at very high cardiovascular risk.
- LDL-C levels < 70 mg/dl (1.8 mmol/l) and a reduction of at least 50% from the baseline in

Table 4.1. The relationship between HbA_{1c} and average plasma glucose level [7]

HbA_{1c}	Average plasma glucose levels [mg/dl]	Average plasma glucose levels [mmol/l]	Average fasting glucose levels [mg/dl]	Average preprandial glucose levels [mg/dl]	Average postprandial glucose levels [mg/dl]
6.0	126	7.0			
< 6.5			122	118	144
6.5–6.99			142	139	164
7.0	154	8.6			
7.0–7.49			152	152	176
7.5–7.99			167	155	189
8.0	183	10.2			
8.0–8.5			178	179	206
9.0	212	11.8			
10.0	240	13.4			
11.0	269	14.9			
12.0	298	16.5			

Correlation between HbA_{1c} and mean glycemic values 0.92.

Table 4.2. Target glycemic parameters in people with type 1 and type 2 diabetes and pregnant women using a continuous glucose monitoring system on a regular basis [1]

	TIR		TBR		TAR	
	% of readings; time per day	Target values	% of readings; time per day	Values below target	% of readings; time per day	Values above target
Type 1 diabetes/ Type 2 diabetes	> 70%; > 16 hours, 48 minutes	70–180 mg/dl (3.9–10.0 mmol/l)	< 4%; < 1 hour < 1%; < 15 minutes	< 70 mg/dl (< 3.9 mmol/l) < 54 mg/dl (< 3.0 mmol/l)	< 25%; < 6 hours < 5%; < 1 hour, 12 minutes	> 180 mg/dl (> 10.0 mmol/l) > 250 mg/dl (> 13.9 mmol/l)
Elderly/ individuals at high risk of hypoglycaemia	> 50%; > 12 hours	70–180 mg/dl (3.9–10 mmol/l)	< 1%; < 15 minutes	< 70 mg/dl (< 3.9 mmol/l)	< 50%; < 12 hours < 10%; < 2 hours, 24 minutes	> 180 mg/dl (> 10.0 mmol/l) > 250 mg/dl (> 13.9 mmol/l)
Pregnant women with type 1 diabetes	> 70%; > 16 hours, 48 minutes	63–140 mg/dl (3.5–7.8 mmol/l)	< 4% < 1 hour < 1% < 15 minutes	< 63 mg/dl (< 3.5 mmol/l) < 54 mg/dl (< 3.0 mmol/l)	< 25% < 6 hours	> 140 mg/dl (> 7.8 mmol/l)

TAR – time above range: hyperglycaemia, TBR – time below range: hypoglycaemia, TIR – time in range

people with diabetes at high cardiovascular risk.

- LDL-C levels < 100 mg/dl (2.6 mmol/l) in individuals at moderate cardiovascular risk (young individuals < 35 years of age with type 1 diabetes without chronic complications and other cardiovascular risk factors, or individuals with type 2 diabetes < 50 years of age, with a diabetes duration of < 10 years, without other risk factors).
- Non-HDL cholesterol concentration ≤ 85 mg/dl (≤ 2.2 mmol/l) in individuals with diabetes who are at very high cardiovascular risk.
- Non-HDL cholesterol concentration ≤ 100 mg/dl (≤ 2.6 mmol/l) in individuals with diabetes who are at high cardiovascular risk.
- Non-HDL cholesterol concentration ≤ 130 mg/dl (≤ 3.4 mmol/l) in individuals who are at moderate cardiovascular risk.
- Triglyceride levels < 100 mg/dl (< 1.2 mmol/l).

IV. Blood pressure targets:

- systolic pressure ≤ 120–129 mm Hg [IA].
- diastolic pressure < 70–79 mm Hg [IA].

For detailed criteria: see Chapter 13.

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5. Organization of Medical Care for Individuals with Diabetes

CHAPTER HIGHLIGHTS

- Contemporary diabetes management necessitates a multidisciplinary approach that includes the expertise of medical professionals, diabetes educators, and dietitians. Care should be personalized, considering each patient's unique circumstances, needs, and preferences. Furthermore, given the complex nature of diabetes, which often presents with various complications and comorbidities, it is essential for specialists from diverse fields to collaborate closely. [**B**]

I. Outpatient Care

Modern diabetes treatment primarily requires competencies in treating, monitoring its effectiveness, and educating people with diabetes to gain the necessary knowledge and motivation to follow recommendations. Cooperation between primary health care physicians (PHC) and specialist care physicians is also necessary.

I.1. Primary health care goals

Health promotion, identification of risk factors, prevention of carbohydrate metabolism disorders, and education on prediabetes and type 2 diabetes.

1. Diagnosis of carbohydrate metabolism disorders.
2. Referral to a diabetes clinic for continuous treatment in case of:
   - type 1 diabetes,
   - other specific types of diabetes,
   - when diagnosis of type of diabetes is in doubt,
   - any type of diabetes in children and adolescents, women planning pregnancy and pregnant women.
3. Treatment of prediabetes.
4. Treatment of type 2 diabetes, including insulin regimen that requires the patient to use basal insulin in combination with other non-insulin antihyperglycemic medications.
5. Referral for diabetologist consultation (less frequently for continuous treatment) in case of:
   - not achieving therapeutic goals; referral primarily for intensification of insulin therapy,
   - occurrence of comorbidities complicating treatment,
   - occurrence of diabetes complications,
   - occurrence of pharmacotherapy complications,
   - other special situations.
6. Implementing therapeutic arrangements and guidelines resulting from a specialist consultation after it has been conducted.

I.2. Specialist health care goals:

- reviewing the treatment outcomes and setting treatment targets for people with diabetes managed in PHC as part of annual check-up,
- management of people with diabetes treated with injections (insulin, GIP/GLP-1 receptor agonists),
- management of people with diabetes treated with continuous subcutaneous insulin infusion (CSII),
- conducting differential diagnosis of types of diabetes, including monogenic diabetes and diabetes associated with other diseases,
- diagnosis, prevention, and management of people with diabetes in terms of late complications,
- diabetes education,
- diagnosis and management of diabetes in women during pregnancy.,
- Diagnosis and treatment of comorbidities with diabetes.,
- Annual check-up in accordance with the current recommendations of the Diabetes Poland (Table 5.1).

II. Specialized inpatient care:

1. Cases of newly diagnosed type 1 diabetes and type 2 diabetes with clinical symptoms of hyperglycaemia, when outpatient treatment is not possible.
2. Acute complications of diabetes (severe, recurrent hypoglycaemia and hyperglycaemia, diabetic ketoacidosis, and comas).
3. Aggravation of chronic complications.
4. Modification of the therapy scheme for patients who cannot achieve therapeutic goals in outpatient settings.
5. Implementation of intensive insulin therapy using a personal insulin pump and/or continuous glucose monitoring system, when outpatient treatment is not possible.
6. Implementation of insulin therapy in gestational or pre-gestational diabetes not pre-

Table 5.1. Recommendations for monitoring adults with diabetes

Parameter	Comments
Dietary and therapeutic education	At every visit
Physical examination, blood pressure measurement, and body weight	At every visit
HbA_{1c}*	Once a year, more often if there is doubt in maintaining normoglycaemia or if there is a need to verify the effectiveness of treatment after its modification
Serum total cholesterol, HDL and LDL cholesterol, triglycerides	Once a year, more frequently in case of dyslipidemia
Albuminuria (ACR)	Once a year in individuals with type 1 diabetes after 5 years of disease duration, in individuals with type 2 diabetes from the time of diagnosis, and in all individuals with diabetes with coexisting hypertension
Serum creatinine and calculation of eGFR	Once a year (in case of type 1 diabetes 5 years after the onset)
Complete blood count, TSH, sodium, potassium, calcium, phosphorus in serum, and general urine examination with sediment analysis	Based on clinical indications
Fundoscopic exam	In people with type 1 diabetes 5 years after the onset; in people with type 2 diabetes – from the moment of diagnosis (details: see Chapter 20)
Screening for diabetic neuropathy and diabetic foot disease	Once a year in cases of very low risk of ulceration (details: see Chapters 21 and 22)

**More often in people with badly managed diabetes after anti-hyperglycaemic treatment adjustment.*

viously treated with insulin when outpatient treatment is not possible.

7. Difficulties in achieving normoglycaemia in pregnant women with pre-gestational diabetes when outpatient treatment is not possible.

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6. Behavioral Therapy

CHAPTER HIGHLIGHTS
· All individuals with diabetes should be educated on the general principles of proper nutrition in diabetes by health care professionals (doctor, dietitian, diabetic nurse, diabetes educator) using various methods and techniques, including telemedicine. Detailed dietary recommendations should be individualized based on the patient's needs and capabilities. [**A**]
· Continuous Glucose Monitoring (CGM) systems play a very important educational role in optimizing the diet, especially in terms of the glycemic effect of meals, in all types of diabetes. [**B**]
· The primary macro-nutrient in the diet that determines postprandial insulin requirements is carbohydrates. A key element of dietary education for individuals with type 1 diabetes should be training in the recognition and estimation of carbohydrate content in meals for optimal insulin dosing. Individuals with type 2 diabetes should be educated about portion control and the proportion of carbohydrates in individual meals and the overall diet. [**A**]
· There is no universal diet for all individuals with diabetes. Optimal macro-nutrient proportions for this patient group should be established individually, considering age, physical activity, the presence of diabetes complications, additional diseases, and the dietary preferences of the person with diabetes. [**E**]
· Physical activity, due to its multifaceted benefits, is an integral part of proper, comprehensive management in the treatment of diabetes. To achieve the optimal effect, physical activity should be regular, undertaken at least every 2–3 days, but ideally daily. [**A**]
· Individuals with diabetes should limit the time spent without breaks in a seated position. [**B**]

Behavioral therapy is a necessary element of treatment for all individuals diagnosed with diabetes (both type 1 and type 2) at any age. Proper nutrition and physical activity are crucial in improving overall health and in the prevention and treatment of chronic diabetes complications. All individuals with diabetes should be educated on the general principles of proper nutrition in diabetes by authorized persons (doctor, dietitian, diabetic nurse, diabetes educator) using various methods and techniques, including interactive methods and telemedicine. The treatment of individuals with diabetes should consider a therapeutic lifestyle that includes a varied diet, regular physical activity, avoiding smoking and alcohol consumption, optimal sleep time, and avoiding stress. Education about a therapeutic lifestyle, tailored to the needs and capabilities of individuals with diabetes, allows for the achievement of the therapeutic goal and reduces the costs associated with the treatment of diabetes complications.

It should be emphasized that one of the priorities of behavioural treatment of diabetes, regardless of its type, should be maintaining the proper body weight of the person with diabetes.

Medical nutrition therapy

I. General Recommendations

The goal of dietary treatment for individuals with diabetes is to achieve and maintain:

- proper (normoglycaemia) blood plasma glucose levels to prevent diabetes complications
- optimal serum lipid and lipoprotein levels,
- optimal blood pressure values to reduce the risk of vascular diseases,
- desired body weight.

Dietary treatment includes guidelines on:

- individually calculated caloric intake,
- distribution of calories among daily meals,
- food sources providing necessary energy, vitamins, minerals, and phytochemicals,
- products of which consumption should be limited.

When planning a diet, individual nutritional and cultural preferences, age, gender, physical activity level, and economic status should be considered. An important part of dietary education should be practical information delivery, allowing direct application in daily life. Meal consumption is an important aspect of life comfort and quality for people with diabetes, and they should be informed about the wide range of individual diet choices and composition. Information on the need to limit or eliminate certain foods should be directed to individuals only in specific situations, for example when the reduction is scientifically justified. Dietary education should be provided at diagnosis and patient knowledge on dietary treatment of diabetes should be annually examined with possible re-education.

Dietary management strategy for individuals with diabetes should include:

- assessment of usual eating habits,
- nutritional diagnosis,
- setting plan and targets of dietary intervention,
- nutritional intervention (individual and/or group counselling),
- monitoring eating habits and evaluating therapy effects,
- change of dietary plan if the therapeutic goal is not met.

Individuals with diabetes should be encouraged to follow the principles of proper nutrition for healthy people and additionally to:

- control portion sizes of commonly consumed foods,
- control the quantity of carbohydrates in the overall diet and individual meals,
- limit foods containing easily digestible carbohydrates, including added and free sugars,
- regularly consume meals, including breakfast,
- eat meals at a slow pace.

There is no universal diet for all individuals with diabetes. Various nutritional strategies such as the Mediterranean diet, DASH diet, flexitarian diet, and plant-based diets may be used in diabetes treatment.

These dietary models assume a significant intake of non-starchy vegetables, maximum reduction of added sugars and refined grains, and an increase in minimally processed foods.

Individuals with type 1 diabetes should avoid easily digestible carbohydrates and follow the general principles of a properly balanced diet. Diet assumptions and insulin therapy should be individually determined. Insulin therapy should be adapted to the eating habits of the individual with diabetes, the composition of consumed meals (content of carbohydrates, proteins, and fats), and their lifestyle and physical activity. Recognizing and estimating the content of digestible carbohydrates in a meal, such as in the carbohydrate exchange system (CE), is a priority when developing diet assumptions. The glycemic index (GI) and glycemic load (GL) values can also be helpful in food selection. There is significant variation

in individual glycemic responses to consuming the same meal or product (e.g., dairy products). The order of consuming products from different food groups within a meal can significantly affect postprandial glycaemia. It is beneficial to consume vegetables and protein-containing products (meat, fish) before starchy products.

For individuals with diabetes in the oldest age groups, dietary education should be simple and understandable. The diet should be individualized, ensuring adequate protein intake.

Although carbohydrates are the primary macronutrient determining postprandial insulin requirements, individuals with type 1 diabetes should also be educated on the glycemic effect of proteins and fats. Continuous glucose monitoring systems are effective tools for assessing the impact of the quantity and quality as well as mutual proportions of dietary macronutrients on glycaemia.

Dedicated applications can also facilitate postprandial glycaemia control. Their selection should be primarily based on indications and recommendations from leading diabetes associations.

In type 2 diabetes, the primary goals of therapy are maintaining optimal metabolic control of the disease, reducing excess body weight, and maintaining desired body weight. Therefore, besides the above recommendations, the total caloric content of the diet adjusted for age, current body weight, and physical activity is of fundamental importance. The energy deficit should be individually established to allow for slow, systematic body weight reduction (about 0.5-1 kg/week). A reduction in body weight of at least 5%/year compared to the initial weight brings measurable improvement in glycemic control, but ideally, the body weight reduction should be at least 7%/year. A daily caloric deficit of 500-750 kcal is considered safe.

Weight reduction can be achieved by using diets with reduced caloric value and different macronutrient proportions (proteins, fats, carbohydrates), but long-term use of diets with significantly reduced carbohydrate intake and fasting is not recommended. All individuals with diabetes and overweight/obesity are advised to control portion sizes.

II. Detailed recommendations

Diet composition.

1. Carbohydrates:

- there is insufficient scientific evidence to determine one optimal amount of carbohydrates for individuals with diabetes,
- carbohydrates should make up about 45% of total energy; if they come from low GI products and are high in fibre, their proportion may be increased (up to 60%); high carbohydrate intake should be recommended for very physically active individuals, whereas a lower intake of less than 45% (25–44%) might be temporarily recommended for those with limited physical activity, e.g., due to coexisting diseases,,
- the main source of carbohydrates should be whole grain products, especially those with a low GI (< 55),
- the primary limitation should be on simple carbohydrates (mono- and disaccharides), which individuals with diabetes should minimize. It's also recommended to limit added sugars and free sugars, primarily from sugar, sweets, as well as honey, juices, and fruit drinks,
- Low-calorie sweeteners (sugar substitutes) should be consumed in moderation, within the recommended dosages specified by the manufacturer. During the registration process for low-calorie sweeteners, an acceptable daily intake (ADI) in mg/kg body weight/day is determined. ADI represents the amount that can be safely consumed daily over a lifetime without adverse health effects. The ADI values for selected low-calorie sweeteners are presented below in Table 1
- daily fructose intake should not exceed 50 g; it's advised not to use fructose as a sugar substitute,
- The minimum daily fibre intake should be 25 g or 15 g/1000 kcal of diet. Efforts should be made to increase fibre intake by including at least 2 servings of whole grain products and 3 servings of high-fibre vegetables; if the recommended amount of dietary fibre cannot be met, fibre supplements should be considered, especially soluble fibre. It is advisable to increase the supply of resistant starch (a fibre fraction) in the diet.

2. Fats:

- in the dietary treatment of diabetes, the fat content should be like those without diabetes and can range from 25% to 40% of the dietary energy value,
- the quality of fat is more important than the total amount; with high fat intake, the proportion of different types of fatty acids is especially important,
- saturated fats should account for less than 10% of the dietary energy value,

Table 6.1. Value of acceptable daily intake for selected low-calorie sweeteners

Substance	Labeling on food product	ADI [mg/kg/day]
Acetosulfam potassium salt	E950	0–15
Aspartame	E951	0–40
Cyclamate	E952	0–7
Saccharin	E954	0–5
Sucralose	E955	0–15
Neotam	E961	0–2
Steviol glycosides	E960	0–4

- polyunsaturated fats should account for about 6–10% of the dietary energy value,
- dietary cholesterol should not exceed 300 mg/day, and for those with dyslipidemia < 200 mg/day,
- to lower LDL-C levels, the intake of saturated fats should be reduced and/or replaced with low-glycemic-index carbohydrates and/or monounsaturated fats,
- for individuals with hypercholesterolemia, introducing foods containing 2–3 g/day of plant sterols/stanols can be beneficial,
- trans fatty acid isomers intake, especially from processed foods, should be limited to the maximum,
- vegetable fats are recommended, except for palm and coconut fats.

3. Proteins:
- the amount of protein should be set individually; there is no evidence of adverse effects of high-protein diets in the dietary treatment of diabetes; for most people with diabetes, as in the general population, the energy from protein should be 15–20% (about 1–1.5 g/kg body weight/day); for individuals with type 2 diabetes and excessive body mass, a reduced-calorie diet containing 20–30% protein provides greater satiety and helps with weight reduction and maintenance; patients with chronic kidney disease should maintain a protein intake of about 0.8–1 g/kg body weight/day,
- there is no need to restrict animal protein; however, for some individuals, replacing animal protein with plant-based protein (e.g., legumes) may be beneficial.

4. Vitamins and minerals:
- supplementation with vitamins or minerals is not recommended for those without deficiencies,
- exceptions are vitamin D_3 (supplementation according to general population guidelines), folic acid (400 µg supplementation for pregnant and breastfeeding women), and vitamin B_{12} for individuals treated long-term with metformin who have confirmed deficiencies,
- multivitamin supplementation may be necessary for elderly individuals, vegetarians, vegans, and those on very low-calorie diets.

5. Alcohol:
- alcohol consumption is not recommended for individuals with diabetes (no safe dose),
- individuals with diabetes should be informed that alcohol inhibits the release of glucose from the liver and thus its consumption (especially without a snack) may lead to hypoglycaemia.

6. Sodium:
- the amount of sodium (from all sources – products and seasoning) should not exceed 5 g/day (2300 mg of sodium/day),
- greater sodium intake restrictions are recommended for those with sodium-sensitive hypertension, in line with DASH diet principles, although data on reducing sodium intake below 1500 mg/day in individuals with diabetes are ambiguous.

Dietary recommendations for individuals with diabetes in special situations, such as during pregnancy, for children and adolescents, or for those with advanced nephropathy, are provided in the relevant chapters. Detailed practical guidelines on the dietary treatment of diabetes can be found in the Recommendations of the Polish Society of Dietetics, which are accessible on their website www.ptd.org.pl.

Physical activity

Physical activity, due to its multifaceted benefits, is an integral part of proper, comprehensive diabetes management. It enhances insulin sensitivity, improves glycemic control, lipid profile, aids weight reduction, and positively affects mood, including in those with depression.

1. Principles of engaging in physical activity:
- initial recommendations should be moderate and based on the individual capacity for exercise,
- for optimal effects, physical activity should be regular, at least every 2–3 days, preferably daily,
- when starting intensive physical activity, perform warm-up exercises lasting 5–10 minutes, followed by calming exercises at the end,
- physical activity can increase the risk of severe or delayed hypoglycaemia,
- alcohol can heighten the risk of post-exercise hypoglycaemia,
- one should pay attention to preventing dehydration in high temperature conditions,
- it is important to keep in mind the risk of foot damage during exercise (especially with coexisting peripheral neuropathy and lowered pain threshold), the need for foot care and comfortable footwear.

2. Intensity of physical activity.

The doctor decides the appropriate intensity based on the full clinical picture.

An appropriate form of exercise in people with diabetes (with co-morbid overweight/obesity) of any age is nordic walking.

The most appropriate form of exercise in people with type 2 diabetes aged > 65 years and/or overweight is brisk (up to breathless) walking, 3–5 times a week (about 150 minutes/week).

Individuals without significant contraindications, especially in younger age groups, should be encouraged to engage in increased physical activity, including sports. Such individuals require additional education about the glycemic effect caused by different types of physical activity (e.g., aerobic, resistance, interval training).

An excellent tool to facilitate glycemic control before, during and after physical activity are continuous glucose monitoring systems, used both in real time and for retrospective assessment of the effects of exercise and therapeutic interventions undertaken on glycaemia.

Dedicated applications can also facilitate glycaemia control before, during and after exercise; their selection should primarily follow indications and recommendations from leading diabetes societies.

A simple yet effective recommendation is to limit uninterrupted sitting time, especially for adults with type 2 diabetes, aiming to avoid sitting for longer than 30 minutes continuously for glycemic benefits.

3. Risks of physical activity in people with diabetes.

Physical activity without appropriate preventive measures may result in hypoglycaemia or, less commonly, hyperglycaemia and metabolic decompensation. These measures should address the pre-exercise period, post-exercise period (up to 12 hours after activity), and long-term management (accounting for improvements in physical fitness over time). Detailed guidelines for peri-exercise management to avoid extreme glycemic values are presented in Chapter 7.

Moderate and intense physical activity may negatively impact the overall condition of patients in certain clinical situations such as:
- proliferative diabetic retinopathy – the risk of haemorrhagic events within the vitreous body of the eye that may lead to retinal detachment,
- diabetic kidney disease – increased albumin excretion and proteinuria,
- autonomic neuropathy – presence of orthostatic hypotonia,
- the risk of myocardial ischemia.

4. Physical activity in the COVID-19 pandemic.

It's important to note that individuals with diabetes should maintain the recommended level of physical activity regardless of the epidemiological situation. When restrictions due to the epidemiological context limit movement or access to sports facilities, alternative forms of physical activity that can be performed within existing constraints, such as at home, should be sought. Because this may involve changes to the nature of the exercise and its glycemic effects, as well as necessary precautions, each such situation requires consultation with the leading physician.

Tobacco control

For any current or past smoker, it is important to determine:
- age at the time the person started smoking,
- the duration of smoking,
- the number of cigarettes smoked daily,
- whether there have been any attempts to stop smoking and how long they lasted,
- the time at which the person with diabetes stopped smoking.

Counselling:
- raising awareness of the risks of smoking and the use of e-cigarettes to people with diabetes who have not previously smoked,
- persuading people to stop smoking altogether and use e-cigarettes,

- supporting a person with diabetes in the decision to stop smoking,
- psychological support and, if necessary, also pharmacological support,
- discussion about smoking at each medical visit,
- written annotation in medical records if a person with diabetes refuses to stop smoking.

Sleep

Proper sleep hygiene is a vital component of a healthy lifestyle. In individuals with diabetes, sleep duration and quality may be disrupted due to the disease's pathophysiology, behavioural factors, and treatment-related factors. Conversely, poor sleep quality and inappropriate sleep duration can lead to worsened metabolic control. Moreover, an evening chronotype (a natural tendency for better functioning in the evening and at night) is an independent risk factor for developing type 2 diabetes, regardless of sleep quality and duration. Promoting appropriate sleep duration and quality should be an integral part of diabetes management. Recommendations to support this include guidance on meal timing and quality, glucose self-monitoring (with appropriate alarm settings for individuals using CGM), avoiding factors that lead to hyperglycaemia or hypoglycaemia, and favouring treatments that ensure stabilization and optimization of nocturnal glycaemia.

Individuals with diabetes or prediabetes should be screened for sleep disorders. To facilitate self-management of sleep, patients may consider using sleep monitors such as watches, bands, specialized mats, or similar devices, as well as self-reported questionnaires on sleep duration and quality.

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7. Physical Activity and Glycemic Management

CHAPTER HIGHLIGHTS
· Individuals with type 1 diabetes without clinically significant chronic diabetes complications can undertake any kind of physical activity, including those of maximum intensity. [**C**]
· Aerobic efforts carried out until shortness of breath is safe and can be recommended to all people with diabetes without contraindications. [**B**]
· People with type 2 diabetes are advised to add resistance exercise elements to aerobic exercises. [**B**]
· Severe hypoglycaemia is a contraindication for undertaking physical activity for 24 hours. [**E**]
· Post-exercise hypoglycaemia can occur up to 24 hours after the end of physical activity. [**B**]
· Proliferative retinopathy is a contraindication to undertaking physical activity until stabilization of the retinal image is achieved. [**E**]
· Hyperglycaemia > 250 mg/dl without confirmed ketonemia and/or ketonuria is not a contraindication to undertaking physical activity, provided the patient feels well and knows the cause of the hyperglycaemia. [**E**]
· The rules for undertaking effort in competitive sports and during competitions differ significantly from amateur sports and require individually developed solutions. [**E**]

I. Recommended duration and intensity of physical activity.

The undertaking of physical activity by a person with diabetes should be assessed by a diabetologist based on the assessment of the person's activity level (type, time, intensity of effort), any contraindications, and their expectations, knowledge, and skills in the prevention of hypoglycaemia and previous training. For individuals with type 2 diabetes over the age of 65 and/or overweight, as well as patients who have had a cardiovascular incident and with cardiovascular diseases, it is recommended to monitor the pulse and assess the intensity of physical activity using the Borg scale. The ranges of heart rate and intensity of physical activity can be determined during an electrocardiographic exercise test. In this group of patients, aerobic effort (until shortness of breath) is safe and should be recommended for at least 150 minutes per week. Obese individuals are advised to engage in 200–300 minutes of physical activity per week, leading to an energy deficit of 500–750 kcal/day. Younger individuals with diabetes (without significant contraindications) are recommended to engage in daily intensive physical activity, including active sports participation.

II. Contraindications to physical activity

Contraindications to recreational sports are discussed in Chapter 6. The diabetologist's decisions may require consultations with other specialists, including an ophthalmologist, cardiologist, nephrologist, and neurologist.

Annex 6 of the Diabetes Poland recommendations includes contraindications for participation in training and sports competitions.

III. Glycaemia monitoring during physical activity.

In physically active individuals treated with insulin, the use of continuous glucose monitoring systems (CGM) is recommended. The therapeutic team's task is to assist in selecting a CGM, educate on the interpretation of results, individual programming of higher hypoglycaemia alarm thresholds, and securing the CGM during sports. In the case of self-monitoring of glycaemia using a glucometer, blood glucose should be measured up to 15 minutes before starting physical activity, during it, and after completing physical activity. Informing accompanying persons about the diabetes during physical activity significantly facilitates self-monitoring of glycaemia.

IV. Hypoglycaemia and hyperglycaemia in relation to physical activity.

Changes in glycaemia during physical activity are illustrated in Figure 7.1.

Severe hypoglycaemia is a contraindication to engaging in physical activity for 24 hours.

In case of a hypoglycaemia alert ≤ 70 mg/dl, it is recommended to consume simple carbohydrates, preferably in liquid form, and physical activity can be continued after the symptoms of hypoglycaemia subside.

In case of severe hypoglycaemia in a person with type 1 diabetes, the action of glucagon after intense physical activity may be weaker, but an attempt should always be made to administer the drug.

Post-exercise hypoglycaemia can occur up to 24 hours after the end of physical activity, and the risk of their occurrence is higher in untrained individuals and those engaging in physical activity irregularly. This group of individuals should particularly apply the prevention of nocturnal hypoglycaemia.

Anaerobic effort may cause hyperglycaemia and correcting it with rapid-acting insulin should be cautious due to the risk of hypoglycaemia occurring several hours after the end of physical activity.

If there is hyperglycaemia > 250 mg/dl and additionally ketonuria and/or ketonemia ≥ 1.5 mmol/l are detected, physical activity is contraindicated.

If hyperglycaemia > 250 mg/dl is not accompanied by ketonuria and/or ketonemia, and/or the cause of the hyperglycaemia is known, light to moderate exercise may be undertaken.

V. Undertaking physical activity by an individual with type 2 diabetes not on insulin regimen

In individuals with diabetes who are not on insulin regimen or sulfonylurea derivatives, there is a very low risk of hypoglycaemia. Blood glucose levels < 100 mg/dl do not require the consumption of additional carbohydrate servings. Self-monitoring of glycaemia in connection with physical activity should only be performed periodically.

Regular physical activity improves insulin sensitivity and thus increases the chance of delaying the start of insulin therapy. An important complement to aerobic training is the addition of resistance strength exercises. It is recommended to load large muscle groups and perform 8–12 repetitions 2–3 times a week.

VI. Undertaking physical activity by an individual on insulin regimen.

Regardless of the type of exercise, the target glucose levels should be between 126–180 mg/dl or slightly higher for individuals at increased risk of hypoglycaemia and/or with impaired hypoglycaemia awareness. Physical activity should not be initiated with a glucose level below 90 mg/dl. For strength training and expected hyperglycaemia, there are no contraindications to starting activity at a glucose level of 90 mg/dl.

Physical activity undertaken up to 2 hours after the administration of a rapid-acting insulin analogue requires a reduction in the insulin dose if the physical activity lasts at least 30 minutes.

The bolus reduction can range from 25–75% and depends on the timing and intensity of the physical activity.

Physical activity requires the consumption of an additional portion of carbohydrates in the amount of:

- 1.0–1.5 g/kg body weight per hour of intense physical activity during the peak action of an insulin bolus that has not been reduced,
- 0.2–0.5 g/kg body weight per hour of intense physical activity during the peak action of an insulin bolus that has been reduced or that

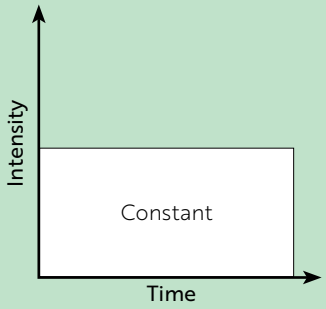
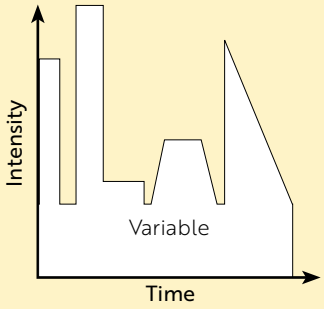
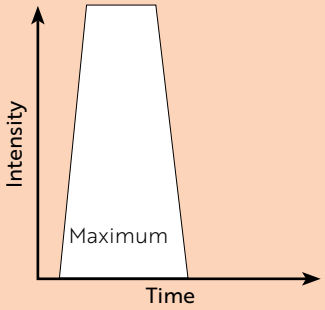
Type of exercise	**Aerobic** Examples: walking, nordic walking, light cycling, jogging	**Mixed (aerobic-anaerobic)** Examples: team games, fast-paced running, swimming, interval cycling	**Anaerobic** Examples: sprints, strength training with maximum load
Intensity			
Heart rate range	< 55 (60)% HR_{max}	60–75 (80)% HR_{max}	> 75 (80)% HR_{max}
Borg scale	7–11	12–15	16–20
Expected change in glycaemia	Decrease	Decrease and/or increase	Increase
Risk of hypoglycaemia	High	Increased	Low
Reduction of meal bolus for activity lasting > 30 minutes (not applicable to automated insulin delivery systems)	25%: Low-intensity exercise 50%: Higher-intensity exercise lasting > 45 minutes 75%: Aerobic, high-intensity, prolonged exercise	Possible no bolus reduction 25%: Anticipated slight decrease in glucose levels 50%: Moderate-intensity exercise, anticipated rapid drop in glucose levels	Dependent on the athlete's experience No bolus reduction Administration of a small insulin bolus before or during physical activity

Figure 7.1. Types of physical activity and their impact on glycaemia changes

was administered more than 2 hours before starting physical activity

The maximum duration of detaching the insulin pump during physical activity should not exceed 3 hours. The condition for detaching the insulin pump is the presence of active insulin, the amount of which should be monitored using a bolus calculator.

A reduction of NPH or long-acting analogue basal insulin should be considered during multi-hour or all-day endurance effort. A preceding reduction in the dose of ultra-long-acting insulin analogues can be considered before multi-day activities.

During treatment with an insulin pump, it is recommended to reduce the basal insulin flow by 20–80%, depending on the intensity and duration of the effort, preferably 2 hours before starting it.

VII. Undertaking physical activity by individuals on automated insulin delivery systems.

The use of a hybrid closed-loop system during physical activity requires the patient to make multiple decisions and modify the therapy. Separate education in this area is indicated.

Recommended therapy modifications:

- setting a higher target glucose level 90 minutes (1–2 hours) before starting physical activity lasting longer than 30 minutes, particularly for aerobic exercise,
- using a function that reduces insulin delivery and is dedicated to physical activity ("Ease-off" for CamAPS FX; "Temporary Target" for 780G) 90 minutes (1–2 hours) before planned physical activity,
- meals consumed up to 2 hours before exercises require a reduction in the insulin dose by 25–33%,
- intake of additional portions of carbohydrates:
  - » they should not be entered into the system,
  - » it is recommended to consume carbohydrates 5–10 minutes before starting the exercises, and these amounts will usually be smaller than in the case of therapy using a traditional insulin pump,
  - » consuming carbohydrates earlier than 20 minutes before physical activity will cause the hybrid closed-loop system to increase insulin delivery, which may result in hypoglycaemia;

- suspending insulin delivery:
  - » if the insulin pump is detached during physical activity, it is necessary to suspend the pump's operation,
  - » the maximum duration of detaching or suspension of the insulin pump during physical activity should not exceed 3 hours.

VIII. Undertaking physical activity by women with hyperglycaemia during pregnancy.

It is recommended that all women with hyperglycaemia during pregnancy and postpartum (without medical contraindications) engage in physical activity during this time. Moderate physical activity contributes to the reduction of the percentage of gestational diabetes, pregnancy hypertension, preterm births, and caesarean sections.

Aerobic physical activity of moderate intensity is recommended for at least 150 minutes per week (3–4 times a week – exercise time 30–60 minutes). Exercises should be performed with an intensity less than 60–80% of the maximum heart rate for the mother's age, most often not exceeding 140 beats per minute. It is also possible to perform static aerobic exercises and muscle strengthening. Adding stretching exercises may also be beneficial.

Preferred physical activities include walking, stationary cycling, dancing, water aerobics, stretching exercises, and lifting light weights. Lifestyle changes and physical activity are essential components of management in gestational diabetes mellitus (GDM) and may be sufficient as a therapeutic approach or delay the initiation of insulin therapy for many women.

In patients treated with insulin for pregestational diabetes mellitus (PGDM), physical activity requires a reduction in the dose of basal insulin and/or insulin boluses, considering the principles applicable before pregnancy.

Undertaking additional physical activity (beyond daily activity) requires consultation with a gynaecologist.

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8. Psychological Management in Diabetes

CHAPTER HIGHLIGHTS
• Psychosocial factors significantly influence the clinical and mental well-being of individuals with diabetes. [**B**]
• Whenever possible, mental health assessments should be conducted at the onset of diabetes treatment and during each subsequent medical visit. [**B**]
• Specific mental health disorders frequently co-occur with diabetes and substantially increase the risk of diabetes-related complications. [**A**]
• Individuals with diabetes should be assessed for symptoms of anxiety, diabetes distress, substance dependence, depression, eating disorders, and cognitive impairment. These conditions can significantly hinder adaptation to the disease. [**B**]
• Psychological and social care should be integrated into a patient-centred approach and made accessible to all individuals with diabetes to optimize treatment outcomes and quality of life. [**A**]

The patient's mental state (their well-being) affects almost all aspects of their therapeutic behaviour. Non-adherence to treatment recommendations is often linked to psychological issues that require diagnosis and appropriate psychotherapeutic interventions. For this reason, education limited to simply providing information about prescribed treatment and recommended actions is often ineffective.

The patient's mental state should be assessed at the initiation of diabetes treatment and during each medical visit. The use of properly designed questionnaires and tests is recommended for this purpose. Under optimal conditions, this assessment should be conducted by a psychologist who is part of the therapeutic team. In the absence of access to a psychologist, the treating physician should carry out this evaluation.

I. Most common emotional problems in individuals with diabetes:

- diabetes distress (DD) – chronic negative emotions associated with diabetes, including the following dimensions:
  - » emotional burnout scale,
  - » stress scale related to the patient-physician relationship,
  - » stress scale related to treatment regimen,
  - » stress scale related to social relationships in the context of diabetes;
- depression,
- fear of hypoglycaemia (FoH),
- fear of complications,
- specific eating disorders, so-called "diabulimia",
- alarm fatigue,
- fear of stigmatization,
- sleep disorders,
- cognitive impairments.

II. Psychological assistance should include:

- appropriate communication methods,
- continuous assessment (monitoring) of mental health and adherence to medical recommendations,
- referral for psychological support, psychiatric care, or psychotherapy when necessary.

III. The individualized approach aims to:

- consider the patient's psychosocial situation and collaborate with them on a treatment plan that they perceive as feasible within their current life circumstances (shared decision-making). It is essential to take into account the possibility of utilizing modern diabetes technologies in treatment,
- foster motivation for optimal management,
- avoid scaring the patient with the consequences of non-adherence to medical recommendations, as this is ineffective and often harmful in most cases,
- apply an optimal method of education based on psychological assessment,
- use appropriate, non-judgmental language, such as "glucose levels outside the TIR range" instead of "bad sugars," or "high glycemic variability" instead of "poor control."

IV. Assessment of mental state (psychological diagnosis) in medical practice for diabetes patients:

- the social and psychological (life) situation,
- the patient's quality of life,
- attitudes, beliefs, difficulties, and responsibilities related to diabetes (unjustified fears and worries can weaken the ability to cope with the disease),

- the sense of control over the course of the disease (a lack of an appropriate sense of control over diabetes can lead to coping styles that involve avoiding thinking about the disease and/or reducing emotions triggered by it),
- assessment of coping styles for managing the disease (a reduction in tendencies to seek optimal strategies for coping with the disease and problem-solving approaches to disease-related challenges is observed),
- assessment of diabetes-specific issues: diabetes distress, depression, fear of hypoglycaemia (FoH), fear of complications, and eating disorders,
- assessment of general anxiety symptoms, addiction, and cognitive impairments (these can significantly hinder adaptation to diabetes).

V. Basic methods for assessing the emotional state of individuals with diabetes.

1. To assess the risk of depression use freely available online tools for depression screening:

- Well-being index WHO-5
  www.who-5.org
  A score < 13 indicates the need for further evaluation for depression, and a score < 7 signifies a high risk of depression.
- Patient Health Questionnaire 9 (PHQ-9)
  www.phqscreeners.com/overview.aspx
  A score < 5 points is considered normal, 5–9 points indicate mild depression, 10–14 points moderate depression, 15–19 points moderately severe depression, and 20–27 points severe depression. In the Polish version, a score > 12 indicates a high risk of depression

and/or ask two questions:

- over the past month, have you often felt down, depressed, or hopeless?
- over the past month, have you often experienced a lack of interest or pleasure in doing things?

A positive response to either question has a sensitivity of 97% and specificity of 67% for diagnosing depression. In such cases, refer the individual for psychiatric consultation.

2. To assess diabetes distress, use the DDS 17 questionnaire – Diabetes Distress Scale. Download here A global scale score above 3 or subscale scores above 3 indicates a level of distress that requires clinical intervention.
3. To examine fear of future complications, ask the following question: To what extent are you worried about the future and the possibility of developing serious complications? (0) This is not a problem; (1) This is a minor problem; (2) This is a moderate problem; (3) This is quite a serious problem; (4) This is a serious problem.

A score of three or more indicates significant risk of developing psychosocial problems.

In case of any doubts, seek a psychological evaluation by a qualified psychologist.

VI. Psychological interventions in a person with diabetes include:

- developing a sense of control over the course of the disease by:
  - » providing patient-understandable information about the disease and its treatment,
  - » joint formulation of goals and therapeutic plans that are, in their opinion, realistic,
  - » gradually achieving the optimal level of adherence to recommendations (strategy of small steps),
  - » helping in case of failures in implementing the established plans (so that the patient knows the doctor will help determine the cause of failure and will not have a negative attitude towards them),
  - » offering the possibility to use psychological self-help applications;
- shaping and maintaining a problem-solving-oriented coping style with diabetes.

VII. Clinically severe depression and psychiatric consultation

The occurrence of clinically severe depression (depressive episode, dysthymia) and other mental disorders requires psychiatric consultation. In the case of adaptive disorders related to adjusting to the disease, psychotherapeutic interventions can be undertaken by the primary care physician or specialist. In more difficult cases, the help of a clinical psychologist or psychotherapist may be needed.

VIII. Teamwork

A consistent attitude of the entire therapeutic team is an essential condition for the effectiveness of therapy. Effective communication among team members is necessary. In diabetes clinics, a psychologist is an essential member of the specialist treatment team.

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9. Therapeutic Education

CHAPTER HIGHLIGHTS
· Education and continuous re-education of all individuals with diabetes, especially those at risk of developing diabetes and with preclinical diabetes conditions, are key elements of effective disease management and prevention of its complications. [**A**]
· Every person with diabetes, as well as their caregivers, should have assured and guaranteed access to diabetes education to acquire the necessary knowledge and skills for self-managing the disease. [**A**]
· The key goals of education are to achieve clinical effects, optimize metabolic control and health status, and improve the well-being and quality of life of the patient and their family. Goals should be measured during routine visits. [**B**]
· There are four critical moments to assess the need for self-monitoring, education, and support to promote/acquire skills in implementing a treatment plan, medical nutritional therapy, and the well-being of a person with diabetes: at diagnosis, annually and/or when treatment goals are not being met, when complicating factors of the disease develop (medical, physical, psychosocial), and when there are changes in the patient's life and care. [**E**]
· Structured (also at the national level), regularly evaluated, and methodologically improved educational programs are required. [**A**]
· Tailoring education to the individual needs of the person with diabetes and their family. [**B**]
· A consistent approach from a physician-led, multidisciplinary therapeutic team (including a physician, nurse/midwife, diabetes educator, dietitian, psychologist, social worker, and others) positively influences metabolic control and psychological aspects of treatment. [**B**]
· Education incorporating digital capability and digital self-management interventions can be an effective method of providing knowledge and support for diabetes self-management. [**B**]

I. General recommendations

- Education targeted at individuals at risk of developing diabetes, with prediabetes, and treated for diabetes, as well as their caregivers and families, is an integral part of treatment and should be regularly conducted during medical and nursing visits, including midwifery appointments, and regularly updated according to patient needs.
- An educational program, coordinated with therapy, is created with the active participation of the patient and their family, and the interdisciplinary therapeutic team.
- The key goals of education are to provide knowledge and support the patient in self-management of the disease, lifestyle modification, healthy eating, physical activity, to improve their health, minimize the risk of acute and chronic complications of the disease, and improve well-being.
- Behavioral strategies should be used to support diabetes self-management and engagement in health behaviours (e.g., medication adherence, use of technology in therapy, physical activity, healthy eating) to promote optimal health outcomes.
- The most effective educational programs are those tailored to the individual experiences and needs of the participants.
- The therapeutic team collaborates with the patient's surrounding, ensuring continuity of care, confidentiality of information, and conveying the latest therapeutic recommendations.
- The person carrying out the education is responsible for checking the degree of achievement of the planned educational effects.

II. Detailed recommendations

- Combining education on self-management of diabetes with promoting healthy habits.
- Providing individual and/or group education (6–10 people), tailored to needs, delivered by a trained team. Education should target not only individuals with diabetes or those at risk (e.g., children, elderly individuals, pregnant women) but also their families and caregivers.
- Introducing and utilizing digital teaching methods, such as tele-education (e.g., webinars and mobile applications), is beneficial. Remote methods should complement and support traditional forms of education.
- Setting individualized therapeutic goals is crucial in educational programs.
- Diabetes education for children, adolescents, and young adults should be adapted to their age, intellectual development level, and needs.
- Programs for specific groups, such as seniors and their caregivers, should address their unique needs.

III. Framework educational program for individuals with diabetes

- Emotional support: help in accepting the diagnosis, strengthening motivation, developing autonomy and self-determination.
- Individual therapeutic goals: tailoring goals to the context of the patient's diabetic life.
- Medical foundations: information about the disease, treatment, medication action, and self-monitoring techniques.
- Principles of a healthy lifestyle: concerning nutrition – practical advice on eating habits (nutrition therapy) and its impact on glucose changes; the role of physical activity – motivation for regular exercises and their impact on health and metabolic control of diabetes; sleep; oral hygiene; intimate life; substance use; smoking; risky behaviours – explanation of the impact of appropriate actions to maintain good health.
- Self-control: techniques for monitoring health indicators, including target glucose values, time in target range, glycated haemoglobin, lipid levels, blood pressure, body weight, well-being.
- Monitoring and interpreting glucose levels measured via CGM and glucometers: the benefits of using CGM, personalization of CGM system selection for individuals with diabetes (advantages and disadvantages of different systems), techniques for using CGM and glucometers, and interpreting data from these devices, including alarms and glucose trends.
- Pharmacotherapy: insulin administration and other subcutaneous medications, and information on types of devices (insulin pumps, injectors, CGM systems) – their advantages and disadvantages.
- Technique and comprehensive operation of devices and applications used for monitoring, treating, and managing diabetes like insulin pens, CGM systems or insulin pumps.
- Discussion and implementation of the planned therapy model.
- Interpretation of self-monitoring data, as well as glycaemic alarms and trends.

- Diabetes complications: recognition, treatment, and prevention.
- Management of special situations, such as: 1) diagnosis of the disease; 2) failure to achieve treatment goals; 3) the appearance of additional factors significantly affecting glycaemia, such as infections, comorbidities, vaccinations, or risky behaviours; 4) life changes, including pregnancy planning, pregnancy, contraception, travel, and time zone changes.
- Psychological support for: diagnosis of diabetes, diabetes-related burnout, therapeutic adherence, diabetes distress, depression, stress, eating disorders, quality of life, sleep, or sexual issues. Diabetes care teams should develop screening protocols, which may include attitudes toward diabetes, family members' risk of the disease, and treatment expectations and outcomes.
- Vaccinations: the role, importance, and types of vaccinations in diabetes; recommended vaccinations for specific age groups.
- Social rights: information on the rights of people with diabetes.
- Utilization of specialized healthcare: guidelines for people with diabetes on preparing for visits (e.g., downloading device memory, sending data, formulating health problems), the importance of regular visits and follow-up tests, and adherence to medical recommendations.
- Additional resources, such as up-to-date information on ongoing clinical trials, new medications or technologies, and support for people with diabetes, those at risk of developing diabetes, and individuals with preclinical diabetes states.

IV. Organizational recommendations

- Education time: depending on the treatment model – 5–11 hours of education, with 9–11 hours for those using insulin therapy; each person with diabetes may require individually determined education time, including the unique educational needs of children, elderly people, their caregivers, and pregnant women.
- Re-education and assessment: periodic, annual assessments of the knowledge of patients and their caregivers performed both in person and electronically.
- Personalization: the number of visits and time of education are determined according to the individual needs of the patient and their caregivers.
- Diabetes education: requires the preparation of a framework program aligned with current diabetes care guidelines, including regular sessions (e.g., webinars).
- Team and funding: Education should be funded separately, in parallel with treatment.
- Communication: Emphasis should be placed on professional relationships between the therapeutic team and the patient, caregivers, and building full trust.
- Accessibility of procedures: In the place of education; maintaining clear and accessible educational procedures.

V. Standards (requirements) of the facility providing education.

- Educational infrastructure: a thoroughly equipped educational room that will enable the achievement of the set goals and the attainment of diabetes education outcomes.
- Documentation and monitoring: comprehensive educational documentation including the framework training program, individual educational plans for patients, information about the person coordinating education, and the scope of duties of employees, along with periodic (preferably annual) checking of patient knowledge and collecting feedback.
- Quality assessment and evaluation: quality assessments of education made by patients and their caregivers; these should be part of evaluation programs conducted at least once a year.
- Communication within the therapeutic team: outlining mechanisms for consulting educational decisions within the therapeutic team and ensuring the continuity of information flow regarding therapeutic goals and progress in education.
- Professional development and support for the therapeutic team: the employer facilitates and creates favourable conditions for raising professional qualifications and self-education of members of the diabetes therapeutic team, including those employed as diabetes educators.

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10. Type 1 Diabetes: Standards of Care

CHAPTER HIGHLIGHTS
· The recommended treatment model is intensive functional insulin therapy using multiple daily subcutaneous insulin injections or continuous subcutaneous insulin infusion (CSII) via a personal insulin pump, with the highest effectiveness in optimizing metabolic control and improving quality of life demonstrated by automated insulin delivery (AID) systems, specifically hybrid closed loop (HCL) insulin pumps. [**A**]
· A key element of type 1 diabetes therapy is the individuals' ability to adjust insulin doses based on the carbohydrate content of meals, initial glycaemia, and planned physical activity. Knowledge of the impact of proteins and fats on glycaemia is also important for the optimization of insulin dosing. [**E**]
· In individuals with type 1 diabetes, the use of insulin analogues is preferred due to the lower risk of hypoglycaemia and greater quality of life. [**A**]
· Continuous glucose monitoring (CGM) systems should be the primary component of glycemic self-monitoring in T1DM. [**A**]
· For those using continuous glucose monitoring systems (CGM), one of the fundamental parameters for assessing diabetes management should be the time in range (TIR), optimally over 70%. [**E**]
· All therapeutic decisions regarding the treatment of type 1 diabetes should be made in consultation with the individual with diabetes and after obtaining their acceptance. [**E**]

I. Type 1 diabetes treatment

1. Individuals with type 1 diabetes absolutely require insulin treatment. Insulin therapy should be maintained even during periods of disease remission.
2. The recommended treatment model is intensive functional insulin therapy using multiple subcutaneous insulin injections or continuous subcutaneous insulin infusion (CSII) administered via a personal insulin pump. A requirement for effective treatment is properly conducted education (according to the guidelines in Chapter 9), enabling a person with diabetes to modify insulin doses independently based on systematically performed self-monitoring of blood glucose levels using a glucometer or other devices registered for this purpose (according to the guidelines in Chapter 3). Treatment of adults with type 1 diabetes with a personal insulin pump should be administered by physicians experienced in therapy with such pumps. It is recommended to have a certificate from the Pump School of the Polish Diabetes Society.
   In individuals with type 1 diabetes, being on insulin analogues is preferred because of their lower risk of hypoglycaemia and greater comfort.
3. In insulin therapy for type 1 diabetes, it is important to optimize insulin dosage. Prolonged use of supra-physiological amounts of insulin without diagnosing the causes of high demand for the hormone and attempting to act causally – aside from justified cases (additional disease, medications that increase insulin demand, stress) – may lead to adverse metabolic consequences, as well as excessive weight gain.
4. A key component of type 1 diabetes therapy is the patient's ability to adjust insulin doses based on the carbohydrate content of meals, baseline glycaemia, and planned physical activity. To optimize insulin dosing, understanding the impact of proteins and fats on glycaemia is also important, although this is less significant when using automated insulin delivery (AID) systems, such as hybrid closed loop (HCL) insulin pumps.
5. The use of continuous glucose monitoring systems (CGM) is the preferred method of self-monitoring in type 1 diabetes.
6. Particularly effective is the combination of CSII and CGM technologies in devices that automatically suspend insulin delivery in hypoglycaemia or impending hypoglycaemia (predictive insulin suspension) and in HCL pumps that autonomously normalize hyperglycaemia as well.
7. HCL pumps can be used at any stage of diabetes treatment, regardless of the individuals' previous technological experience. Although there is a positive correlation between the initial degree of metabolic control and the results obtained using HCL pumps, it should be noted that significant glycemic improvement can be expected in every individual with type 1 diabetes regardless of the results obtained before implementing this technology. It must be emphasized that for many individuals with type 1 diabetes who for various reasons can-

not achieve good or even acceptable glycemic control, the use of HCL may be the only way to improve metabolic control and limit the risk of disease complications.

8. Devices operating on a similar principle to HCL are pumps based on the open APS (artificial pancreas system), known as DIY (do it yourself) pumps. Thanks to such systems, many people can significantly improve metabolic control, but it should be emphasized that these are not certified systems, and the individual with diabetes bears the responsibility for using them.
9. Individuals treated with semi-automatic pumps (predictive insulin suspension), HCL pumps, or DIY systems require appropriately specialized education that considers the specificity of these devices. One of the clinically important differences is the management of hypoglycaemia, in which case smaller amounts of glucose (5–15 g) are usually sufficient for normalization of glycaemia.

   When implementing HCL pumps in individuals with no prior experience with CSII, focus should be on issues related to the operation of the pump in hybrid mode, principles of switching to manual mode in emergency situations, and technical matters. Training in other issues, important when treating with traditional insulin pumps, which will not be applied in HCL, should be minimized. From the individual education perspective using HCL, it is important to emphasize that with these devices, the administration of a mealtime bolus is based on estimating the carbohydrate content of the meal. There is no need for precise estimation of proteins, fats, or calories in the meal.
10. Telemedicine is an important tool for optimizing diabetes control. For all individuals with type 1 diabetes, the therapeutic team should work with the individual to develop a system that allows for an effective remote medical visit. The development of such a system should be based on individual's education and encouraging them to use appropriate technological solutions. Remote medical visits for persons with type 1 diabetes can be both a part of regular diabetes care and used in an epidemiological emergency.
11. Medications that, in combination with insulin therapy, may improve glycemic control and reduce body weight in type 1 diabetes include SGLT-2 inhibitors and GLP-1 receptor agonists. However, these drug classes are not currently approved for adjunctive treatment of type 1 diabetes.

    If the use of these medications is necessary in individuals with T1DM for indications other than direct antihyperglycemic effects (such as cardiovascular or renal indications, or obesity treatment), strict and ongoing insulin therapy adjustments are required, ideally based on CGM data or with the use of automated insulin delivery (AID) systems. It is essential to monitor ketonuria/ketonemia to prevent euglycemic diabetic ketoacidosis when using SGLT-2 inhibitors, especially in individuals using AID systems.

    For some individuals with type 1 diabetes and insulin resistance, the addition of metformin may provide certain clinical benefits.

    General principles of antihyperglycemic management in individuals with type 1 diabetes are illustrated in Figure 10.1.
12. At every stage of treatment, a person with type 1 diabetes must be provided with psychological counselling. The diabetologist in charge of the individual 's treatment should refer the patient for psychological consultation both at the individual 's request and personally proactively offer him/her such consultation if necessary, keeping in mind that psychological problems can affect up to half of individuals with type 1 diabetes.

II. Organization of care for an individual with type 1 diabetes

1. From the very beginning of the diagnosis and during the further course of the treatment, a person with type 1 diabetes should be under the care of a specialist diabetologist. This approach ensures continuous cooperation with the educational team (according to the principles given in Annex 7) and access to necessary consultations. Treatment with personal insulin pumps should ideally be conducted in centres where at least one team member holds a current Diabetes Poland Pump School certificate or is in the process of training.
2. Cases of new onset of type 1 diabetes, as well acute complications of diabetes that are difficult to manage, require hospitalization in a reference unit.

III. Treatment goals for type 1 diabetes

1. Metabolic control and maintaining blood glucose levels as close to normal as possible.

The primary therapeutic goal is to achieve $HbA_{1c} \leq 7\%$. Striving for lower HbA_{1c} (≤ 6.5%) is justified if it does not increase the risk of hypoglycaemia or worsen the quality of life of the person with diabetes.

2. Achieving treatment goals from the beginning of the disease can prevent the occurrence of acute and chronic complications and enable leading a normal, active family, professional, and social life.
3. For individuals systematically using CGM (Continuous Glucose Monitoring), the primary therapeutic goal is to achieve a high (over 70%) percentage of time spent in the therapeutic range, understood as glycaemia values in the range of 70–180 mg/dl. It should be emphasized that one of the priorities of treatment should be the avoidance of hypoglycaemia (the permissible time spent at values lower than 70 mg/dl and 54 mg/dl is respectively a maximum of 4% and 1% of the time). The target glycaemia parameters for people using CGM are given in Table 4.2. In selected individuals, therapeutic goals may be defined based on the time spent in a tight therapeutic range (TITR – Time in Tight Range) of 70–140 mg/dl. The decision to assess glycemic control using TITR as a supplement to TIR should be made cautiously, considering the patient's level of education, engagement in treatment, available technology, and psychological profile. Currently, the use of TITR should likely be limited to a selected group of patients using HCL insulin pumps and individuals in the remission phase of diabetes.
4. It should be emphasized that one of the key goals of type 1 diabetes treatment is also to maintain the highest possible quality of life for the individual.

IV. Early detection of chronic complications of diabetes

1. Possible based on screening tests for nephropathy, retinopathy, and diabetic neuropathy. The principles of conducting these tests in people with type 1 diabetes are discussed in Chapters 19, 20, and 21. In people with type 1 diabetes and a long duration of the disease, especially those who became ill at a young age, large vessel disease (diabetic macroangiopathy) may manifest earlier than in the healthy population. This can take the form of coronary heart disease, cerebrovascular disease, or peripheral artery disease. The principles of diagnosis and treatment of coronary heart disease are discussed in Chapter 17, while the approach to stroke and acute coronary syndrome is consistent with those presented in Chapters 18 and 17.1.
2. Diagnosis and treatment of acute complications. A properly educated person with type 1 diabetes must know the principles of managing severe, moderate, and mild hyperglycaemia and hypoglycaemia and should be able to cope independently in such situations. More severe conditions require medical assistance, in accordance with the principles presented in Chapters 15 and 16. Special situations in people with type 1 diabetes:
   a) a person with type 1 diabetes (metabolically well-balanced) treated with intensive insulin therapy may undergo "one-day" surgery (minor surgical procedures),
   b) in hospital conditions, a person with type 1 diabetes who has previously effectively used advanced technologies such as CGM systems or personal insulin pumps should be able to continue self-treatment based on these systems, provided it takes place under appropriate supervision and the individuals' general condition allows it,
   c) a well-educated individual with type 1 diabetes who has achieved satisfactory treatment results before hospitalization should participate in making therapeutic decisions regarding diabetes treatment in hospital conditions; in selected cases, the individual may conduct this treatment independently, provided that the glycemic therapeutic goals are achieved; the principles of perioperative management in people with type 1 diabetes are presented in Chapter 26,
   d) type 1 diabetes more often than in the general population is accompanied by endocrinopathies, especially autoimmune thyroid diseases (Hashimoto's disease, Graves' disease) and adrenal cortex diseases (Addison's disease), as well as celiac disease, vitamin B_{12} deficiency anaemia, and collagen vascular diseases; their coexistence can significantly worsen the course of type 1 diabetes,
   e) a person with type 1 diabetes may have obesity with accompanying indicators of insulin resistance – this increases the daily insulin dose and worsens metabolic control; diagnosis and management in such a situation require specialist diagnosis and treatment,
   f) an increasing problem among young people with type 1 diabetes is eating disorders

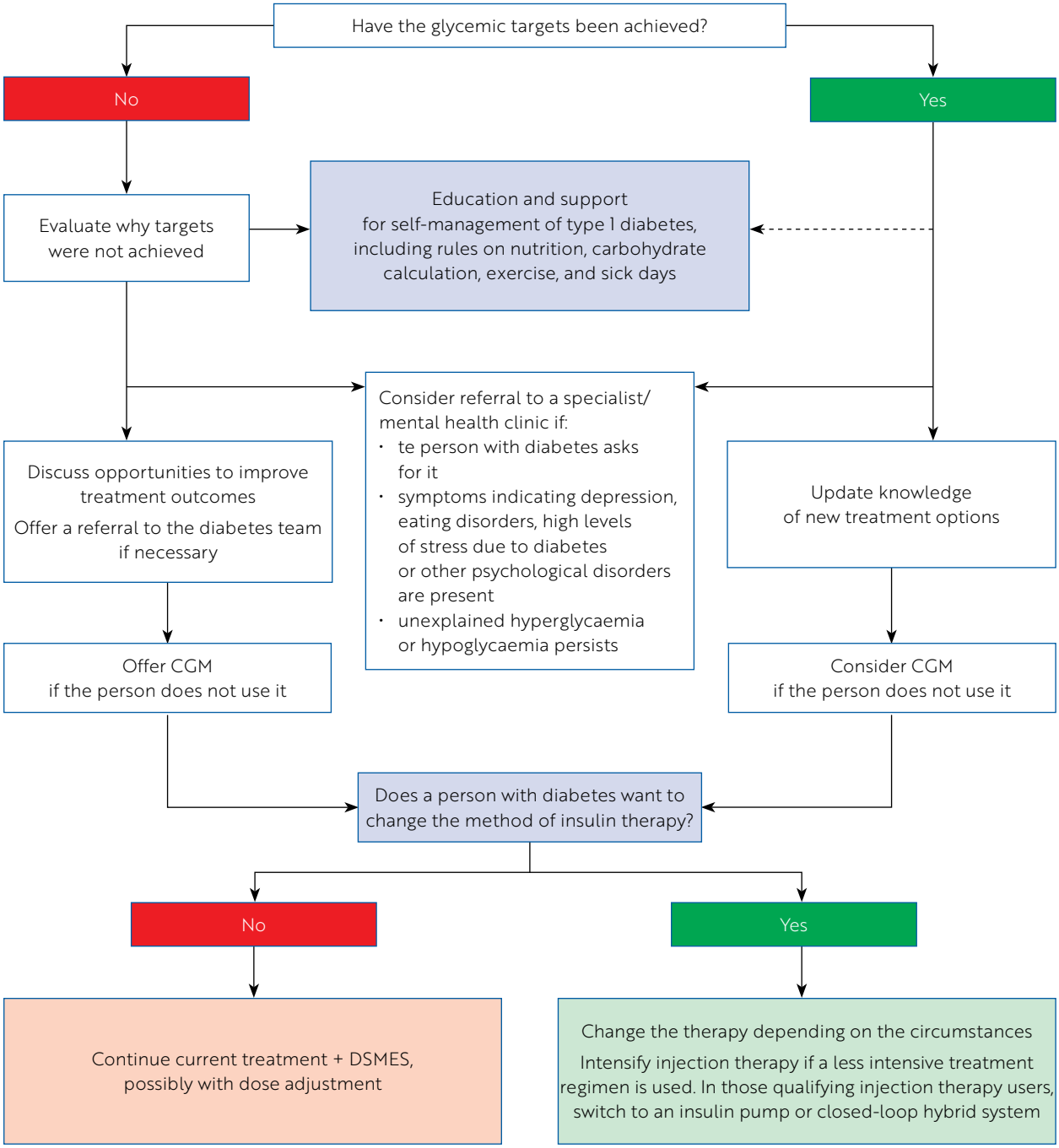

Figure 10.1. General principles of antihyperglycemic management in individuals with type 1 diabetes [12]

characterized by bulimia or anorexia as well as a phobia of hypoglycaemia; diagnosis and treatment of such conditions require specialist psychiatric treatment in close cooperation with a diabetologist,

g) an increasing problem among young people, in most cases undiagnosed and causing significant glycemic fluctuations, is the use of narcotics and psychoactive substances,

h) some older individuals with type 1 diabetes may require liberalization of therapeutic goals; in this case, the main guide should be biological age, not chronological age; in older individuals with type 1 diabetes who are in good biological condition, there should not be a priori a resignation from the continuation of treatment using advanced technologies or the implementation of such treatment; a well-educated person with type 1 diabetes, treated with intensive insulin therapy and metabolically well-balanced, is capable of the same physical activity and achieving similar professional goals as people of similar age without diabetes.

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11. Oral Antihyperglycemic Medications, Injectable GLP-1 Receptor Agonists, and GIP/GLP-1 in Type 2 Diabetes

CHAPTER HIGHLIGHTS
· The pharmacotherapy of type 2 diabetes should be accompanied by comprehensive, structured education, appropriate nutritional management, psychological support, and planned physical activity. The choice of medications should consider all individual patient characteristics, including their priorities, lifestyle and health behaviours, comorbidities, motivation, cognitive impairments, and social aspects. [**E**]
· SGLT2 inhibitors (flozins) or GLP-1 receptor agonists, or metformin, should be considered as the first-choice medications for initiating pharmacological treatment in type 2 diabetes. In patients with documented atherosclerotic cardiovascular disease, heart failure, chronic kidney disease, or the coexistence of multiple cardiovascular risk factors, the choice should prioritize the cardiovascular and nephroprotective effects of the drugs. [**A**]
· Combination therapy in newly diagnosed type 2 diabetes should be regarded in patients in the risk groups listed above and in severe hyperglycaemia (HbA_{1c} ≥ 8.5%). [**A**]
· If treatment started with monotherapy becomes insufficient to achieve or maintain the target HbA_{1c} value, a second antihyperglycemic drug should be added. This decision should not be delayed for longer than 3–4 months. [**A**]
· In patients with atherosclerotic cardiovascular disease, heart failure, chronic kidney disease, or numerous cardiovascular risk factors, drugs with proven beneficial effects on the risk of progression of these diseases and on total and cardiovascular mortality should be used first when intensifying treatment. [**A**]
· In patients with heart failure, the use of flozins should be recommended, and in case of contraindications to their use, GLP-1 receptor agonists should be prescribed. [**A**]
· In patients with diagnosed atherosclerotic cardiovascular disease or numerous risk factors, or chronic kidney disease, the use of both groups of drugs should be considered: SGLT inhibitor or GLP-1 receptor antagonist. Early combined therapy with metformin and/or flozins, and/or GLP-1 receptor agonists should be considered in the above cases for every patient regardless of achieving the therapeutic goal. [**A**]
· All patients with type 2 diabetes should aim to achieve individually defined goals – normoglycaemic, body mass related, and other targets of multifactorial therapy. [**B**]
· The progressive nature of type 2 diabetes means that insulin therapy in individually tailored models is recommended for many people with the disease. [**B**]
· All therapeutic decisions regarding the treatment of type 2 diabetes should be made in agreement with the patient and after obtaining their acceptance. [**E**]

Individually tailored pharmacological reduction of hyperglycaemia, which is accompanied by Behavioral management in the multifactorial treatment of type 2 diabetes (along with treatment of obesity, arterial hypertension, dyslipidemia), is crucial in preventing and slowing the progression of chronic diabetes complications (macrovascular and microvascular).

I. Hyperglycaemia reduction

Hyperglycaemia is reduced by correcting the pathogenetic mechanisms of type 2 diabetes – insulin resistance, impaired insulin secretion, and impaired incretin effect. A separate therapeutic mechanism of antihyperglycemic drugs is the glycosuric action. The treatment of type 2 diabetes must be progressive and adjusted in stages to the progressive nature of the disease and consider accompanying diseases. If the therapy used at a given stage ceases to be effective (the target HbA_{1c} for a given patient is not achieved), it should proceed to the next stage after 3–4 months. Avoiding therapeutic inertia is one of the foundations of effective treatment of type 2 diabetes.

II. Stages of type 2 diabetes treatment

1. Initiation of therapy:
- lifestyle modification involving reducing the caloric content of meals and increasing physical activity to a minimum of 30–45 minutes per day to reduce body weight,
- pharmacological treatment can be initiated through monotherapy or combination therapy; SGLT-2 inhibitors, GLP-1 receptor agonists and metformin should be considered first as first choice medications when initiating pharmacological treatment in type 2 diabetes,
- GLP-1 receptor agonists and SGLT-2 inhibitors with proven benefits should be preferred in people with cardiovascular diseases, numerous risk factors, or chronic kidney disease; in patients with heart failure, the choice of flozins should be preferred, and in the case of contraindications to their use, GLP-1 receptor agonists should be used; in patients with diagnosed atherosclerotic cardiovascular disease or numerous risk factors, or chronic kidney disease, the use of both groups of drugs should be considered; PPAR-γ agonists and saxagliptin should not be used in people with heart failure,
- the therapeutic effectiveness of the implemented oral treatment can be evaluated only after several weeks of use,
- the decision to initiate combination therapy in newly diagnosed diabetes should be particularly considered in patients with a very high cardiovascular risk, and with severe hyperglycaemia (HbA_{1c} > 8.5%). In patients in the aforementioned risk groups, the combination model should include an SGLT-2 inhibitor and/or a GLP-1 receptor agonist.

2. Intensification of therapy with oral drugs or GLP-1 receptor agonists, or dual GIP/GLP-1 receptor agonists:
- lifestyle modification and addition to monotherapy or dual-medication combination therapy of a medication from a class that was not previously used: metformin or SGLT-2 inhibitor, or an incretin drug (DPP-4 inhibitor or GLP-1 receptor agonist, or dual GIP/GLP-1 receptor agonist), or sulfonylurea derivative, or PPAR-γ agonist. The choice of the drug at each stage should consider comorbidities, primarily diagnosed cardiovascular disease and chronic kidney disease, as well as the coexistence of obesity, the risk of hypoglycaemia, and the patient's financial ability. Patients with atherosclerotic cardiovascular disease, heart failure, chronic kidney disease, or numerous cardiovascular risk factors, should be prioritized for agents with proven beneficial effects on the risk of progression of these conditions and on total and cardiovascular mortality. This effect has been demonstrated for some SGLT2 inhibitors and some drugs from the group of GLP-1 receptor agonists. Early combined therapy with flozins and/or some GLP-1 receptor agonists, and/or metformin should be considered in the above cases for every patient regardless of achieving the therapeutic goal. Also, in the case of coexisting obesity, preference should be given to GLP-1 receptor agonists or dual GIP/GLP-1 receptor agonists. With a high risk of hypoglycaemia, the same groups of drugs and the DPP-4 inhibitor or PPAR-γ agonist should be considered,
- lifestyle modification and triple or quadruple drug therapy using drugs with different mechanisms of action from the following groups: metformin, SGLT2 inhibitors, GLP-1 receptor agonists, dual GIP/GLP-1 receptor agonist, sulfonylurea derivatives, DPP-4 inhibitors, PPAR-γ agonist. The choice of drugs at this stage is based on the same considerations as at the earlier stage and on the general principles of antihyperglycemic drug combination.

3. Intensification of treatment with implementation of insulin regimen:
- lifestyle modification and simple insulin therapy, primarily using basal insulin (NPH insulin, long-acting analogue, ultra-long-acting analog; see Chapter 12 for various formulations), with continued administration of metformin and other oral medications or infectable GLP-1 receptor agonist, or a dual GIP/GLP-1 receptor agonist, especially with coexisting obesity. For patients on the first injectable therapy, such as basal insulin or a GLP-1 receptor agonist, intensification is possible by using compound formulations with a fixed ratio of basal insulin and GLP-1 receptor agonist; these formulations can also be the first injectable therapy,
- lifestyle modification and complex insulin therapy with the recommended continuation of metformin and other oral drugs (metformin, incretin drug, PPAR-γ agonist, SGLT-2 inhibitor) or a GLP-1 receptor agonist in injections, or a dual GIP/GLP-1 agonist, especially with persistent excessive body weight (see Chapter 12.).

At every stage of treatment, the goal should be to achieve individually defined glycemic targets, body weight, and other goals of multifactorial therapy.

4. Simplification of the antihyperglycemic treatment model:
- many patients with type 2 diabetes need to reduce the complexity and burden of treatment, particularly insulin therapy, and consider liberalizing the glycemic target; this includes, for example, patients with a high risk of hypoglycaemia, cognitive impairment, nonadherence to medication, a short, expected survival time or the negative impact of a complex treatment regimen on quality of life,
- the tool for this type of procedure is to reduce the number of insulin injections and its administered dose by individually tailored combination with non-insulin antihyperglycemic drugs.

The lack of simplification of antihyperglycemic therapy in patients with indications for this type of procedure is a form of therapeutic inertia.

III. List of medications

Medications used in the therapy of type 2 diabetes are presented in Table 11.1.

When selecting therapy and combining drugs, their impact on non-glycemic parameters should be considered (risk of death, cardiovascular diseases, chronic kidney disease, body weight, risk of hypoglycaemia, lipid metabolism, etc.) and thera-

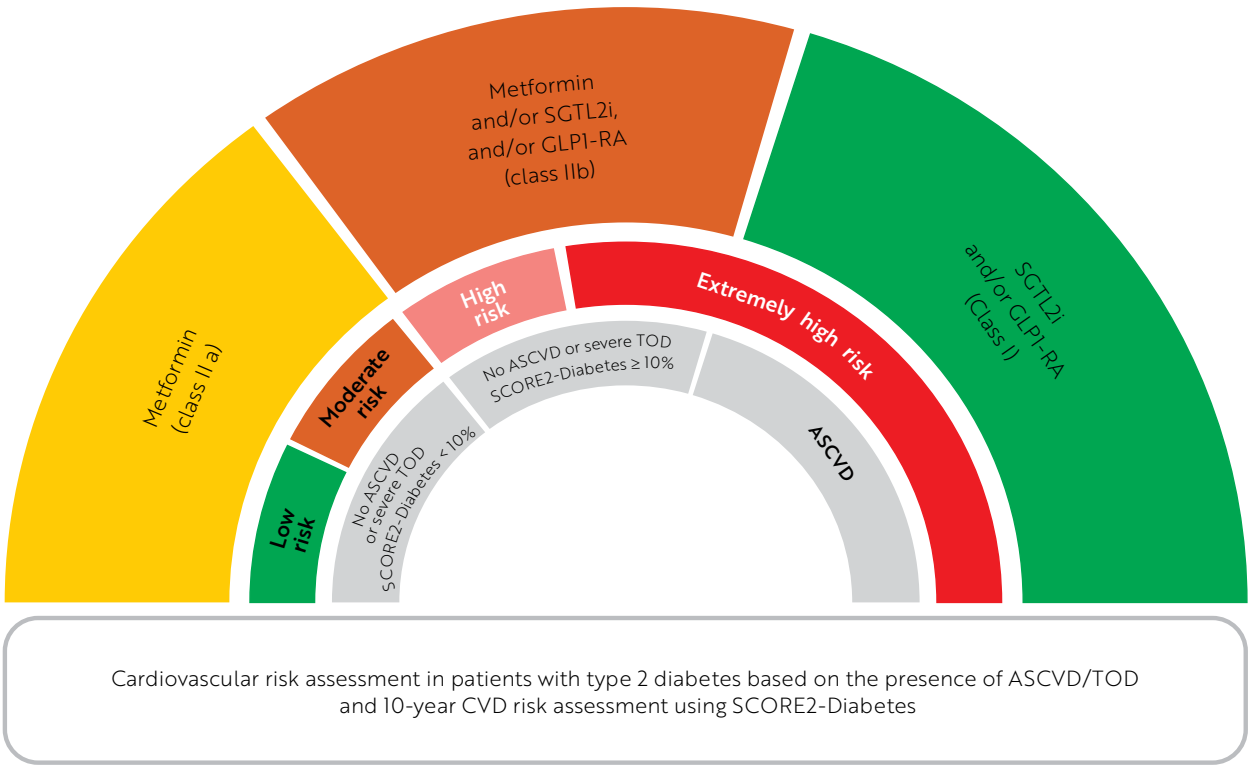

Figure 11.1. Cardiovascular risk categories and recommended antihyperglycemic therapy in patients with type 2 diabetes according to the ESC [13].

Table 11.1. List of drugs used in the treatment of type 2 diabetes*

	Metformin	SGLT-2 inhibitors	GLP-1 receptor agonist	GIP/GLP-1 receptor agonist	DPP-4 inhibitors	Sulfonylurea derivatives	PPAR-γ agonist
Main effect/ mechanism	Reduction in hepatic glucose production. Increased peripheral sensitivity to insulin	Induction of glycosuria	Increase in insulin secretion dependent on the intensity of hyperglycaemia, inhibition of appetite	Increase in insulin secretion dependent on the intensity of hyperglycaemia, inhibition of appetite	Increase in insulin secretion depending on severity of hyperglycaemia	Increased insulin secretion	Increase in peripheral insulin sensitivity
Strength of hypoglycaemic effect	High	High	High	High	Medium	High	High
Beneficial cardiovascular effect		Yes#,A	Yes#				
Beneficial renal effect		Yes	Yes#				↓
Plasma insulin	↓	↓	↑↑	↑↑	↑	↑↑	↓
LDL cholesterol	↓	↔ or ↑	↓	↓	↓ or ↔	↔	↔
HDL cholesterol	↑	↑	↑	↑	↑	↔	↑
Triglycerides	↓	↔	↓	↓	↔	↔	↓
Body weight	↓ or ↔	↓	↓↓	↓↓	↔	↑	↑
Risk of hypoglycaemia	↔	↔	↔	↔	↔	↑	↔
Side effects	Gastrointestinal disorders	Infections of the external genital organs, dehydration, especially in older people	Gastrointestinal disorders (nausea, vomiting)	Gastrointestinal disorders (nausea, vomiting)	Significant does not occur	Hypoglycaemia, weight gain	Fluid retention (edema), weight gain, increased risk of fractures of long bones
Contraindications	According to the current SmPC (Summary of Product Characteristics).						

**Insulin: see chapter 12.*

*** See table 19.4.*

#Proven for some drugs in the class, according to currently published results of randomized trials.

In the case of empagliflozin and canagliflozin, no differences were found in CVOT (Cardiovascular Outcome Trials) studies between doses of 10 and 25 mg for empagliflozin and 100 and 300 mg for canagliflozin.

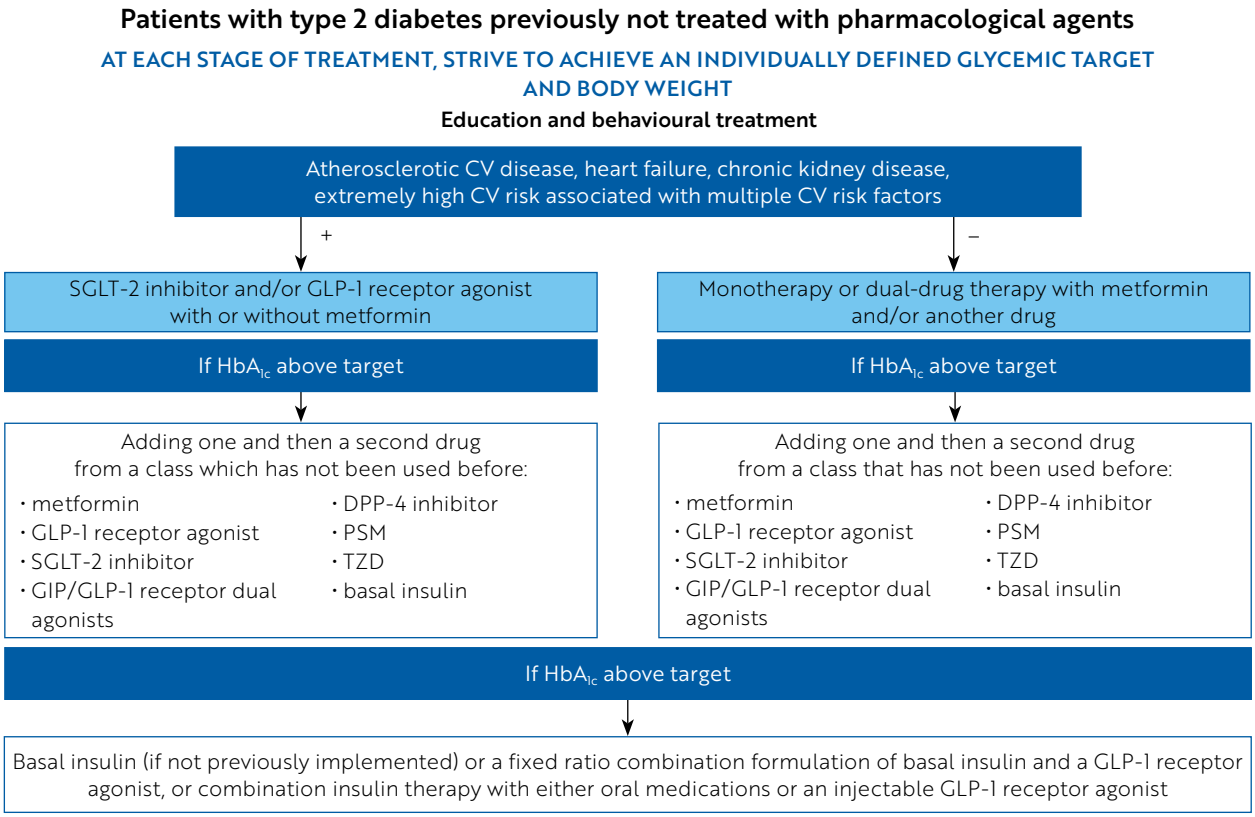

Figure 11.2. Treatment regimen scheme for people with type 2 diabetes previously untreated with pharmacotherapy
CV – cardiovascular system, PSM – sulfonylurea derivatives, TZD – thiazolidinediones (PPAR agonist-γ)

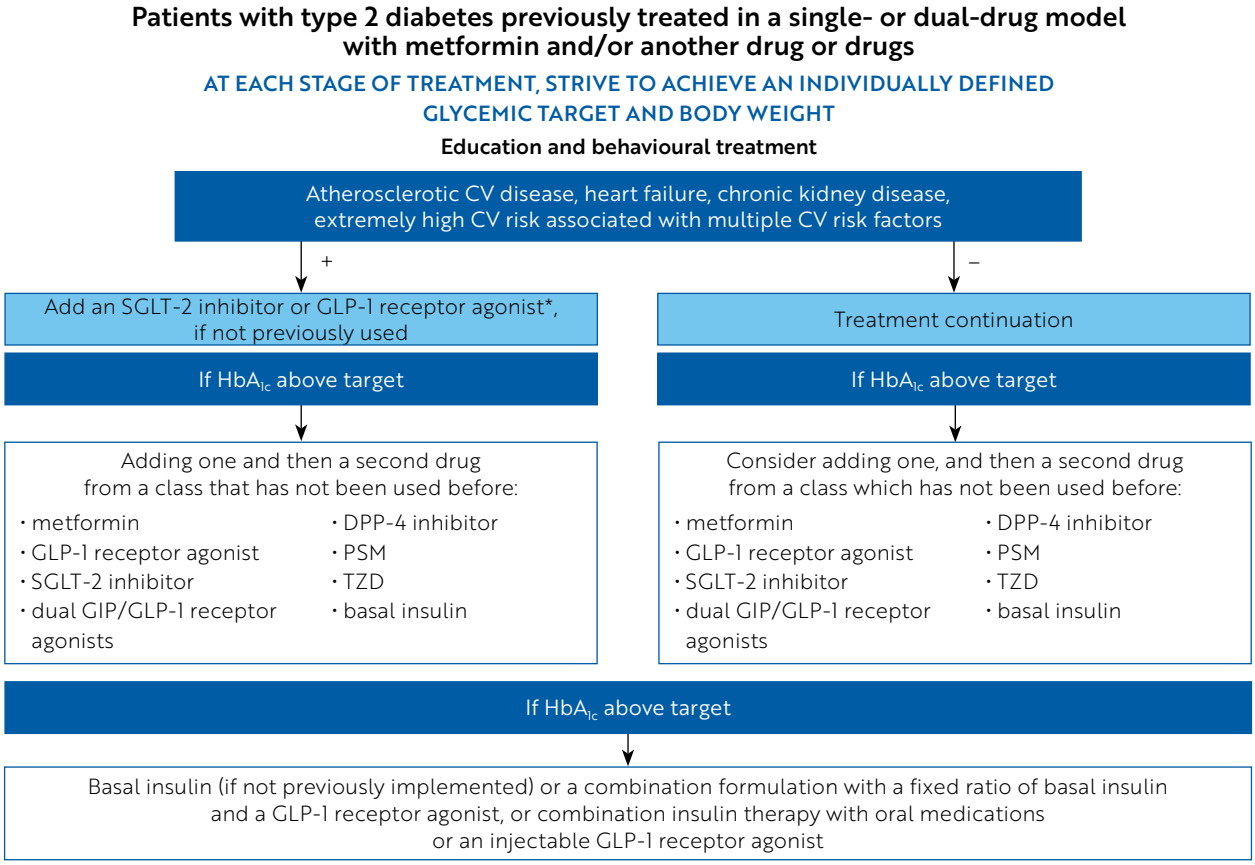

Figure 11.3. Therapeutic management scheme for people with type 2 diabetes previously treated with a single or dual drug model using metformin and/or another drug or drugs
CV – cardiovascular system, PSM – sulfonylurea derivatives, TZD – thiazolidinediones (PPAR agonist-γ)
**Flozins (SGLT-2 inhibitor) or a GLP-1 receptor agonist should be added regardless of the complexity of the model (e.g., triple, and quadruple therapy, complex insulin therapy model) in every patient at very high cardiovascular risk who has not previously received drugs from these groups.*

py should be individualized (see Subchapter 4.I.3). Results of randomized clinical trials indicate benefits in terms of reduction in total and cardiovascular mortality as well as cardiovascular and renal endpoints as a result of using certain drugs from the group of GLP-1 receptor agonists and SGLT-2 inhibitors.

IV. Practical algorithm for pharmacotherapy of type 2 diabetes mellitus

The algorithm is shown in Figures 11.2 and 11.3.

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12. Insulin Therapy in Type 2 Diabetes and Other Specific Types of Diabetes

CHAPTER HIGHLIGHTS
• For individuals with type 2 diabetes, insulin analogs are preferred due to the lower risk of hypoglycaemia. [**A**]
• Type 2 diabetes is progressive. The accumulation of pathophysiological disturbances underlying it, especially the β-cell defect, necessitates the gradual intensification of treatment, including the initiation of insulin therapy. [**B**]
• The use of CGM (Continuous Glucose Monitoring) systems improves the effectiveness and safety of insulin therapy. [**B**]

I. Indications for initiating insulin treatment in type 2 diabetes:

- new onset diabetes (with the possibility of returning to the typical algorithm and discontinuing insulin): blood glucose ≥ 300 mg/dl (16.7 mmol/l) with concurrent clinical symptoms of hyperglycaemia,
- ineffectiveness of treatment without insulin (HbA_{1c} exceeding target values despite therapy intensification) (Figure 12.1).

II. Indications for changing the current antihyperglycemic treatment method:

Shift from oral antihyperglycemic drug therapy to insulin combination therapy when glycemic control is found to be uncontrolled:

- confirmation of a continued state of hyperglycaemia,
- poor tolerance of oral medications,
- unsuccessful attempts to eliminate potentially fixable causes of hyperglycaemia, such as:
  - » dietary errors,
  - » insufficient physical activity,
  - » irregular intake of oral antihyperglycemic drugs (lack of cooperation)
  - » infections,
  - » incorrect dosage of oral medications,
- utilization of the antihyperglycemic potential of GIP/GLP-1 receptor agonists, which should be the first injectable therapy in type 2 diabetes (considering the financial possibilities of the patient and drug tolerance).

III. Indications for starting insulin therapy regardless of glycemic values:

- diabetes associated with cystic fibrosis,

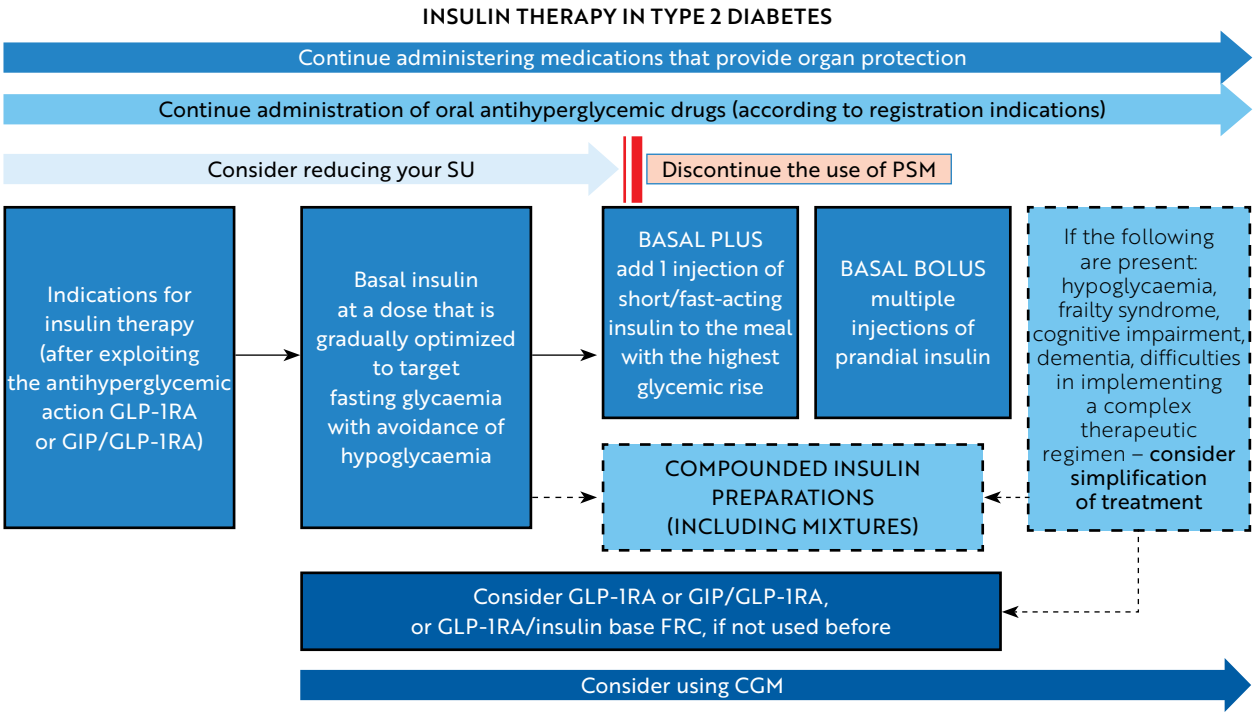

Figure 12.1. Practical algorithm for insulin treatment of type 2 diabetes. Models for initiation and intensification of insulin therapy

- carriers of mutations in insulin genes and double mutation in glucokinase gene,
- reasonable request of the patient.

IV. Indications for temporary insulin therapy:

- diabetes decompensation due to temporary causes (infection, trauma, steroid therapy, etc.),
- surgical procedure (see Chapter 26),
- stroke (see Chapter 18)
- percutaneous transluminal coronary angioplasty procedure (PTCA),
- acute coronary syndrome,
- other severe conditions requiring hospitalization in an intensive care unit.

V. Algorithm of insulin therapy in type 2 diabetes

1. Long-acting insulin analogue (administered daily or once weekly) or NPH human insulin in a single injection:
- for morning hyperglycaemia – in the evening; the use of long-acting analogs reduces the risk of nocturnal and severe hypoglycaemia,
- for fasting normoglycaemia and daytime hyperglycaemia – in the morning (multiple injections of a short-acting/fast-acting insulin preparation for postprandial hyperglycaemia are also to be considered).
2. The initial dose of basal insulin is 0.1–0.2 IU/kg body weight or 10 IU, or 70 IU in the case of once-weekly insulin.
3. In some cases, when the introduction of insulin has been delayed for too long, as a result of which the patient develops severe hyperglycaemia and the HbA_{1c} value significantly exceeds the therapeutic target (usually by 1.5% or more), the introduction of **more intensive models of insulin therapy can be implemented immediately (see Section 6)**, which should be particularly considered in patients of relatively young age and long expected survival. The final choice of agent should be individual, considering the patient's preferences, daily activity, number of meals and cost of therapy.
4. Oral antihyperglycemic medications and injectable incretin therapies can be used according to registration in people treated with insulin:
- continued therapy with drugs with proven cardiovascular risk-reducing effects is recommended,
- in cases of coexisting overweight or obesity, combination therapy with an SGLT-2 inhibitor or incretin drug (**receptor agonist for GLP-1, dual GIP/GLP-1 agonist** or DPP-4 inhibitor) with metformin should be preferred,
- in all patients, the goal should be to maintain metformin therapy as long as it is tolerated and there are no contraindications to its continuation.
5. Insulin dose optimalization every 4-5 days by 2-4 units untill individual glycaemic targets are achieved.
6. In the case of basal insulin requirements > 0.3–0.5 IU/kg per day and lack of glycemic control, **and the situations described in point 3**, treatment intensification can be considered by:
   a) gradually adding short-acting insulin/fast-acting analog injections to basal insulin, initially to the meal with the heighest postprandial increase, and then with the following meals ("basal plus", intensive insulin therapy). Recommended initial doses of post-meal insulins are 4 units or 10% of the daily dose of basal insulin,
   b) inclusion of an injectable **GLP-1 receptor agonist or a dual GIP/GLP-1 agonist, if not already used, including a fixed ratio combination (FRC) formulation, with a fixed ratio of basal insulin and GLP-1 receptor agonist** (this preparation may be the first injectable therapy),
   c) use of complex insulin preparations, i.e. insulin mixtures, including analogs.

   At this stage of therapy, discontinuation of insulin-stimulating drugs should be considered.
8. When using high doses of insulin, more than 100 IU per day (proving insulin resistance), the reasons for this should be considered and the potential for side effects should be considered. It is recommended to try to reduce the degree of insulin resistance by using 72–96-hour subcutaneous or intravenous continuous insulin infusion.

VI. Intensive insulin therapy

Intensive insulin therapy is implemented according to similar principles in all types of diabetes with multiple insulin injections per day or using a personal pump for continuous subcutaneous insulin infusion.

1. Principles of intensive insulin therapy:
- the use of CGM or multiple blood glucose readings per day,
- independent decision-making by the patient on modification of insulin dose and possible additional doses depending on the glycaemia, caloric intake and physical activity,

- accurate determination of individualized target glycemic values,
- proper therapeutic and nutritional education and motivation of the patient,
- the possibility of quick communication between the patient and the therapeutic team,
- in type 2 diabetes, subcutaneous insulin delivery using a personal insulin pump is not a standard procedure.

2. Algorithms for multiple injections:
- short-acting insulin or rapid-acting analogue before meals, and
- long-acting insulin analog (administered daily or once weekly) or isophane insulin (NPH) to ensure a constant basal insulin level before bedtime and/or in the morning.
  In some cases of type 2 diabetes, with normal fasting glycaemia, it is sufficient to use only prandial insulin.
3. Therapy with personal automatic insulin delivery systems be conducted in centers that have experience in this type of treatment, and which qualify for this type of procedure.

VII. Simplification of therapeutic regimens

In individuals who have achieved satisfactory parameters of glycaemia, but the implementation of the insulin therapy algorithm encounters difficulties (in the elderly, those with frailty syndrome, cognitive impairments, or requiring third-party care), or significantly increases the risk of hypoglycaemia, efforts should be made to simplify the insulin therapy regimen. The failure to simplify such a regimen is currently considered a manifestation of therapeutic inertia.

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13. Arterial Hypertension: Standards of Care

Developed in collaboration with Assoc. Prof. Jacek Wolf, MD, PhD.

CHAPTER HIGHLIGHTS
· The overall goal for blood pressure control in people with diabetes is reaching 120–129/70–79 mm Hg. [**A**]
· Pharmacotherapy for hypertension should be initiated if, after a maximum 3-month period of non-pharmacological treatment, blood pressure remains ≥ 130/80 mm Hg. [**A**]
· Pharmacotherapy should begin with a combination of two drugs, preferably in a single-pill combination (SPC): an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) combined with either a dihydropyridine calcium channel blocker or a thiazide/thiazide-like diuretic. [**A**]
· Pharmacotherapy of hypertension should be continued continuously, as only then is cardiovascular risk reduction achieved. [**A**]
· In the treatment of hypertension in people with diabetes, the goal should be not only to achieve target blood pressure values, but also to maintain or restore normal daily blood pressure variability as assessed by 24-hour monitoring, especially in pregnant women with diabetes. [**B**]

In people with diabetes, it is recommended to start pharmacotherapy when blood pressure values are ≥ 130/80 mm Hg. The therapeutic target is to optimally reduce the overall risk of cardiovascular complications by lowering the systolic blood pressure < 130 mm Hg, as long as this is well tolerated (such lowering carries the benefit of reducing the risk of stroke). In terms of diastolic pressure, values < 80 mm Hg are optimal. Hypertension can be diagnosed based on the results of office measurements, 24-hour blood pressure measurement by automatic blood pressure monitoring (ABPM) or reliably conducted home measurements.

Monotherapy at the initiation of pharmacotherapy is indicated when:
- blood pressure is 130/80–139/89 mm Hg
- moderate or advanced frailty syndrome
- symptomatic orthostatic hypotension
- age ≥ 80 years

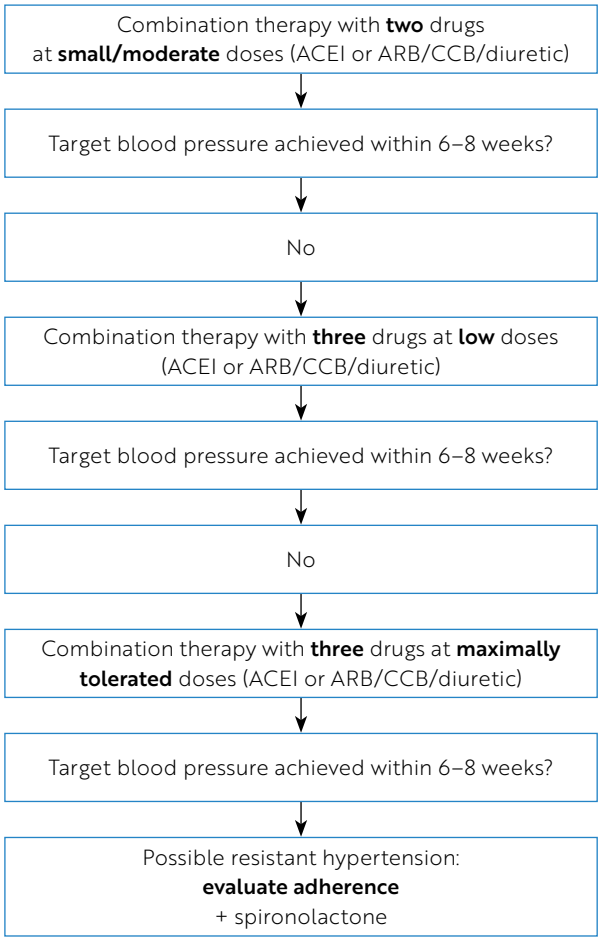

Figure 13.1. Practical algorithm for hypertension treatment in individuals with diabetes

Note!
The effectiveness of newly introduced therapy should be optimally assessed after 1 month, and overall blood pressure control should be evaluated at least once a year.
At any stage, a β-blocker can be added in the presence of specific indications: chronic coronary syndrome, post-myocardial infarction, heart failure, tachycardia.
As the fifth and subsequent antihypertensive drugs, the following may be used depending on clinical indications: loop diuretic (preferably torasemide), α-blocker (preferably doxazosin XL/XR), centrally acting drug (preferably clonidine)
ACEI – angiotensin-converting enzyme inhibitor, ARB – angiotensin receptor blocker, CCB – dihydropyridine calcium channel blocker

I. Blood pressure measurement

Blood pressure should be measured at each visit, also while upright position to assess for orthostatic hypotonia. In individuals without a diagnosis of hypertension, with systolic blood pressure values not lower than 140 mm Hg or diastolic blood pressure not lower than 90 mm Hg, the measurement should be repeated on another day, and out-of-office blood pressure monitoring should be recommended. A repeated detection of blood pressure values of not less than 140 mm Hg or diastolic pressure of not less than 90 mm Hg confirms the diagnosis of hypertension. Nocturnal hypertension, as well as masked hypertension (when blood pressure values in the doctor's office are lower than at home), is often found in people with diabetes, so it is recommended that 24-hour ambulatory blood pressure monitoring be performed in these individuals, as well as that the person with diabetes take blood pressure measurements at home (so-called home, self-measurements). Self-monitoring at home is recommended for all individuals diagnosed with hypertension.

II. Hypertension treatment (Figure 13.1)

- Considering the above treatment goals for hypertension in individuals with diabetes, pharmacological lowering of systolic blood pressure below 120 mm Hg should be avoided.
- In individuals with chronic kidney disease target blood pressure values should be 120–129/70–79 mmHg with regular monitoring of serum creatinine levels, while avoiding excessively low values.
- Diastolic blood pressure should not be lowered below 70 mm Hg.
- In any case of diagnosed hypertension, pharmacological management should be combined with lifestyle changes.
- As a general rule, therapy should begin with a combination of two drugs: an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin

II receptor blocker (ARB) combined with a calcium channel blocker or a thiazide/thiazide-like diuretic. However, in the presence of certain comorbidities (e.g., ischemic heart disease, chronic kidney disease, etc.), the choice of drug combination may differ.
- Due to the above recommendations, the use of fixed-dose combination drugs is advisable as they improve adherence to therapeutic guidelines.
- The presence of proteinuria does not change the target blood pressure.
- In the therapy of individuals with hypertension and heart-related complications (such as ischemic heart disease and heart failure), the combination of an ACE inhibitor and a β-blocker is commonly used.
- Combinations of drugs with similar mechanisms of action or similar side effects have limited value because the hypotensive effect is smaller than additive, or there is an increased risk of adverse effects.
- In individuals with a lack of nocturnal blood pressure dip (non-dipping) or excessive morning blood pressure surge, it is important to ensure that the prescribed medications are long-acting and consider modifying the timing of antihypertensive drug administration.
- Long-acting antihypertensive medications that provide 24-hour effectiveness when administered once a day should be preferred.
- When using ACE inhibitors, ARBs, or diuretic medications, it is important to monitor serum creatinine levels, eGFR (estimated glomerular filtration rate), and potassium levels in the blood.
- In individuals over 80 years of age with mild frailty syndrome, episodes of hypotension, or isolated systolic hypertension, more liberal treatment targets should be adopted, i.e., < 140/90 mm Hg.

III. Choice of hypotensive drug

Effective treatment that achieves normal blood pressure values is more important for preventing vascular complications than the type of medication used. However, antihypertensive treatment should be based on combination therapy in SPC (single-pill combination) form for most patients, including those initiating therapy:
- for most patients initiating pharmacotherapy, the basic antihypertensive treatment regimen should include an ACE inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) in an SPC (single-pill combination) with a thiazide-like/thiazide diuretic or a dihydropyridine calcium channel blocker;
- in the presence of albuminuria/proteinuria, drugs that inhibit the renin-angiotensin-aldosterone (RAA) system should be favoured in the selection;
- pairing an ACEI with an ARB is contraindicated,
- drugs used in combination therapy can be selected from the above-mentioned or other groups, keeping in mind the principles of combination;
- therapeutic treatment of hypertensive individuals with coexisting renal dysfunction or structure is described in Chapter 19;
- ACEIs or ARBs are not recommended in normotensive subjects with normoalbuminuria for primary prevention of diabetic kidney disease;
- ACEIs or ARBs are recommended for normotensive individuals with albuminuria ≥ 30 mg/g to prevent the onset and progression of diabetic kidney disease;
- in individuals with coronary artery disease and a history of heart attack, especially in cases of heart failure, it is advisable to use beta-blockers and ACE inhibitors as first-line medications to reduce the risk of death;
- in the presence of peripheral artery disease, it is advisable to avoid using non-selective β-adrenergic receptor blockers;
- thiazide or thiazide-like diuretics should be used when GFR is ≥ 30 ml/min/1.73 m^2; in cases where GFR is < 30 ml/min/1.73 m^2, loop diuretics should be considered.

Clinical studies indicate that, for most individuals, achieving therapeutic goals requires the use of three different antihypertensive medications. This often necessitates drugs from additional classes, including α-blockers, centrally acting agents, and vasodilators.

In diabetes, resistant hypertension is common and often requires the simultaneous use of more than three medications. In such cases, spironolactone should be considered as the fourth drug, and if contraindicated, alternative medications from other classes should be used. Patients with diabetes and resistant hypertension should also be screened for obstructive sleep apnea.

Among antihyperglycemic medications, SGLT-2 inhibitors and GLP-1 receptor agonists exhibit a hypotensive effect and can be recommended for diabetes treatment for this reason as well.

For guidelines on diabetes management in children and adolescents, women planning preg-

nancy or currently pregnant, and individuals over 65 years of age, please refer to the relevant chapters.

IV. Specific management for hypertension in pregnant women

Target blood pressure values for pregnant women with diabetes are systolic 110–139 mm Hg and diastolic 81–85 mm Hg. In pregnant women with diabetes and vascular complications, the target blood pressure value is < 130/80 mm Hg.

In pregnant women with hypertension, the preferred oral medications are (in order): labetalol, methyldopa, and calcium channel blockers. In life-threatening situations, labetalol, or nitroglycerine (parenterally) are the preferred agents. In the absence of these options, hydralazine may be used parenterally, but there have been reports of an increased incidence of adverse effects in the peripartum period.

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14. Dyslipidemia: Standards of Care

CHAPTER HIGHLIGHTS – THERAPEUTIC GOALS
• LDL-C levels < 55 mg/dl (< 1.4 mmol/l) with at least a 50% reduction from baseline values in individuals with diabetes at very high cardiovascular risk. As a secondary target, non-HDL-C levels should be lowered to < 85 mg/dl (< 2.2 mmol/l). [**A**]
• LDL-C levels < 70 mg/dl (< 1.8 mmol/l) with at least a 50% reduction from baseline values in individuals with diabetes at high cardiovascular risk. As a secondary target, non-HDL-C levels should be lowered to < 100 mg/dl (< 2.6 mmol/l). [**A**]
• LDL-C levels < 100 mg/dl (< 2.6 mmol/l) in individuals with diabetes at moderate cardiovascular risk. As a secondary target, non-HDL-C levels should be lowered to < 130 mg/dl (< 3.4 mmol/l). [**A**]

CHAPTER HIGHLIGHTS – TREATMENT
• Statins are the first-choice lipid-lowering medications. In individuals at very high and high cardiovascular risk, it is recommended to use statins at the highest recommended or tolerated doses to achieve therapeutic goals. [**A**]
• If the treatment goal is not achieved, combining a statin with ezetimibe is recommended. [**A**]
• In individuals at very high cardiovascular risk who do not reach the target LDL-C level despite optimal statin and ezetimibe therapy or who cannot tolerate statins, the addition of PCSK9 inhibitors is recommended. [**A**]
• In cases of complete statin intolerance, consider ezetimibe as monotherapy [C] or in combination with PCSK9 inhibitors [**B**]. Alternatively, bempedoic acid may be used. [**B**]
• For individuals with hypertriglyceridemia (TG: 151–499 mg/dl; 1.7–5.6 mmol/l), the use of high-dose eicosatetraenoic acid (EPA) (2 g twice daily) in combination with a statin may be considered. [**B**]

LDL-C is the primary target of lipid-lowering therapy. In individuals with diabetes and high triglyceride levels (TG), obesity, and low LDL-C levels, it is recommended to measure non-HDL-C or apo-B. Treatment goals vary for individuals with type 2 diabetes depending on their cardiovascular risk (see Table 14.1). Non-HDL-C should be considered as a secondary treatment target.

I. Diagnosing lipid disorders

1. The individual history should include:
   a) the presence of cardiovascular diseases related to atherosclerosis: coronary heart disease, ischemic stroke, peripheral artery disease (PAD),
   b) assessment of secondary causes of hyperlipidaemia, such as diet, coexisting conditions, and medications (see Table 14.2),
   c) the presence of a family history with an initial LDL-C level > 190 mg/dl, indicating lipid disorders and premature cardiovascular disease. Calculate the likelihood of familial hypercholesterolemia according to the Dutch Lipid Clinic Network (DLCN) scale and refer individuals with a score of ≥ 6 points to specialized centres with a lipid-lowering program (see Table 14.3).
2. Lipid profile testing can be performed in non-fasting individuals, but in individuals with hypertriglyceridemia (TG > 150 mg/dl, > 1.7 mmol/l), the test should be performed after an 8–12 hour fast from their last meal.
3. Consider measuring Lp(a) levels at least once in a person's lifetime to identify individuals with very high Lp(a) levels (> 430 nmol/l, > 180 mg/dl), whose cardiovascular risk is similar to that of familial hypercholesterolemia individuals. Measurement of Lp(a) should be considered in all individuals with premature cardiovascular disease (heart attack, ischemic stroke), persons with aortic stenosis, peripheral artery disease, familial hypercholesterolemia, and to refine the risk assessment in individuals at the borderline of moderate/high cardiovascular risk.

II. Lipid control and monitoring

Lipid testing should be performed at the time of diabetes diagnosis, and thereafter, lipid levels should be monitored annually or more frequently based on their levels.

If lipid levels are above therapeutic targets, it is recommended to monitor them every 8–12 weeks from the start of therapy until the recommended levels are achieved. This recommendation excludes individuals after an acute coronary syndrome, where lipid testing should be performed within 4–6 weeks after treatment initiation.

Before initiating lipid-lowering therapy, ALT, CK, and TSH levels should be measured.

If lipid levels are within the desired range, follow-up lipid profile testing should be conducted annually, and ALT and CK should only be assessed if symptoms arise.

Table 14.1. Cardiovascular risk categories in people with type 2 diabetes and recommended target lipid levels according to ESC 2023 guidelines

Cardiovascular risk	Criteria	Recommended target lipid levels
Extremely high	Type 2 diabetes and atherosclerotic cardiovascular disease* or target organ damage**, or a 10-year cardiovascular risk ≥ 20% according to the SCORE2-Diabetes calculator	Primary objective: LDL-C < 55 mg/dl (< 1.4 mmol/l) and LDL-C reduction of ≥ 50% Secondary target: non-HDL < 85 mg/dl (< 2.2 mmol/l) apoB < 65 mg/dl
High	Type 2 diabetes without criteria for very high risk and a 10-year cardiovascular risk of 10% to < 20% according to the SCORE2-Diabetes calculator	Primary objective: LDL-C < 70 mg/dl (< 1.8 mmol/l) and LDL-C reduction of ≥ 50% Secondary target: non-HDL < 100 mg/dl (2.6 mmol/l) apoB < 80 mg/dl
Moderate	Type 2 diabetes without criteria for very high risk and a 10-year cardiovascular risk of 5% to < 10% according to the SCORE2-Diabetes calculator	LDL-C < 100 mg/dl (< 2.6 mmol/l) Non-HDL-C < 130 mg/dl (< 3.4 mmol/l) apoB < 100 mg/dl
Low	Type 2 diabetes without criteria for very high risk and a 10-year cardiovascular risk of < 5% according to the SCORE2-Diabetes calculator	Target lipid levels have not been established due to lack of sufficient data

**Atherosclerotic cardiovascular disease – coronary artery disease, heart attack, peripheral artery disease (PAD), carotid artery disease, aortic aneurysms, ischemic stroke, transient ischemic attack (TIA), revascularization of arteries due to atherosclerosis.*
***Severe target organ damage: eGFR < 45 ml/min/1.73 m² regardless of albuminuria or eGFR 45–59 ml/min/1.73 m² and albuminuria [urinary albumin-to-creatinine ratio (UACR) 30–300 mg/g; stage A2], or proteinuria (UACR > 300 mg/g; stage A3), or the presence of microvascular disease in at least three different sites, e.g., albuminuria (stage A2) plus retinopathy, plus neuropathy.*
SCORE2-Diabetes refers to individuals aged 40–69 with type 2 diabetes, without atherosclerotic vascular disease and/or severe organ damage.

Table 14.2. Secondary causes of hyperlipidaemia

Diet	Comorbidities	Drugs
High in fat High in carbohydrates Alcohol	Hypothyroidism Diabetes Obesity Lipodystrophies Kidney diseases – nephrotic syndrome, uraemia Liver diseases – primary cholangitis, primary sclerosing cholangitis, post-alcoholic cirrhosis, MASLD Mental anorexia Cushing's syndrome Systemic lupus erythematosus Psoriasis HIV Pregnancy – third trimester: increase in TG	Glucocorticosteroids (ICS) Oral estrogens Oral retinoids Ion exchange resins Protease inhibitors (lopinavir with ritonavir, saquinavir, fosamprenavir) Nucleoside reverse transcriptase inhibitors (stavudine, zidovudine) Non-nucleoside reverse transcriptase inhibitors (efavirenz) Thiazide diuretics Non-cardio selective β-blockers (except carvedilol) Tamoxifen Cyclophosphamide Cyclosporine Sirolimus Everolimus L-asparaginase Second-generation antipsychotics (clozapine, olanzapine)

MASLD – metabolic dysfunction-associated steatotic liver disease

III. Non-pharmacological treatment of dyslipidemia.

1. Lifestyle changes include:
- increased physical activity,
- weight reduction in individuals with overweight or obesity,
- smoking cessation.

2. Dietary modifications should involve:
- limiting saturated fat intake to < 10% of total energy intake,
- cholesterol intake < 300 mg/day or < 200 mg/day in the presence of elevated LDL cholesterol levels,
- maximum restriction of trans unsaturated fats,
- consuming 4–8% of energy from n-6 polyunsaturated fatty acids,
- a daily intake of 2 g of α-linolenic acid and 200 mg of very-long-chain fatty acids from n-3 polyunsaturated fats.

IV. Pharmacological treatment of dylipidemia in individuals with diabetes

1. **Statins:**

a) statins remain first-choice therapy to lower LDL-C levels in individuals with type 1 or type 2 diabetes and dyslipidemia due to their effectiveness in preventing cardiovascular events and reducing cardiovascular mortality, regardless of gender,

b) statins with strong lipid-lowering effects (such as rosuvastatin and atorvastatin) are indicated in individuals with diabetes at high or very high cardiovascular risk because they reduce LDL-C levels by 40–63% and significantly decrease the occurrence of major cerebrovascular and coronary events. High doses of statins are recommended for these individuals: rosuvastatin 20–40 mg/day, atorvastatin 40–80 mg/day.,

c) the beneficial effects of statins outweigh their potential diabetogenic effects, estimated as a 9% increased risk of developing diabetes, especially in older persons and those at risk of diabetes development,

d) statins are generally safe and well-tolerated. Subjective side effects (such as fatigue, muscle pain, and neurological symptoms) are more common than objective adverse effects due to a nocebo effect. Women experience adverse effects more frequently than men. In most cases of myopathy or rhabdomyolysis, they are associated with drug interactions, especially when used with higher doses of statins or in combination with gemfibrozil. Risk factors for myopathy include advanced age, intense physical activity, hypothyroidism, and drug interactions,

e) contraindications to statin use:
- pregnancy and breastfeeding,
- reproductive age if a woman is not using effective contraception,
- initial ALT values three times above the upper limit without an established cause,
- initial creatine kinase (CK) values four times above the upper limit,
- active viral hepatitis,
- liver failure (Child-Pugh class B and C),
- choroideremia,

f) assessment of statin therapy safety:
- ALT should be checked before starting treatment, after 8–12 weeks of therapy, and after each statin dose increase or if symptoms occur.
- CK levels should be determined before starting treatment but do not require ongoing

Table 14.3. Criteria for the diagnosis of familial hypercholesterolemia (FH) – point scale (according to the Dutch Lipid Clinic Network scale)

Physical examination	Points
Tendon jaundice	6
Corneal seam	4
LDL-C	
> 330 mg/dl (> 8.5 mmol/l)	8
250–329 mg/dl (6.5–8.4 mmol/l)	5
190–249 mg/dl (5.0–6.4 mmol/l)	3
155–189 mg/dl (4.0–4.9 mmol/l)	1
Genetic testing	
Mutation in *LDLR, APOB, PCSK9* genes	8
Family history	
First-degree relatives with premature coronary or vascular disease	1
First-degree relatives with LDL-C levels > 190 mg/dl	1
First-degree relatives with yellow deposits on tendons and/or corneal arcus	2
Children and adolescents aged < 18 years with LDL-C levels > 155 mg/dl	2
Clinical history	
Premature coronary artery disease*	2
Premature cerebrovascular or peripheral vascular disease*	1

Certain diagnosis: > 8 points, probable diagnosis: 6–8 points, possible diagnosis: 3–5 points, unconfirmed diagnosis: < 3 points
**Premature cardiovascular disease: age < 55 years in men, < 60 years in women.*

monitoring, except in the case of myalgia during therapy,
g) statin intolerance:

- **total intolerance:** statin intolerance means an inability to use the drug due to clinically significant adverse effects and/or a significant increase in biomarkers (ALT/AST > 3 × ULN or CK > 5 × ULN) without other factors increasing the risk of side effects, such as hypothyroidism, drug interactions, physical exertion, or muscle diseases.
  Total statin intolerance should apply to at least two different statins, including one irrespective of the dose and the other at the lowest dose (rosuvastatin 5 mg/day, atorvastatin 10 mg/day, simvastatin 10 mg/day, pitavastatin 2 mg/day). In case of total statin intolerance, consider monotherapy with ezetimibe or combination therapy with PCSK9 inhibitors. Alternatively, bempedoic acid, a prodrug that reduces cholesterol synthesis by inhibiting adenosine triphosphate (ATP) citrate lyase, with very limited musculoskeletal side effects, may be used. In individuals at high cardiovascular risk intolerant to statins, the use of bempedoic acid (180 mg once daily) was associated with a reduction in cardiovascular events, although there was a higher incidence of gout and gallstone formation.
- intolerance to high statin doses: if a person experiences adverse effects during treatment with high-dose statins (fatigue, muscle pain, or neurological symptoms), several strategies can be considered:
  - » discontinue the statin and attempt re-introduction of the same statin at a lower dose in combination with ezetimibe or
  - » switch to another statin at a lower dose in combination with ezetimibe.

Evidence suggests that even a low dose of statin (atorvastatin or rosuvastatin) administered every 2–3 days can have a favourable lipid-lowering effect.

Approximately 70–90% of individuals who report statin intolerance (fatigue, muscle pain, neurological symptoms) can tolerate statin therapy upon re-introduction.

2. **Combination hypolipidemic therapy**
   a) **statin + ezetimibe:** if the target LDL-C level is not achieved with statin therapy, combination therapy with a statin and ezetimibe is recommended. In individuals after acute coronary syndrome (ACS), consider initiating combination therapy with a high-dose statin (atorvastatin 80 mg or rosuvastatin 40 mg) and ezetimibe 10 mg from the outset.,
   b) **statin + ezetimibe + PCSK9 inhibitors (alirocumab, evolocumab) or statin + ezetimibe + inclisiran:** in individuals at very high cardiovascular risk who do not achieve the target LDL-C levels despite optimal statin and ezetimibe therapy, the addition of PCSK9 inhibitors (alirocumab or evolocumab) or inclisiran is recommended.

Evolocumab and alirocumab are monoclonal antibodies that bind to PCSK9 protein and significantly lower LDL-C levels by 60% when used as monotherapy, and by 85% when combined with a high-dose statin and ezetimibe. They have substantially reduced cardiovascular events (death from cardiovascular causes, heart attack, stroke, hospitalization due to unstable angina, or coronary revascularization) in subgroups of individuals with diabetes and atherosclerotic cardiovascular disease. Besides LDL, they also significantly reduce other atherogenic lipids (TG, non-HDL-C, apo-B-containing particles) in individuals with diabetes and mixed dyslipidemia. There is no significant association between the use of these antibodies and the risk of developing diabetes. They are recommended for use in individuals with eGFR > 30 ml/min/1.73 m^2. Evolocumab is administered subcutaneously at a dose of 140 mg every 2 weeks, while alirocumab is administered subcutaneously at a dose of 150 mg every 2 weeks or 300 mg once a month.

Inclisiran-siRNA is a small interfering RNA molecule that inhibits PCSK9 synthesis in the liver. When added in a high-dose to statin, it reduces LDL by an additional 50–55% in individuals with or without diabetes. It is recommended for use in individuals with eGFR > 15 ml/min/1.73 m^2 and is administered subcutaneously at a dose of 284 mg every 6 months. Studies evaluating the impact of inclisiran on cardiovascular events are ongoing.

In Poland, treatment with PCSK9 inhibitors or inclisiran is possible through the B.101 therapeutic program in specialized clinics. Individuals suspected of familial hypercholesterolemia (according to the DLCN scale, with a score of at least 6 points) and individuals who have had an acute coronary syndrome in the last 2 years can be referred to the program.

c) **statin + fibrate:** in high cardiovascular risk groups of individuals who achieve target LDL-C levels but have persistently high TG levels (> 200 mg/dl or > 2.3 mmol/l), consider

adding fenofibrate to statin therapy. Combination therapy of statin + fibrate (especially gemfibrozil) is associated with an increased risk of abnormal liver function tests, myopathy, and rhabdomyolysis, particularly in individuals with underlying chronic kidney disease and with the use of high-dose medications. Kidney function should be evaluated before therapy, after 3 months, and after 6 months. Combination therapy should not be recommended for individuals with a eGFR < 30 ml/min/1.73 mm^2. If a decrease in eGFR < 30 ml/min/1.73 mm^2 is observed during fenofibrate therapy, discontinue the treatment.

d) **statin + icosapent ethyl (EPA):** In individuals with hypertriglyceridemia (TG: 150–499 mg/dl or 1.7–5.6 mmol/l), consider using icosapent ethyl (ethyl ester of eicosatetraenoic acid) in high doses, i.e., 2 × 2 g, in combination with a statin. EPA lowers TG levels and has a favourable effect on cardiovascular events. However, at the highest dose (4 g/day), it increases the risk of atrial fibrillation.

V. Hypertriglyceridemia

The risk of acute pancreatitis (AP) occurs at triglyceride (TG) levels > 880 mg/dl (> 10 mmol/l) and depends on the presence of chylomicrons in the serum. Hypertriglyceridemia accounts for approximately 10% of AP cases. The optimal fasting triglyceride concentration should be < 100 mg/dl (< 1.2 mmol/l). Hypertriglyceridemia, based on fasting TG levels, can be classified as:

a) borderline – TG: 100–150 mg/dl (1.2–1.69 mmol/l),
b) mild – TG: 151–499 mg/dl (1.7–5.6 mmol/l),

Table 14.4. Management of hypertriglyceridemia according to TG levels

	Mild to severe Increased VLDL-TG Increased cardiovascular risk	Severe Chylomicrons and VLDL-TG present Increased risk of acute pancreatitis
TG levels	Mild: 151–499 mg/dl (1.7–5.6 mmol/l), severe: 500–880 mg/dl (5.7–10 mmol/l)	> 880 mg/dl (> 10 mmol/l)
Primary goal of therapy	Target LDL-C levels	TG reduction
Secondary goal of therapy	Target non-HDL-C levels	Target LDL-C and non-HDL-C if the risk of acute pancreatitis is reduced
Non-pharmacological treatment	Reduction in consumption or alcohol abstinence Weight reduction, if overweight, obesity Reduction of carbohydrate intake, especially fructose and sucrose Increasing physical activity Replacing saturated fats with polyunsaturated fats	Alcohol abstinence Restrictive low-fat diet: limit fat intake below 20% of calories, 10–20 g of fat per day (2000 kcal diet) Use of MCT-triglycerides of medium chain length (C6–12) Reduce intake of total carbohydrates, especially fructose and sucrose Reducing body weight, if overweight, obesity Increasing physical activity
Pharmacological treatment	Statin (atorvastatin, rosuvastatin) Consider adding fibrate if target LDL-C is achieved and TG still > 200 mg/dl (> 2.3 mmol/l) in individuals at high cardiovascular risk Consider including EPA at a dose of 2 × 2 g	Fenofibrate + omega 3 acids (4 g/day) In acute conditions, rapid TG reduction can be achieved with plasmapheresis In non-insulin-treated diabetics, insulin therapy should be initiated, usually intravenously using an infusion pump, to achieve optimal glycemic control; this management can reduce triglyceridemia within 2–5 days; in addition to insulin, the use of low-molecular-weight or unfractionated heparin should be considered
Genetic tests	No indication for genetic testing in most cases, except for suspected familial dysbetalipoproteinemia*	Genetic diagnosis for FCS or MCS

** Familial dysbetalipoproteinemia (TG-rich lipoprotein remnant disease) – should be suspected at TG levels of 300–1000 mg/dl. apoB < 120 mg/dl, non-HDL-C/apoB > 3.69 mmol/g (1.43 mg/dl) in individuals with a burdensome family history of premature atherosclerotic cardiovascular disease (myocardial infarction, stroke, PAD).*
FCS – familial chylomicronaemia syndrome, MCS – multifactorial chylomicronaemia syndrome

c) severe – TG: 500–880 mg/dl (5.7–10 mmol/l),
d) extreme – TG > 880 mg/dl (> 10 mmol/l).

Management of hypertriglyceridemia (HTG) is presented in Table 14.4.

VI. Type 1 diabetes

In type 1 diabetes, high LDL-C values are observed in individuals with uncontrolled glycaemia. High HDL-C levels can be pro-inflammatory and therefore atherogenic.

Determining cardiovascular risk in individuals with type 1 diabetes is less investigated than in individuals with type 2 diabetes. Based on the Scottish-Swedish Diabetes Registry, a tool has been developed to predict 10-year cardiovascular risk in individuals with type 1 diabetes: https://diabepi.shinyapps.io/cvdrisk/.

Statins are the basis of lipid-lowering treatment in type 1 diabetes.

In individuals with type 1 diabetes who are above 40 years old and without coronary artery disease, statin therapy should be considered to reduce cardiovascular risk.

In younger individuals with type 1 diabetes below 40 years old, early initiation of statin therapy may be justified by the presence of other cardiovascular risk factors, microvascular complications, or a 10-year cardiovascular risk > 10% calculated using the Scottish Swedish model.

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15. Hypoglycaemia

CHAPTER HIGHLIGHTS
• A person with diabetes should be asked about symptoms and the frequency of hypoglycaemia during each visit. [**C**]
• Every person at high risk of clinically significant hypoglycaemia (< 54 mg/dl, < 3.0 mmol/l) should have a prescription for glucagon. Family members and caregivers of individuals with diabetes, as well as teachers of children and adolescents with diabetes, should be familiar with how to administer glucagon. [**E**]
• A change of the method of diabetes treatment in the presence of severe hypoglycaemic episodes and hypoglycaemia unawareness should be considered. [**B**]
• In the treatment of hypoglycaemia in conscious individuals (with a glucose level ≤ 70 mg/dl, 3.9 mmol/l), it is crucial to administer 15 g of glucose or other simple carbohydrates orally. If glucose levels continue to indicate hypoglycaemia after 15 minutes, the administration of glucose/carbohydrates should be repeated. After hypoglycaemia has subsided, if there is a possibility of recurrence, the person with diabetes should eat a snack/meal. [**C**]
• In individuals with diabetes treated with insulin and experiencing hypoglycaemia unawareness or severe hypoglycaemic episodes, the therapeutic goal should be to maintain slightly higher glucose levels for at least several weeks to partially restore the awareness of hypoglycaemia symptoms and prevent future episodes. [**A**]
• In individuals with diabetes experiencing hypoglycaemia unawareness or frequent hypoglycaemic episodes treated with insulin, the use of CGM is absolutely indicated. [**A**]

I. Definition

Hypoglycaemia is diagnosed when the blood glucose level is below 70 mg/dl (3.9 mmol/l), regardless of the presence of clinical symptoms. Some individuals, especially those with long-standing type 1 diabetes, may only experience symptoms at lower glucose levels. The value of 70 mg/dl (3.9 mmol/l) is considered an alert level, requiring the consumption of simple carbohydrates or adjustment of medication doses to prevent further glucose decline, regardless of the presence or absence of symptoms. This justifies setting the threshold for threatening hypoglycaemia at 70 mg/dl (3.9 mmol/l). Clinically significant hypoglycaemia is defined as a value less than 54 mg/dl (3.0 mmol/l). Hypoglycaemia symptoms can also occur at higher glucose values, even > 100 mg/dl (5.6 mmol/l), when there is a rapid decrease in glucose levels. The so-called hypoglycaemia unawareness, characterized by the inability to perceive pathologically low (≤ 70 mg/dl or ≤ 3.9 mmol/l) glucose levels, is a significant complication of frequent hypoglycaemic episodes.

The classification of hypoglycaemia according to the International Hypoglycemia Study Group (2017) is presented in Table 15.1. Severe hypoglycaemia is an episode that requires assistance from another person to administer carbohydrates, glucagon, or take other actions. Blood glucose values during the episode may not be available, but the subsidence of symptoms after the administration of glucose and/or glucagon is considered sufficient evidence that the episode was caused by low blood glucose levels.

Recurrent severe hypoglycaemia refers to two or more cases of severe hypoglycaemia in the past 12 months.

II. General remarks

1. Individuals with diabetes should not be automatically considered at risk of hypoglycaemia, and employment and social consequences arising from this should not be imposed on them.
2. The risk of hypoglycaemia increases in the following situations:
   - use of insulin as monotherapy or in combination with other antihyperglycaemic drugs,
   - use of sulfonylurea derivatives as monotherapy or in combination with other antihyperglycaemic drugs,

Table 15.1. The classification of hypoglycaemia according to the International Hypoglycaemia Study Group [6]

Glucose levels	Criteria	Comment
Alert glucose levels (level 1)	≤ 70 mg/dl ≤ 3.9 mmol/l	Glucose levels requiring therapeutic treatment with simple carbohydrates – dose adjustment of glucose-lowering drugs indicated
Clinically significant hypoglycaemia (level 2)	< 54 mg/dl < 3.0 mmol/l	Sufficiently low glucose levels indicating clinically significant hypoglycaemia
Severe hypoglycaemia (level 3)	No specific blood glucose threshold	Hypoglycaemia accompanied with severe cognitive impairment requiring third-party assistance

- improper dosing of these drugs in situations of increased physical exertion, reduced calorie intake, or alcohol consumption,
- pursuit of rapid normalization of HbA_{1c} values,
- the coexistence of other conditions predisposing to hypoglycaemia (including chronic kidney disease, hypothyroidism, adrenal insufficiency, eating disorders, conditions associated with impaired intestinal absorption, and cognitive disorders),
- hypoglycaemia unawareness,
- episodes of severe hypoglycaemia in recent weeks.

3. Hypoglycaemia can, in certain situations (e.g., in the elderly, individuals with ischemic heart disease), pose a direct threat to life.

III. Management of recurrent hypoglycaemia involves:

- conducting a thorough analysis of the habits of individuals with diabetes, their diabetes treatment, and any other health conditions,
- providing education to individuals with diabetes on hypoglycaemia prevention (e.g., recommending a reduction in insulin dose before planned physical activity),
- modification of diabetes therapy to reduce the risk of hypoglycaemia (e.g., replacing sulfonylureas with medications that carry a lower risk of hypoglycaemia, changing the insulin therapy model, using insulin preparations with a lower risk of hypoglycaemia, implementing insulin pumps, preferably with automatic insulin suspension in case of hypoglycaemia risk, or automated insulin delivery (AID) systems),
- frequent self-monitoring and using continuous glucose monitoring (CGM) systems if available to the individual.

IV. Management of hypoglycaemia unawareness

In addition to the steps taken for recurrent hypoglycaemia, the following measures should be implemented:

- educating individuals with diabetes and their close contacts on recognizing subtle and atypical signs of hypoglycaemia (hypoglycaemia awareness training),
- considering this condition in their professional activities and when operating vehicles,
- modifying therapy to significantly reduce the frequency of hypoglycaemia as the primary method to improve hypoglycaemia awareness.

V. Emergency management of hypoglycaemia

1. In a conscious individual:

- it is recommended to consume 15 g of glucose or other simple carbohydrates and check blood glucose after 15 minutes. If hypoglycaemia continues, it is advisable to consume another 15 g of glucose or simple carbohydrates and check blood glucose after 15 minutes,
- in cases where there is a risk of recurrent hypoglycaemia, such as after an excessive insulin dose, alcohol consumption, or prolonged physical activity, it is recommended, in addition to the above intervention, to consume complex carbohydrates and monitor blood glucose.

2. In an unconscious individual or someone with impaired consciousness who cannot swallow:

- administer intravenously 10% or 20% glucose solution (initial bolus dose of 0.2–0.5 g of glucose per kg of body weight) and then, if necessary, continue a continuous intravenous infusion of 10% glucose with glucose control,
- if there is a risk of recurrent hypoglycaemia, maintain the infusion of 10% glucose under glucose control,
- in cases of difficulty in accessing veins, administer 1 mg of glucagon intramuscularly or subcutaneously (0.5 mg in children weighing < 25 kg and 1 mg in children weighing ≥ 25 kg). Glucagon can also be administered intranasally at a dose of 3 mg in individuals with diabetes aged 4 years and older, regardless of body weight,
- after regaining consciousness, and in cases where there is a risk of recurrence of hypoglycaemia, it is recommended to provide 10–20 g of oral carbohydrates and monitor blood glucose,
- individuals with diabetes treated with insulin or sulfonylurea derivatives may experience prolonged episodes of hypoglycaemia, sometimes requiring multi-hour glucose infusions,
- in the event of a severe hypoglycaemia incident, consider hospitalizing the individual due to life-threatening conditions associated with the possibility of irreversible changes in the central nervous system, especially in cases of possible recurrent severe hypoglycaemia,
- in ambulatory settings, trained individuals from the person's environment should be recommended to administer intramuscular or subcutaneous glucagon or intranasal glucagon.

3. In individuals treated with intensive insulin therapy, using insulin analogues or a personal insulin pump, the approach to managing hypo-

glycaemia typically involves administering 15 g of glucose orally and checking blood glucose after 15 minutes. If low blood glucose continues, repeat glucose administration and check blood glucose after another 15 minutes (the 15/15 rule). In cases of hypoglycaemia or hypoglycaemia risk with personal insulin pump therapy, it is advisable to suspend the basal insulin infusion and recheck blood glucose. In individuals using HCL, in case of hypoglycaemia or the risk of hypoglycaemia, 5–8 mg of oral glucose can be administered, and blood glucose should be checked after 15 minutes.

4. In the case of an excessive dose of long-acting insulin (human or analogue) administered, consider the possibility of delayed recurrence of hypoglycaemia after the initial recovery from hypoglycaemia.

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16. Acute Diabetes Complications in Hyperglycaemia

CHAPTER HIGHLIGHTS
• Treatment of acute hyperglycaemic conditions should follow established guidelines for fluid and electrolyte replacement and insulin therapy. Adhering to a protocol for managing diabetic ketoacidosis (DKA) shortens the treatment duration. [**C**]
• In diabetic ketoacidosis, crystalloids, which have advantages over colloid fluids, are preferred in supplementing the body's water deficit. [**C**]
• In acute hyperglycaemic states, particularly in DKA, continuous intravenous insulin infusion is recommended. The initial insulin dose should be calculated based on the current body weight, not blood glucose levels. [**C**]
• In acute hyperglycaemic states, especially in DKA, potassium should be replaced, with serum potassium levels being monitored. [**B**]
• Administration of bicarbonates is not recommended in DKA when the pH is > 6.9. [**B**]

I. Classification

1. Diabetic ketoacidosis (DKA) – mortality: < 1% with standard treatment; the risk of death is increased in individuals with recurrent episodes and coexisting hyperosmolality.
2. Hyperglycaemic hyperosmolar state – mortality: 5–10%.
3. Lactic acidosis – historically, the mortality rate was about 50%, but currently, it largely depends on the experience of the treating centre, the advancement of the underlying disease, and the coexistence of comorbidities.

II. Diabetic ketoacidosis (DKA)

1. Causes of DKA:
- discontinuation or errors in insulin therapy,
- late diagnosis of type 1 diabetes,
- alcohol abuse, cigarette smoking,
- acute inflammatory states (such as bacterial, viral, fungal infections),
- pregnancy,
- acute kidney injury or chronic kidney disease (especially in advanced stages),
- the use of SGLT-2 inhibitors in individuals with diabetes requiring insulin therapy and an increased risk of diabetic ketoacidosis.
- others.

2. Diagnosis: see Table 16.1.
3. Differential diagnosis:
- starvation ketosis,
- alcoholic ketoacidosis (blood glucose rarely > 250 mg/dl (13.9 mmol/l), bicarbonate usually ≥ 18 mmol/l),
- metabolic acidosis with an anion gap > 20 mEq/l (poisoning by ethylene glycol, methanol, paraldehyde, and salicylates),
- lactic acidosis (it's important to note that in ketoacidosis, lactate levels in the blood can increase),
- other comatose conditions leading to hyperglycaemia and ketosis, or situations where they are accompanied by, for example, a stroke or uremic coma.

4. Monitoring of DKA:
- assessment of blood pressure, heart rate, respiratory rate, level of consciousness: every 1–2 hours,
- fluid balance: every 1–2 hours,
- body temperature assessment: every 8 hours,
- blood glucose measurement: every 1 hour,
- measurement of serum or plasma sodium and potassium levels every 4 hours [the corrected serum sodium concentration should be calculated according to the formula: for every 100 mg/dl (5.6 mmol/l) of blood glucose above 100 mg/dl (5.6 mmol/l), add 2 mmol/l to the current serum Na^+ result],
- in cases of hyperkalaemia > 5.5 mmol/l, when potassium is not administered: check after 2 hours; with a kalemia < 5.5 mmol/l and potassium supplementation: check every 4 hours,
- blood gas analysis: every 4 hours,
- initial determination of blood and/or urine ketones.

5. Treatment:

A. Hydration of the patient

The water deficit (on average 100 ml/kg body weight) should be replenished intravenously over 24–48 hours with cardiovascular status monitoring:
- 1000 ml of 0.9% NaCl solution in the first hour, then:
- 500 ml/hour of 0.9% NaCl solution for 4 hours, then:
- 250 ml/hour of 0.9% NaCl solution until the acid-base balance is restored,
- after reducing blood glucose below 250 mg/dl (13.9 mmol/l), a 5% glucose solution infusion at a rate of 100 ml/hour should be initiated; if glucose is added after 24 hours of fluid therapy, the amount of 0.9% NaCl solution should be reduced to 150 ml/hour,
- in states of increased energy demand (e.g., infection accompanying ketoacidosis, hyperthyroidism, pregnancy), it is recommended to administer a 10% instead of a 5% glucose solution at an infusion rate of 70 ml/hour,
- in cases where body weight is < 50 kg, intravenous fluid resuscitation should be administered according to paediatric guidelines (Figure 23.1).

Table 16.1. Diagnosis criteria with severity assessment for ketoacidosis

Parameters	Diabetic ketoacidosis		
	Mild	Moderate	Severe
Plasma glucose levels*	≥ 200 mg/dl (11.1 mmol/l)	≥ 200 mg/dl (11.1 mmol/l)	≥ 200 mg/dl (11.1 mmol/l)
Blood pH	7.25–7.30	7.00–7.24	< 7.00
Blood bicarbonate concentration [mEq/l]	15–18	10–15	< 10
Ketone bodies in urine**	Present	Present	Present
Ketosis (β-hydroxybutyrate) [mmol/l]	3–6	3–6	> 6
Serum osmolality [mOsm/kg/H_2O]	Variable	Variable	Variable
Anion gap***	> 10	> 12	> 12
Disturbance of consciousness	Consciousness	Consciousness/ disorientation	Stupor/sleep

** Does not apply to individuals who are being treated with SGLT2 inhibitors (flozins), in which the glycemic value may be lower (euglycemic diabetic ketoacidosis). **Method using nitroprusside. ***Following the formula: Na^+ (mEq/l) – [Cl^- (mEq/l) + HCO_3^- (mEq/l).*

- in euglycemic diabetic ketoacidosis (blood glucose < 200 mg/dl; 11.1 mmol/l), from the beginning of treatment, in addition to 0.9% NaCl solution, a 5% glucose solution should be administered at a rate of 100 ml/hour, or in cases of increased energy demand, a 10% glucose solution should be infused at 70 ml/hour.

B. Managing hyperglycaemia

Intravenous insulin therapy:

- an initial bolus dose of insulin is 0.1 units/kg body weight; this is given to adults with severe DKA who have not previously received subcutaneous insulin (lack of subcutaneous insulin depot),
- then continue intravenous insulin infusion at a rate of 0.1 IU/kg b.w./hour under glycemic control; in individuals who have subcutaneous insulin deposition after previous injections, intravenous insulin therapy should be started with an infusion of 0.1 IU/kg b.w./hour without a preceding bolus,
- the infusion speed should be adjusted according to the current blood glucose levels, monitored hourly,
- the reduction in glycemic values per hour should not be greater than 100 mg/dl (5.6 mmol/l),
- if plasma glucose levels do not decrease by 50–70 mg/dl (2.8-3.9 mmol/l) from baseline within the first hour, increase (usually double) the rate of intravenous insulin infusion every hour until a steady decrease in glycaemia of 50–70 mg/dl/hr. (2.8-3.9 mmol/l/hr.) is achieved.

NOTE: In the case of DKA in individuals previously treated with an ultra-long-acting insulin analogue, it is recommended that therapy not be discontinued for the duration of recovery from DKA. The administration of basal insulin or the connection of a personal insulin pump should be timed appropriately so that the individual is not exposed to an insulin deficit when the intravenous insulin infusion is disconnected.

C. Compensation of electrolyte abnormalities:

- the potassium deficit in a person with ketoacidosis is 3–5 mmol/kg b.w.,
- potassium supplementation should be administered according to the following rules.

Serum potassium levels:

- K^+ > 5.5 mmol/l → do not administer KCl,
- K^+ 5–5.5 mmol/l → 5–10 mmol/hr. KCl,
- K^+ 4–5 mmol/l → 10–15 mmol/hr. KCl,
- K^+ 3–4 mmol/l → 15–20 mmol/hr. KCl,
- K^+ < 3 mmol/l → suspend insulin administration, use intravenous infusion of 25 mmol/hr. KCl.

Potassium supplementation of > 15 mmol/hr. should be administered into a vena cava after central venipuncture or into two peripheral veins.

D. Use of bicarbonate - consider only if pH < 6.9 is found in arterial blood (in low doses, not more than 1 mmol/kg b.w.); finding elevated lactate levels in the course of ketoacidosis (during which there is often a slight increase in lactate due to tissue hypoxia) is not an indication for bicarbonate administration.

E. Low-molecular-weight heparin – consider a prophylactic dose in individuals with severe diabetic ketoacidosis (DKA).

6. Adverse effects and complications of the treatment for DKA:

- hypokalaemia associated with insulin administration and acidosis compensation using bicarbonates,
- hypernatremia mainly related to unjustified administration of $NaHCO_3$, which may lead to complications like pulmonary oedema or cerebral oedema; in cases of cerebral oedema, intravenous mannitol infusion at a dose of 1–2 g/kg body weight over 20 minutes is recommended,
- hyperglycaemia caused by discontinuing intravenous insulin without timely transition to subcutaneous administration,
- hypoglycaemia due to aggressive insulin therapy,
- hyperchloremia from excessive use of saline solution.

7. Complications of DKA:

- hypovolemic shock,
- acute kidney injury (AKI),
- cerebral oedema, more common in children.

8. The specifics of managing acute ketoacidosis in children are presented in Figure 23.1.

III. Hyperglycaemic hyperosmolar state (HHS)

1. Causes:

- HHS typically develops due to delayed diagnosis or inadequate treatment of type 2 diabetes,
- cardiovascular events like stroke or myocardial infarction,
- alcohol consumption,
- certain diuretic medications,
- chronic renal failure,
- mental illnesses, and infections.

2. Diagnosis

Diagnostic criteria of HHS include:

- blood glucose levels: > 600 mg/dl or > 33.3 mmol/l,
- pH > 7.3,

- serum bicarbonate > 15.0 mmol/l,
- corrected hypernatremia (calculated according to the formula) ≥ 150 mmol/l,
- absent or trace ketone bodies in serum,
- effective osmolality > 320 mOsm/kg H_2O.

Effective molality (mOsm/kg H_2O) =
= 2 [Na^+ (mmol/l)] + glycaemia (mmol/l)
{2 [measured Na (mEq/l)] + [glycaemia (mg/dl)]/18}

The normal plasma molality is 280–300 mOsm/kg H_2O.

3. Differential diagnosis:
- ketone coma,
- coma states in the course of diseases of the central nervous system,
- uremic coma,
- comas in the course of poisoning.

4. Treatment
Similar to DKA treatment, it includes:
- lowering blood glucose (similar doses of insulin as in ketoacidosis treatment)
- normalizing plasma osmolality— gradual reduction of osmolality (not more than 3 mOsm/kg H_2O/hr.),
- administering low-molecular-weight heparin subcutaneously,
- correcting water and electrolyte deficits: significantly higher water loss than in individuals with ketoacidosis,
- use of a hypotonic solution (0.45% NaCl or emergency rehydration fluid), and after achieving normal plasma osmolality, switch to a 0.9% NaCl intravenous infusion under the control of the cardiovascular system; the infusion rate of the NaCl solution should be determined based on the concentration of sodium in the serum and the osmolality of the plasma.,
- monitoring of blood glucose every hour and electrolytes every 4-6 hours.

IV. Lactid acidosis

1. Causes:
- type A arises from cardiogenic shock, severe bleeding, septic shock, acute and chronic respiratory failure; it may occur in individuals with diabetes,
- type B acidosis occurs for reasons other than hypoxia and is found in diabetics, those with liver diseases, proliferative diseases, and after intake of ethyl alcohol, biguanides, salicylates, and methyl alcohol.

2. Laboratory diagnostic criteria:
- blood glucose moderately elevated, but may be normal,
- decreased blood pH (< 7.30), bicarbonate concentration < 10 mmol/l, anion gap > 16 mmol/l,
- lactate levels > 5 mmol/l,
- serum sodium levels unchanged (may be lowered in alcoholics),
- usually increased serum potassium levels.

3. Treatment includes:
- counteracting shock (rehydration and hypovolemia correction, moderate administration of vasoconstrictors),
- counteracting hypoxemia and hypoxia,
- preventing excessive lactic acid production (glucose and insulin infusion under glycemic control),
- alkalization by administering sodium bicarbonate (requirement: BE × 0.3 × body weight (in kg)),
- in justified cases (biochemical and/or clinical indications), renal replacement therapy may be necessary.

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17. Diagnosis and Therapeutic Management of Individuals with Chronic Coronary Syndrome, Heart Failure and Coexisting Diabetes Mellitus

CHAPTER HIGHLIGHTS
· In diabetic individuals with chronic coronary syndrome (CCS) and no contraindications, acetylsalicylic acid and a statin should be used [A] and treatment with RAA system blockers should be considered. [**B**]
· After myocardial infarction, the use of a beta-blocker is recommended indefinitely. [**A**]
· After myocardial infarction, drugs with documented cardioprotective action (SGLT2 inhibitors, GLP1 receptor agonists) should be included indefinitely. [**A**]

Coronary artery disease (CAD) is a pathological process involving the formation of atherosclerotic plaques in the epicardial arteries, which may or may not lead to their narrowing and/or closure. It is a chronic and usually progressive disease, which is why it is considered serious even during seemingly stable periods. The dynamic nature of CAD is associated with a variety of clinical manifestations, which can be practically divided into acute coronary syndromes (ACS) and chronic coronary syndromes (CCS).

In the suspicion or diagnosis of CCS, we most often encounter the following clinical situations:

- an individual with suspected CCS and "stable" angina and/or shortness of breath,
- an individual with newly diagnosed heart failure or left ventricular dysfunction and suspected CCS,
- an asymptomatic individual or with stable symptoms in the 1st year after diagnosis of the disease or revascularization,
- an individual with symptoms of angina and suspected vasospastic or microvascular disease,
- an asymptomatic individual who was diagnosed with CCS during screening tests.

All the above situations are classified as CCS, but each of them is associated with a different risk of future cardiovascular events, which may change over time.

I. Clinical course

Differences in the clinical course of chronic coronary syndromes in people with diabetes indicate the necessity of performing at least annual control examinations to assess the presence of risk factors for this disease.

II. Indications for testing for chronic coronary syndromes

Indications for diagnostic, functional, and anatomical tests aimed at diagnosing CCS and risk stratification in diabetic individuals (cardiological consultation):

1. Presence of typical or atypical symptoms from the cardiovascular system.
2. Abnormal resting ECG.
3. Coexistence of atherosclerotic changes in the peripheral arteries, including the carotid arteries.
4. Planned commencement of intensive physical exercises in people over 35 years of age, who have previously led a sedentary lifestyle.
5. Type 1 diabetes lasting more than 15 years.
6. Presence – apart from diabetes – of two or more CCS risk factors:

- abnormal lipid metabolism parameters,
- hypertension,
- smoking,
- family history of premature atherosclerosis,
- presence of albuminuria,
- presence of autonomic neuropathy (Figure 17.1).

III. Treatment of individuals with diabetes and chronic coronary syndrome according to the new terminology of the European Society of Cardiology

1. Implementation of a healthy lifestyle (see Chapter 6).
2. Antihyperglycemic treatment aimed at achieving therapeutic goals (see Chapter 4).
3. Limitation or normalization of coronary disease risk factors:

- normalization of blood pressure (see Chapter 13.),
- treatment of lipid disorders (see Chapter 14).

4. Specifics of CCS pharmacotherapy in diabetes:

- antiplatelet therapy – acetylsalicylic acid (ASA); it should also be used in individuals with type 2 and type 1 diabetes > 40 years of age who are at increased risk of cardiovascular incidents (> 5% risk of developing coronary heart disease within 10 years); the effectiveness of ASA in primary prevention in individuals with diabetes with low cardiovascular risk has not been confirmed:
  - » the recommended dose of ASA is 75–100 mg/day,
  - » in case of contraindications to the use of ASA, administration of clopidogrel at a dose of 75 mg/day may be appropriate and indicated,
  - » after percutaneous coronary intervention (PCI), it is recommended to use ASA at a dose of 75–100 mg/day and clopidogrel at a dose of 75 mg/day for 1–6 months; in cases of increased risk of bleeding complications, it is advisable to shorten treatment to 1–3 months; in situations of high risk of coronary complications, such as: high risk associated with planned stent implantation (e.g., suboptimal stent implantation or other situations during the procedure associated with a high risk of stent thrombosis, narrowing of the left coronary artery trunk with high anatomical complexity or implantation of stents into many vessels) or if dual antiplatelet therapy (DAPT) cannot be used due to ASA intolerance, consideration may be given to using a second drug, in place of clopidogrel, prasugrel or ticagrelor,
- use of cardio selective β-blockers or multifunctional β-blockers blocking α1 and β1 receptor,
- medications blocking the renin–angiotensin–aldosterone system (RAA): ACE inhibitors/sartans.

In case of pharmacotherapy failure, revascularization therapy should be considered.

Exercise tests and other functional methods are used to: confirm the diagnosis, document ischemia, stratify risk, as well as facilitate the choice of treatment methods and assess their effectiveness. Given its still the easiest access, the exercise test is the most performed test, however, its sensitivity and specificity in detecting ischemia

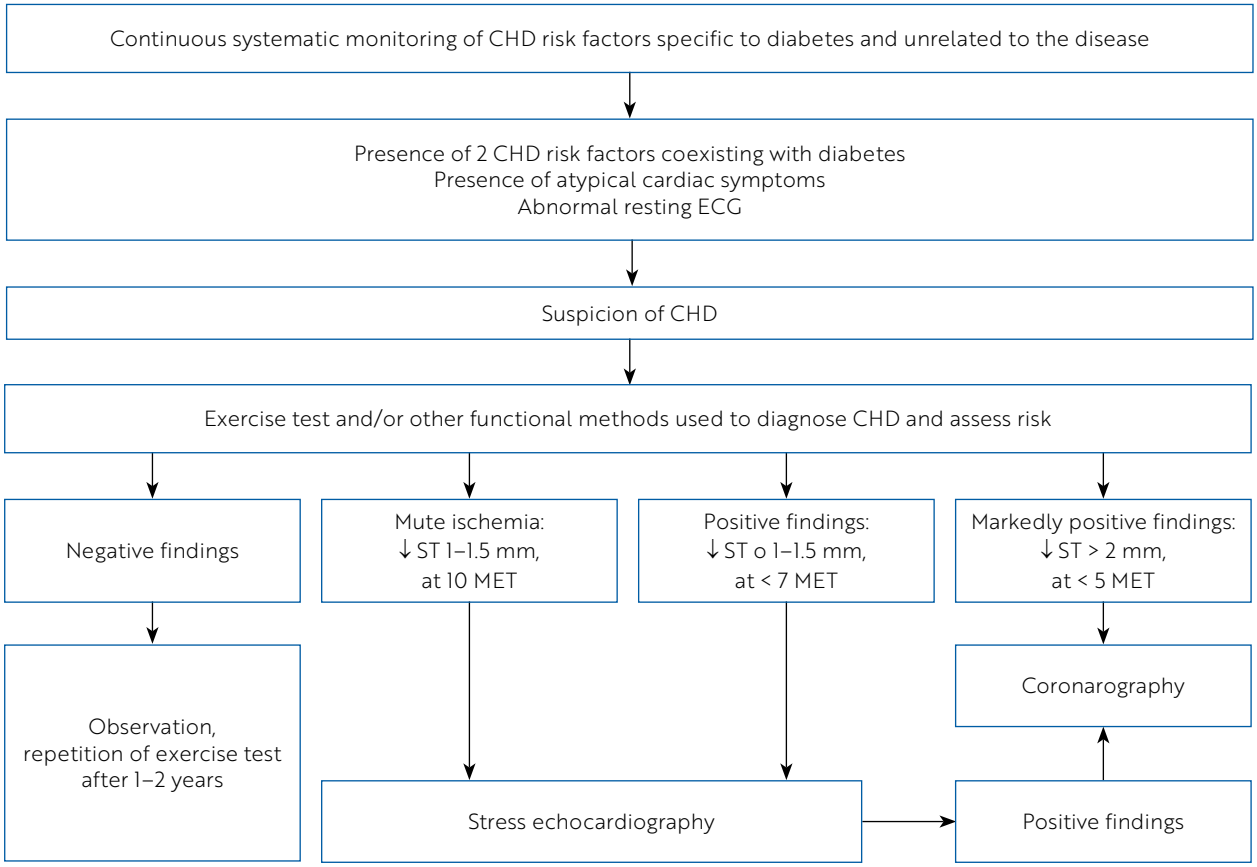
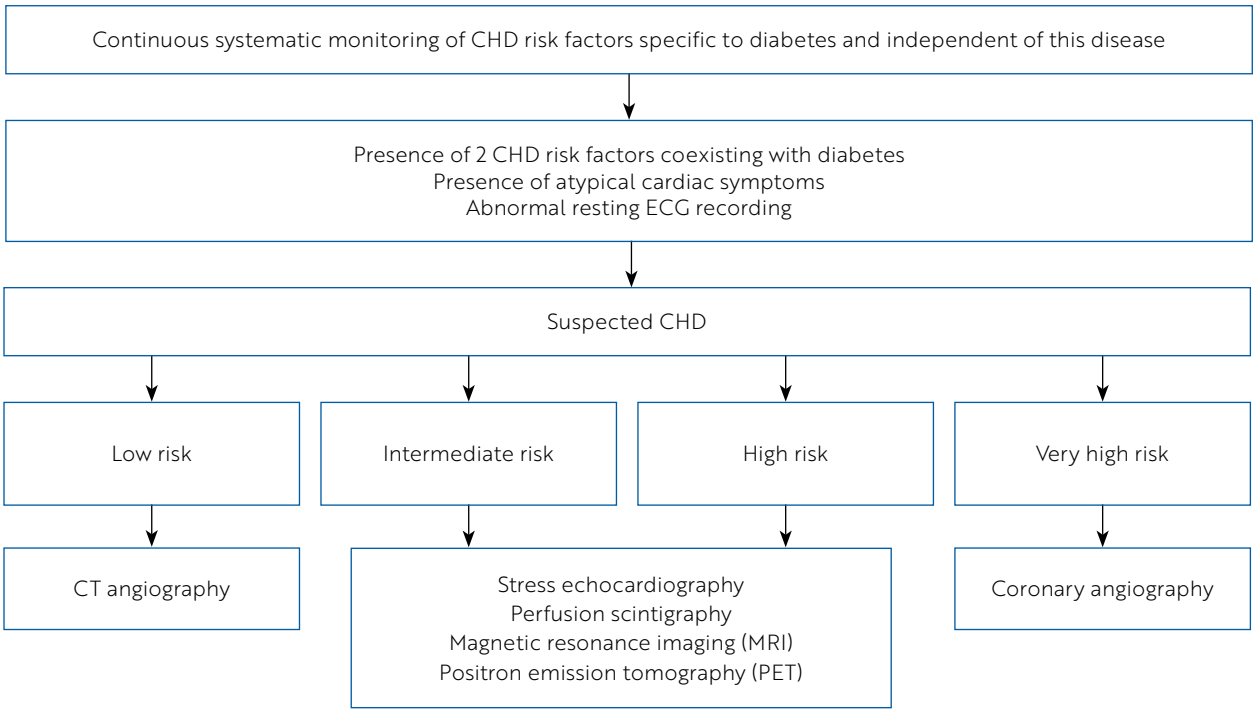


Figure 17.1. Diagnostic algorithm for confirming the diagnosis and risk stratification of coronary heart disease in individuals with diabetes, considering limited access to modern diagnostic methods

CHD – coronary heart disease



Rycina 17.2. Diagnostic algorithm for confirming the diagnosis and risk stratification of coronary artery disease in individuals with diabetes, considering access to modern diagnostic methods

CHD – coronary heart disease

are limited, especially in women. It is permissible in cases of limited access to modern diagnostic methods (Figure 17.1) and is rather useful for ruling out significant narrowing of the coronary arteries. Other functional methods include stress echocardiography, perfusion scintigraphy, magnetic resonance imaging, and positron emission tomography. The algorithm for management considering access to modern diagnostic methods is presented in Figure 17.2. Among anatomical methods, invasive coronary angiography remains the gold standard, and angio-CT may also be useful. It should be noted that people with diabetes are most often classified as high and very high risk for coronary artery disease. In the high-risk group, functional tests are recommended in the first place, while among individuals with very high risk, the basis of diagnostics, already at the first stage, is coronary angiography. Angio-CT has a high negative predictive value, so it is rather useful to exclude significant narrowing in the coronary arteries. It is not recommended for use in high-risk individuals, as it constitutes an unnecessary burden related to the use of contrast and exposure to radiological exposure.

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17.1. Acute Coronary Syndrome in Individuals with Diabetes – Antihyperglycemic Treatment

CHAPTER HIGHLIGHTS

- When an individual is hospitalized with acute coronary syndrome, it is essential to assess their glycemic levels. For those with diabetes who do not have recent test results, an HbA_{1c} test is also required. [**A**]
- In the first 24 hours of acute coronary syndrome, intravenous insulin infusion is recommended under glycemic control with target blood glucose levels of 100–180 mg/dl. [**C**]

In acute coronary syndrome, in states of unspecified relative hyperglycaemia, normalization of glycaemia with intravenous insulin infusion is recommended. Relative hyperglycaemia should be considered as glycaemia above 140 mg/dl (7.8 mmol/l) in individuals with previously diagnosed diabetes or over 180 mg/dl (10.0 mmol/l) in individuals without previously diagnosed diabetes. Intravenous insulin administration is the only way to quickly normalize glycaemia and improve prognosis after acute coronary syndrome. Treatment of ischemic heart disease in people with carbohydrate metabolism disorders should be conducted with the involvement of a diabetologist specialist whenever possible.

I. The first 24 hours of acute coronary syndrome

1. Oral antidiabetic medications should be discontinued.
2. In every case of acute coronary syndrome, glycaemia should be measured upon admission.
3. If the glycaemia exceeds 140 mg/dl (7.8 mmol/l) in individuals with previously diagnosed diabetes or 180 mg/dl (10.0 mmol/l) in individuals without previously diagnosed diabetes, intravenous insulin infusion should be administered at the rate specified in Table 17.1.1. The recommended frequency of glycaemia checks throughout the day is hourly, and after achieving normoglycaemia, every two hours. The glucose level should be maintained within 100–180 mg/dl (5.6–10 mmol/l), adjusting the insulin infusion rate accordingly.
4. Potassium levels should be monitored during insulin infusion.

In cases where glycaemia rises above 180 mg/dl (10.0 mmol/l), the intravenous glucose infusion should be temporarily stopped and restarted after glycaemia has been lowered to 180 mg/dl (10.0 mmol/l), with a simultaneous increase in the rate of insulin infusion.

5. If meals are consumed, additional short-acting/rapid-acting insulin should be injected intravenously.
6. In the case of diabetic ketoacidosis, follow the recommendations for acidosis therapy (see Chapter 16).

II. From the second day of acute coronary syndrome to the end of hospitalization

1. Antihyperglycaemic treatment must ensure blood glucose levels remain within the range of 100–180 mg/dl (5.6–10.0 mmol/l) throughout the day. Therefore, it must be individualized, preferably conducted in cooperation with a diabetologist.
2. In individuals without indicators of ketoacidosis, with carbohydrate metabolism disorders diagnosed on the first day of acute coronary syndrome or earlier successfully treated with metformin, good metabolic control of diabetes during this period can be ensured by an appropriate diet (see Chapter 6). In other cases, insulin therapy in a multiple injection model should be applied according to previously given principles (see Chapter 12).
3. In individuals with type 2 diabetes with overweight or obesity directly before the end of hospitalization, even already on the third day after intervention, metformin, SGLT2 inhibitors, and/or GLP-1 receptor agonists can be additionally applied if there are no contraindications to their administration.

III. After the hospitalization

In every individual with type 2 diabetes after an acute coronary syndrome, SGLT2 inhibitors and/or GLP-1 receptor agonists, and/or metformin should be implemented unless there are contraindications or drug intolerance.

In individuals with type 2 diabetes who achieved good metabolic control on the day of discharge from the hospital, with a daily insulin

Table 17.1.1. Approximate insulin infusion rate according to glucose levels

Glycaemia	10% glucose solution [ml/hr.]	Insulin [IU/hr.]
< 100 mg/dl < 5.5 mmol/l	50	Stop the infusion for 15–30 minutes
100–139 mg/dl 5.5–7.8 mmol/l	50	0.5–1.0
140–179 mg/dl 6.7–10 mmol/l	50	1.0–2.0
180–249 mg/dl 10–13.9 mmol/l	Stop the infusion until the glycaemia decreases < 180 mg/dl (10.0 mmol/l)/hour, then 50	2.0–4.0
250–300 mg/dl 13.9–17.4 mmol/l	Stop the infusion until the glycaemia decreases < 180 mg/dl (10.0 mmol/l)/hour, then 50	4.0–6.0

requirement not exceeding 30 units, it is possible to return to the therapy used before the occurrence of acute coronary syndrome. In individuals diagnosed with diabetes during hospitalization who have achieved good metabolic control by the day of discharge, with a daily insulin requirement not exceeding 30 units, but who are characterized by obesity or overweight, therapy can be managed with oral medications and/or injectable GLP-1 receptor agonists or GIP/GLP-1 receptor agonists, which have a beneficial effect on body weight. If good metabolic control of diabetes cannot be achieved or if the daily insulin requirement exceeds 30 units, insulin therapy should be continued, and the possibility of combining it with oral therapy and/or injectable GLP-1 receptor agonists or GIP/GLP-1 receptor agonists should be considered. Every patient with carbohydrate metabolism disorders who has experienced an acute coronary syndrome should be urgently referred to a diabetology specialist.

NOTE 1: In every individual with acute coronary syndrome, apart from those with previously diagnosed diabetes, before leaving the hospital, hbalc should be measured or a glucose tolerance test should be performed after discharge from the hospital (Chapter 1, point III, Table 17.1.1). In the case of diagnosing glucose intolerance or diabetes, a diabetological consultation is indicated.

NOTE 2: Before planned coronary angiography performed for diagnostic or therapeutic purposes, metformin should be discontinued at least 48 hours before the procedure. It can be resumed 24 hours after performing coronary angiography.

NOTE 3: Randomized trial results indicate an additional cardioprotective effect of drugs from the group of SGLT2 inhibitors and GLP-1 receptor agonists. Their inclusion in therapy should be considered in individuals with high or very high cardiovascular risk.

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17.2. Chronic Heart Failure

I. Introduction

Heart failure (HF) is a clinical syndrome manifested by several main subjective symptoms (e.g., dyspnea, ankle swelling, and fatigue), which may be accompanied by objective symptoms (e.g., signs of elevated jugular venous pressure, crackles over lung fields, and peripheral edema). This syndrome is caused by structural and/or functional cardiac disorders that lead to increased intracardiac pressure and/or inadequate cardiac output at rest and/or during exertion.

II. Classification of heart failure based on left ventricular ejection fraction.

Chronic HF is classified based on the measured left ventricular ejection fraction (LVEF). The European Society of Cardiology has introduced the following HF classification:

- HF with reduced LVEF is defined as values ≤ 40%, i.e., significant impairment of LV contractile function – this condition is referred to as HFrEF,
- HF with mildly reduced LVEF (41–49%) – this condition is referred to as HFrEF,
- HF with preserved LVEF ≥ 50% – HFrEF; in individuals with this form, subjective and objective symptoms of HF are present, abnormalities in heart structure and/or function are identified, and/or elevated levels of natriuretic peptides are observed.

III. Main principles of HF diagnosis

In the diagnosis of individuals with HF, in addition to subjective and objective examination, it is advisable to perform a standard 12-lead ECG and determine the levels of natriuretic peptides (BNP or NT-proBNP). If HF is strongly suspected or natriuretic peptide measurements are not available, an echocardiographic examination is indicated. In cases where the diagnosis is confirmed, this examination is the basis for classification into the respective types of HF.

A regular ECG interpretation makes the diagnosis of HF unlikely. The ECG can reveal abnormalities such as atrial fibrillation (AF), Q waves, left ventricular hypertrophy (LVH), and widened QRS complexes, which increase the likelihood of HF diagnosis and may also provide therapeutic clues.

Normal levels of natriuretic peptides make the diagnosis of HF unlikely.

Echocardiography is recommended as the primary examination to assess heart function. In addition to determining LVEF, echocardiography also provides information about other parameters, such as the size of the heart chambers, eccentric or concentric LVH, regional contractile function abnormalities (which may indicate CAD, takotsubo cardiomyopathy, or myocarditis), right ventricular (RV) function, pulmonary hypertension, valve function, and diastolic function indicators.

Moreover, in the diagnosis of HF, the performance of basic laboratory blood tests is recommended, such as serum creatinine and electrolytes, complete blood count, as well as liver and thyroid function tests, to differentiate between HF and other conditions, as well as to obtain prognostic information and treatment guidance.

A chest X-ray is recommended to assess other potential causes of dyspnea (e.g., lung disease). It may also provide evidence supporting the diagnosis of HF (e.g., congestion in the pulmonary circulation or an enlarged heart).

In the next step, determining the etiology and implementing treatment, including causal treatment, is recommended.

IV. General principles of pharmacotherapy for heart failure with reduced ejection fraction

It has been shown that modulation of the renin-angiotensin-aldosterone system (RAA) and the sympathetic nervous system using angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) with neprilysin inhibitor (ARNI), β-blockers, and mineralocorticoid receptor antagonists (MRA) increases survival, reduces the frequency of hospitalizations due to HF, and alleviates symptoms in individuals with HFrEF. These medications, unless contraindicated or poorly tolerated, form the basis of pharmacotherapy in individuals with HFrEF and should be invariably used.

An important factor affecting prognosis is that doses of ACEI or ARNI and β-blockers should be systematically increased to the highest tolerable doses. ARNI can and should be considered as first-line treatment instead of ACEI.

Sodium-glucose co-transporter 2 inhibitors (SGLT2i), such as dapagliflozin and empagliflozin, added to the treatment with ACEI/ARNI, β-blocker, and MRA, reduced the risk of death from cardiovas-

cular causes and exacerbation of HF in individuals with HFrEF. If these drugs are not contraindicated or intolerated, their use is recommended in all individuals with HFrEF already treated with ACEI/ARNI, β-blocker, and MRA, regardless of whether they have diabetes or not.

Diuretics, among which loop diuretics are preferred, are recommended to reduce subjective and/or objective symptoms of congestion in individuals with HFrEF.

ARBs are currently recommended for individuals who do not tolerate ACEI or ARNI. Ifunny channel inhibitor – ivabradine – slows the heart rate and should be considered for use in individuals with HFrEF with sinus rhythm and a heart rate ≥ 75 beats per minute, with LVEF ≤ 35%. Before considering ivabradine, all efforts should be made to start β-blocker treatment and increase its dose to the guideline-recommended or maximum tolerated dose.

V. Automatic cardioverter-defibrillator in the prevention of sudden death in individuals with HFrEF

An important component of the therapy for individuals with HFrEF is the use of automatic cardioverter-defibrillators (ICD) in primary prevention of sudden cardiac death due to malignant ventricular arrhythmias. In the population of individuals with ischemic etiology HF, **ICD is recommended** to reduce the risk of sudden death and overall mortality in individuals with symptomatic HF (NYHA class II–III) and LVEF ≤ 35% despite ≥ 3 months of optimal conservative (pharmacological) treatment, if a life expectancy longer than one year in good functional condition can be expected. Among individuals with post-myocardial infarction, qualification for ICD should be carried out at least 40 days after the infarction.

On the other hand, in the population of individuals with HF of other, non-ischemic etiologies, ICD has a lower recommendation class – **implantation should be considered** to reduce the risk of sudden death and overall mortality in individuals with symptomatic HF (NYHA class II–III) of etiology other than ischemic and LVEF ≤ 35% despite ≥ 3 months of optimal conservative treatment, if a life expectancy longer than one year in good functional condition can be expected..

VI. Resynchronization therapy in individuals with HFrEF (CRT/CRT-D)

Cardiac resynchronization therapy (CRT) in appropriately selected individuals reduces the need for hospitalization due to the progression of HF symptoms, improves heart function, quality of life, and most importantly reduces overall mortality. This type of cardiac stimulation is used in the population of individuals with HF who have a delay in activation and consequently a delay in the contraction of the left ventricle relative to the right ventricle, leading to a significant reduction in LV stroke volume. This is particularly important in individuals with significantly reduced LVEF, where the LV stroke volume is already compromised at baseline. A symptom/parameter indicating this delay in activation and consequently contraction of the left ventricle relative to the right ventricle is the widening of the QRS complexes duration on the ECG, particularly the pattern of left bundle branch block (LBBB) in the ECG.

Current guidelines indicate which individuals with HFrEF and LVEF ≤ 35% should consider CRT therapy. A precondition is the prior use of causal therapy and optimal pharmacotherapy for at least 3 months.

Also important is the assessment of indications and the use of CRT with or without defibrillator function – CRT-D or CRT-P. Indications for CRT apply to individuals with significantly reduced LVEF, thus also with an indication for ICD. The decision on the type of device, CRT-P or CRT-D, belongs to the cardiology center ultimately qualifying the individual with HFrEF for these therapy forms.

Current recommendations for CRT:

1. CRT is recommended in symptomatic individuals with HF, sinus rhythm, QRS complexes ≥ 150 ms duration, and LBBB morphology.,
2. CRT should be considered in symptomatic individuals with HF, sinus rhythm, QRS complexes ≥ 150 ms duration, and non-LBBB morphology,
3. CRT should be considered in symptomatic individuals with HF, sinus rhythm, QRS complexes duration of 130–149 ms, and LBBB morphology,
4. CRT can be considered in symptomatic individuals with HF, sinus rhythm, QRS complexes duration of 130–149 ms, and non-LBBB morphology.

Individuals with HFrEF after CRT require strict cardiological supervision conducted by specialized cardiology centers.

VII. Chronic heart failure in people with diabetes

Individuals with diabetes are particularly at risk for developing HF. Diabetes predisposes to the de-

velopment of HF through associated macroangiopathic complications, including coronary artery disease.

Optimal pharmacotherapy in treating HF in individuals with and without diabetes is similar. However, antihyperglycemic drugs differ in their action in individuals with HF, so those drugs that are both safe and reduce the frequency of HF-related incidents should be preferred.

VIII. Heart failure with preserved left ventricular ejection fraction

HFrEF differs from HFrEF in many respects. Individuals with HFrEF are often older, there is a higher percentage of women, and they frequently have numerous comorbidities, including atrial fibrillation, chronic kidney disease, and other non-cardiovascular diseases.

Criteria and principles for diagnosing this form of HF have been presented above. The basic criteria for diagnosing HFrEF are:

1. Subjective and objective symptoms of HF
2. LVEF ≥ 50%.
3. Objective features of structural and/or functional abnormalities in the heart corresponding to the presence of LV diastolic dysfunction/increased LV filling pressure, including elevated natriuretic peptides.

Until 2021, no treatment was shown to unequivocally reduce mortality and morbidity in this individuals' population. After the publication of the ESC guidelines on the diagnosis and treatment of individuals with heart failure in 2021, publications evaluating the impact of dapagliflozin and empagliflozin on the prognosis of individuals with HFrEF in terms of the need for hospitalization and mortality from cardiovascular causes emerged. These studies demonstrated a clear beneficial impact of these drugs on the prognosis of individuals with HFrEF, regardless of the coexistence of diabetes (DELIVER and EMPEROR – Preserved). These studies have been included in the 2023 update of the European Society of Cardiology guidelines, changing the therapy principles in the population of individuals with HFrEF.

Dapagliflozin and empagliflozin are recommended and should be used (if there are no contraindications to their use) in the therapy of individuals with HFrEF. Similarly high recommendation class applies to the therapy of comorbidities and conditions predisposing to the development of this form of HF. This includes modulation of the RAA system, sympathetic nervous system using ACEI or ARNI, β-blockers, and MRA.

Diuretics, among which loop diuretics are preferred, should be used in cases with fluid retention.

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18. Stroke in Individuals with Diabetes

CHAPTER HIGHLIGHTS
· Hyperglycaemia observed upon hospital admission in the acute phase of stroke is associated with higher mortality, more severe stroke course, and greater neurological deficit in both individuals with and without diabetes. [**A**]
· Interventional studies conducted to date do not provide evidence that maintaining normoglycaemia in the acute phase of stroke achieved through intravenous insulin therapy improves individual's prognosis. Such therapy, however, is associated with a higher risk of hypoglycaemia. [**A**]
· Current guidelines regarding the correction of hyperglycaemia during stroke are based only on the recommendations/opinions of experts. [**E**]

Diabetes is a strong risk factor for both ischemic and haemorrhagic stroke. Elevated glucose levels are found in over 60% of individuals hospitalized for acute stroke. About 20% of hyperglycaemia cases concern individuals with previously diagnosed diabetes, 16–24% are individuals with previously undiagnosed diabetes, and in the remainder is transient (stress-induced) hyperglycaemia.

Hyperglycaemia observed in the acute phase of stroke is a negative prognostic factor in both

individuals with and without diabetes. Its presence is associated with an increased risk of a larger ischaemic lesion and haemorrhagic transformation, a more severe course of the disease, and worse outcomes, including reduced patient independence and higher early and late mortality. Hyperglycaemia detected upon hospital admission typically shows a gradual, spontaneous decline over the first several hours or days of the illness.

Few interventional studies with randomization conducted in the acute phase of stroke (up to 72 hours) do not provide evidence that maintaining normoglycaemia achieved through intravenous insulin therapy reduces mortality or improves neurological deficit. The recommended target glucose values for individuals diagnosed with acute stroke are similar to those recommended for other severe, acute conditions. Insulin therapy should be initiated at glycaemia values ≥ 180 mg/dl (10 mmol/l), and then glycaemia should be maintained in the range of 140–180 mg/dl (7.8–10 mmol/l), avoiding the risk of hypoglycaemia.

Insulin should be administered intravenously in a 0.9% NaCl solution using an infusion pump, under strict glycemic control. The rate of insulin infusion should be modified depending on the glycaemia values measured at the patient's bedside every 1 hour, and after achieving normoglycaemia, every 2 hours. An approximate scheme for modifying the rate of intravenous insulin infusion depending on the observed glycaemia is presented in Table 26.1. During the insulin infusion, potassium levels should be checked 2–3 times a day.

The administration of insulin in the form of an intravenous GIK (glucose, insulin, potassium) infusion is not recommended. In the first days after stroke and in individuals who remain unconscious for longer, insulin should not be administered subcutaneously.

A specific algorithm for dosing insulin administered in an intravenous infusion, considering changes in the infusion rate depending on glycaemia values, should be followed in the unit treating strokes. The therapeutic team of doctors and nurses should be trained in hyperglycaemia therapy.

When the patient's condition improves and they start consuming meals, the intravenous insulin infusion should be discontinued, and subcutaneous insulin administration should be started. The disconnection of the intravenous insulin infusion should be preceded by a subcutaneous administration of short-acting or rapid-acting insulin about an hour before stopping the intravenous infusion. The recommended subcutaneous insulin therapy regimen consists of short-acting insulin or its rapid-acting analogue administered before meals, along with long-acting insulin or a long-acting insulin analogue. In some cases, administering only short-acting or rapid-acting insulin before a meal may be sufficient. Insulin should be administered before meals based on glycaemia measurements made directly before them.

Due to the high probability of undiagnosed diabetes in individuals with fresh ischemic brain stroke, it is necessary to perform diagnostics in this direction after stabilizing the patient's condition.

Recommendations regarding blood pressure and other aspects of managing patients with ischemic brain stroke are the same as for individuals without diabetes, as there is no data indicating benefits from different or special management in individuals with diabetes.

Secondary prevention after stroke is consistent with generally accepted principles.

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19. Diabetic Kidney Disease: Prevention, Diagnosis, and Treatment.

CHAPTER HIGHLIGHTS
• Screening for increased urinary albumin excretion should be performed annually in individuals with type 1 diabetes starting from the 5th year of the disease, in those with type 2 diabetes from the time of diagnosis, and in all patients with diabetes with concomitant hypertension. [**B**]
• To reduce the risk of diabetic kidney disease and/or slow its progression, glycemic, blood pressure, and lipid control should be optimized. [**A**]
• In cases where increased urinary albumin excretion is detected, therapy with ACE inhibitors or angiotensin AT1 receptor antagonists should be used, as they reduce the risk of diabetic kidney disease progression (considering contraindications to their use). [**A**]
• SGLT2 inhibitors, GLP-1 analogues, and the nonsteroidal mineralocorticoid receptor antagonist (ns-MRA) reduce the risk of chronic kidney disease progression and cardiovascular complications in individuals with type 2 diabetes and chronic kidney disease. [**A**]
• When using ACE inhibitors, angiotensin AT1 receptor antagonists, mineralocorticoid receptor antagonists, and/or diuretics, monitoring of serum creatinine, sodium, and potassium levels is necessary. [**E**]

In individuals with diabetes, to detect or assess the severity of diabetic kidney disease, it is necessary to determine urinary albumin excretion, serum creatinine concentration, and estimated glomerular filtration rate (eGFR).

Albuminuria and eGFR are independent predictors of cardiovascular and renal risk in people with diabetes. A reduction in eGFR without preceding or accompanying albuminuria occurs in about half of the cases of diabetes regardless of type.

I. Screening for albuminuria

Screening should be performed annually in the case of:

- individuals with type 1 diabetes from the 5th year of the diagnosis,
- individuals with type 2 diabetes from the time of diagnosis.

To assess urinary albumin excretion, the albumin/creatinine ratio (ACR) should be determined based on quantitative measurements in a single urine sample, ideally collected in the morning (for interpretation of results see: Table 19.1). The diagnosis of increased urinary albumin excretion is justified by obtaining two positive ACR results.

II. Creatinine levels

In individuals with diabetes, blood creatinine levels should be measured at least once a year, regardless of the amount of albumin excreted in the urine. Blood creatinine levels should be used to calculate the estimated glomerular filtration rate (eGFR).

III. Glomerular filtration rate (GFR)

To determine the estimated glomerular filtration rate (eGFR), the CKD-EPI formula should be used.

$$eGFR = 141 \times \min(Scr/k, 1)^{a} \times \max(Scr/k, 1)^{-1.209} \times \times 0.993^{Age} \times 1.018 \text{ [for women]},$$

where: Scr – serum creatinine levels, k – 0.7 for women and 0.9 for men, a = –0.329 for women and

Table 19.1. Definition of abnormal urinary albumin excretion*

Category	AER [mg/day]	ACR (random urine sample) [mg/day or mg/g of creatinine] *,**
A1: normal albuminuria or slightly increased albuminuria	< 30	< 30
A2: moderately increased albuminuria	30–299	30–299
A3: overt proteinuria	≥ 300	≥ 300

**The amount of albumin excreted in urine in relation to 1 g of creatinine approximately corresponds to daily albuminuria, while also avoiding errors associated with 24-hour urine collection.*

***If the ACR is received from the laboratory in mg/mmol of creatinine, the result should be multiplied by 8.85 to obtain the value in mg/g of creatinine.*

ACR – albumin/creatinine ratio, AER – albumin excretion rate

Table 19.2. Stages of chronic kidney disease

Category	Description	eGFR [ml/min/1.73 m²]
G1	Kidney damage* with normal or elevated eGFR	≥ 90
G2	Kidney damage* with mildly decreased eGFR	60–89
G3a	Moderate decrease in eGFR	45–59
G3b	Moderate to severe decrease in eGFR	30–44
G4	Significant decrease in eGFR	15–29
G5	End-stage renal failure	< 15

**Renal damage is said to occur if there are abnormalities in the biochemical composition and/or urine sediment, and/or abnormal values in blood indicators of kidney damage, and/or in imaging studies of the kidneys or urinary tract that continues for more than 3 months.*

–0.411 for men, min – the minimum of Scr/k or 1, max – the maximum of Scr/k or 1.

If it is not possible to use the CKD-EPI formula, trends in eGFR should be monitored using other methods of assessment (e.g., using the MDRD formula).

IV. Chronic kidney disease

The stages of chronic kidney disease progression are defined in Table 19.2.

V. Nephrological consultation

A nephrological consultation should be considered if:

- eGFR decreases to < 60 ml/min/1.73 m² and non-diabetic kidney disease is suspected,
- eGFR decreases to < 30 ml/min/1.73 m².

VI. Preventive recommendations

1. To reduce the risk of diabetic kidney disease and/or slow its progression, glycaemia control, blood pressure, and lipidemia should be optimized.
2. Patients should be encouraged to quit smoking, as it is an independent risk factor for the development and progression of diabetic kidney disease.

VII. Treatment

1. To slow the progression of diabetic kidney disease, it is necessary to aim for the therapeutic targets for glycaemia, lipidaemia, and arterial pressure presented in Chapter 4.
2. In the case of detected albuminuria, therapy with ACE inhibitors or angiotensin AT1 receptor antagonists should be administered, as they reduce the risk of chronic kidney disease progression (considering contraindications to their use). These drugs should be used at the maximum tolerated doses.
3. When using an ACE inhibitor, angiotensin II receptor antagonist (AT1 antagonist), mineralo-

Table 19.3. Risk of progression of chronic kidney disease, frequency of visits and need for nephrology consultation according to eGFR and albuminuria [2]

	A1: normal albuminuria or slightly increased albuminuria < 30 mg/g < 3 mg/mmol	A2: moderately increased albuminuria 30–299 mg/g 3–29 mg/mmol	A3: overt proteinuria ≥ 300 mg/g ≥ 30 mg/mmol
G1: ≥ 90 ml/min/1.73 m²	Control 1	Treatment 1	Treatment and referral to nephrologist 3
G2: 60–89 ml/min/1.73 m²	Control 1	Treatment 1	Treatment and referral to nephrologist 3
G3a: 45–59 ml/min/1.73 m²	Treatment 1	Treatment 2	Treatment and referral to nephrologist 3
G3b: 30–44 ml/min/1.73 m²	Treatment 2	Treatment and referral to nephrologist 3	Treatment and referral to nephrologist 3
G4: 15–29 ml/min/1.73 m²	Treatment and referral to nephrologist 3	Treatment and referral to nephrologist 3	Treatment and referral to nephrologist 4+
G5: < 15 ml/min/1.73 m²	Treatment and referral to nephrologist 4+	Treatment and referral to nephrologist 4+	Treatment and referral to nephrologist 4+

Low risk (if there are no other markers of kidney disease, without CKD), moderate risk, high risk, extremely high risk.

The numbers in the boxes describe guidelines for screening or monitoring frequency per year. Suggested frequency of monitoring ranges from once a year ( ) to 4 times or more per year (i.e., every 1-3 months, ( )) depending on the risk of progression of CKD and complications of CKD.

corticoid receptor antagonist, and/or diuretics, serum creatinine, sodium, and potassium levels should be monitored. An increase in serum creatinine levels/a decrease in eGFR of ≤ 30% within 4 weeks after initiating or increasing the dose of these medications is not an indication for discontinuation but rather for closer monitoring of renal function and serum potassium levels, as well as identifying other causes of decreased eGFR/hyperkalaemia (e.g., dehydration, diet, other factors). To continue therapy with an ACE inhibitor, angiotensin II receptor antagonist (AT1 antagonist), or mineralocorticoid receptor antagonist, or to maintain appropriate dosing in patients with elevated potassium levels, the use of potassium-binding agents that inhibit gastrointestinal potassium absorption (patiromer, sodium zirconium cyclosilicate) may be considered.

Table 19.4. Dosage recommendations for oral antihyperglycemic drugs, GLP-1 receptor agonists and dual GIP/GLP-1 receptor agonist according to the severity of kidney disease in type 2 diabetes [2]

	Chronic kidney disease (CKD) categories (stages) according to KDIGO (eGFR)				
	Stage G1 and G2 (eGFR > 60 ml/min/1.73 m²)	Stage G3a (eGFR 45–59 ml/min/1.73 m²)	Stage G3b (eGFR 30–44 ml/min/1.73 m²)	Stage G4 (eGFR 15–30 ml/min/1.73 m²)	Stage G5 (eGFR < 15 ml/min/1.73 m²) for the initiation of renal replacement therapy
Metformin		Reduce the dose to a maximum of 2000 mg/day	More frequent eGFR monitoring Dose reduction to a maximum of 1000 mg/day		
Sulfonylurea derivatives		Increase risk of hypoglycaemia if eGFR < 60, consider reducing dose; glycoside is preferred drug because it is metabolized by the liver			
Pioglitazone					
Linagliptin					
Saxagliptin	No dose modification required				
Sitagliptin			Dose reduction to 50 mg/day	Dose reduction up to 25 mg/day	
Wildagliptin		Reduce dose to 50 mg/day if eGFR < 50			
Canaglifosin	Initial dose of 100 mg, gradually increasing the dose to 300 mg, if required	Initiation or continuation 100 mg/day		Continuation of 100 mg/day, treatment should not be initiated, discontinue drug in dialysis patients; may continue if well tolerated (cardiovascular and renal protection)	
Dapagliflozin	Possibility of initiating treatment down to eGFR = 25				Can be continued if well tolerated (cardiovascular and renal protection))
Empagliflozin	Possibility of initiating treatment down to eGFR = 20				Can be continued if well tolerated (cardiovascular and renal protection))
Dulaglutide	Possibility of initiating treatment down to eGFR = 15				
Exenatide (administered 2 × daily)		Gradual dose escalation at eGFR 30–50			
Exenatide (administered 1× week)	Possibility of initiating treatment down to eGFR = 30				
Liraglutide	No dose modification required				
Lixisenatide	Possibility of initiating treatment down to eGFR = 15				
Semaglutide	No dose modification required				
Thirzepatide	No dose modification required				

■ *No dose adjustment necessary depending on eGFR,* ■ *recommended dose adjustment of drug depending on eGFR,* ■ *not recommended to use drug at given eGFR.*

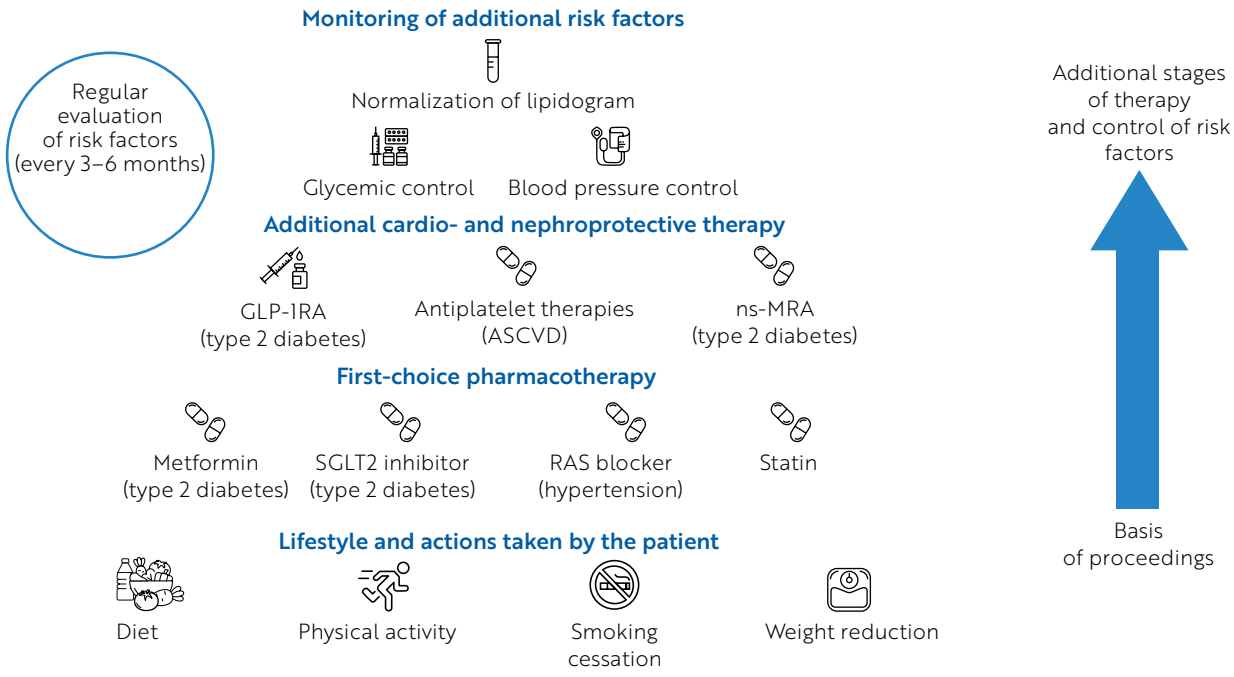

Figure 19.1. Holistic approach to cardio-renal risk [2]

4. The combined use of ACE inhibitors with angiotensin AT1 receptor antagonists is contraindicated
5. Metformin should not be used in patients with an eGFR < 30 ml/min/1.73 m^2. The dose of metformin should be reduced to 1000 mg/day in patients with an eGFR of 30–44 ml/min/1.73 m^2 and in patients with an eGFR of 45–59 ml/min/1.73 m^2 who are at high risk of lactic acidosis.
6. In individuals with type 2 diabetes and chronic kidney disease with an eGFR ≥ 20 ml/min/1.73 m^2 of creatinine, the use of a sodium-glucose cotransporter-2 inhibitor (SGLT2i) with proven effects in reducing the risk of progression of diabetic kidney disease and the risk of cardiovascular complications is recommended, regardless of HbA_{1c} values, to reduce the progression of chronic kidney disease and cardiovascular events. Creatinine level monitoring is not required after initiating SGLT2i therapy.
7. The use of a glucagon-like peptide-1 (GLP-1) receptor agonist with proven cardiovascular benefits is recommended for individuals with type 2 diabetes and chronic kidney disease with eGFR ≥ 25 ml/min/1.73 m² and ACR ≥ 100 mg/g. Semaglutide is the first GLP-1 receptor agonist (FLOW study) for which a slowing of GFR decline and a reduction in the risk of kidney-related mortality have been demonstrated, as well as benefits independent of the underlying cause across a broad range of eGFR values (25-75 ml/min/1.73 m²).
8. The use of a non-steroidal mineralocorticoid receptor antagonist (ns-MRA) with proven cardiovascular and nephroprotective benefits should be considered for patients with type 2 diabetes, an eGFR ≥ 25 ml/min/1.73 m², normal serum potassium levels, and albuminuria (≥ 30 mg/g), despite the use of the maximum tolerated dose of a renin-angiotensin system (RAS) inhibitor.
9. SGLT2i, GLP-1 analogues, and ns-MRA reduce the risk of progression of chronic kidney disease and cardiovascular complications in individuals with type 2 diabetes and chronic kidney disease.

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20. Diabetic Retinopathy

CHAPTER HIGHLIGHTS
• Optimization of glycemic, blood pressure, and lipidaemia control reduces the risk of development and progression of diabetic retinopathy. [**A**]
• Fundus examination after pupil dilation should be performed no later than 5 years after the onset in adults with type 1 diabetes and immediately upon diagnosis of type 2 diabetes. [**B**]
• Laser photocoagulation reduces the risk of vision loss in patients with proliferative retinopathy. [**A**]
• Intravitreal anti-VEGF injections in patients with macular oedema may improve vision. [**A**]
• Aspirin therapy for cardio protection is not contraindicated in patients with retinopathy and does not increase the risk of vitreous haemorrhage. [**A**]

Diabetes-related complications affect nearly all anatomical structures in the visual system. The most common and severe complication, posing a risk of vision loss, is diabetic retinopathy and the associated diabetic macular oedema. Retinopathy is a highly specific neurovascular complication of both type 1 and type 2 diabetes. Among extra-retinal complications of diabetes, cataracts and secondary glaucoma have the greatest clinical significance. The following recommendations take into account the new classification of diabetic retinopathy.

I. Natural History and Classification of Diabetic Retinopathy

1. No signs of diabetic retinopathy.
2. Mild non-proliferative diabetic retinopathy (NPDR) – only microaneurysms present.
3. Moderate non-proliferative diabetic retinopathy – more changes than in the mild form and fewer than in the severe form.
4. Severe non-proliferative retinopathy:

- haemorrhages (> 20) in 4 quadrants of the retina and/or

- venous beading in at least 2 quadrants and/or
- intraretinal microvascular abnormalities in at least 1 quadrant.

5. Proliferative diabetic retinopathy (PDR) (neovascularization and connective tissue growth in the retina) leading to vision loss through mechanisms:
- recurrent vitreous haemorrhages from newly formed vessels,
- retinal detachment due to traction by proliferative membranes,
- development of glaucoma.

II. Natural history and classification of diabetic macular oedema

1. No diabetic macular oedema.
2. Mild diabetic macular oedema – changes away from the centre of the macula.
3. Moderate diabetic macular oedema – changes near the centre of the macula.
4. Severe diabetic macular oedema – changes involving the centre of the macula.

III. Risk factors for development and progression of diabetic retinopathy

1. Duration of diabetes – the strongest prognostic factor for the development and progression of diabetic retinopathy.
2. Metabolic imbalance of diabetes:
- intensive treatment reduces the risk of development and progression of retinopathy in type 1 diabetes patients,
- intensive treatment of type 2 diabetes reduces the frequency of microangiopathy complications, and a 1% reduction in HbA_{1c} significantly reduces the risk of developing microangiopathy.

3. Arterial hypertension.
4. Lipid metabolism disorders.
5. Diabetic kidney disease.
6. Pregnancy in women with diabetes.
7. Adolescence.
8. Cataract surgery.
9. Post kidney and pancreas transplantation or kidney only.

IV. Diagnosis of Diabetic Retinopathy

1. Visual acuity examination.
2. Colour vision testing.
3. Fundus examination (ophthalmoscopy, always after pupil dilation).
4. Digital, colour photographs of the fundus mainly used in screening studies (do not replace a full ophthalmologic examination).
5. Fundus fluorescein angiography – indications:
- detection of changes in the course of moderate and severe non-proliferative retinopathy,
- detection of initial foci of neovascularization in proliferative retinopathy,
- assessment of the effectiveness of laser photocoagulation,
- clarification of the cause of unjustified deterioration of visual acuity.

6. Wide-field fluorescein angiography of the peripheral fundus.
7. Optical coherence tomography (OCT) – the basic method for the diagnosis and monitoring of macular oedema.
8. Ultrasound, especially in patients with vitreous haemorrhage.
9. Confocal microscopy (assessment of corneal nerve fibre density as an early indicator of neuropathy).

V. Indications for ophthalmic examinations in patients with diabetes

1. First examination:
- in type 1 diabetes, it should be conducted within the first 5 years from the onset of the disease,
- in type 2 diabetes, it must be done at the time of disease diagnosis or shortly thereafter.

2. Follow-up examinations and possible treatment:
- indicated due to the initially asymptomatic nature of retinopathy,
- the frequency of examinations depends on the severity of diabetic retinopathy:
  - » without retinopathy – every 1–2 years,
  - » mild and moderate non-proliferative retinopathy – every 6–12 months,
  - » severe non-proliferative retinopathy – laser treatment; follow-up examination at least every 3–6 months,
  - » proliferative retinopathy – urgent laser treatment or other ophthalmic surgery (e.g., vitrectomy),
  - » diabetic macular edema – if outside the macular centre, laser treatment; if involving the macular centre, intravitreal anti-VEGF injections are indicated, which may be supplemented by laser treatment,
  - » after retinal laser procedures – one month after the procedure,
  - » after vitrectomy surgery, the timing of examination is determined individually, depending on the condition of the fundus,

- » n pregnant women with diabetes: every 1–3 months throughout the pregnancy depending on the eye condition, in women planning pregnancy – before conception and then, if necessary, retinal laser procedures are performed.

3. Urgent indications for ophthalmic examination:
- risk of vision loss:
  - » presence of proliferative retinopathy,
  - » presence of advanced ocular complications (neovascularization in the iris, haemorrhage into the vitreous body, fresh retinal detachment),
- presence of changes potentially threatening vision loss:
  - » severe non-proliferative retinopathy,
  - » non-proliferative retinopathy with diabetic macular oedema,
  - » other abnormalities present in the fundus, difficult to interpret or unexplained deterioration in visual acuity,
  - » pregnancy.

The recommended frequency of ophthalmic examinations in different patient groups is presented in Table 20.1.

VI. Screening tests

Screening for diabetic retinopathy is conducted by an ophthalmologist or a trained professional using an ophthalmoscope or a fundus camera with pupil dilation based on a colour fundus photograph. Screening can also be performed via telemedicine using a fundus camera, with images assessed by qualified personnel or analysed through appropriate image processing software. Colour fundus photography has significant potential for providing monitoring services in areas where access to specialized professionals is limited. Retinal photography can thus serve as a screening tool for diagnosing retinopathy; however, it does not replace a comprehensive eye examination, which should be performed no later than five years after diagnosis in adults with type 1 diabetes and at the time of diagnosis for type 2 diabetes. Subsequent examinations should be conducted at intervals recommended by the ophthalmologist.

In individuals with type 1 diabetes, if no retinal changes are detected in two consecutive annual screenings, fundus examinations may be performed every two years. In individuals with type 2 diabetes with good metabolic control and no retinal abnormalities, examinations can be conducted every 2–3 years.

In women with type 1 and type 2 diabetes, ophthalmic examinations should be conducted before pregnancy or in the first trimester of pregnancy, then repeated each trimester and for a year postpartum, assessing the degree of retinopathy.

Regular fundus monitoring and treatment can prevent vision loss due to diabetic retinopathy by up to 98%.

Developed screening strategies significantly reduce the risk of blindness and lower the costs

Table 20.1. Recommended frequency of eye examinations by patient group

First-time examination	
Type 1 diabetes	5 years after disease onset (when diagnosed during puberty – shortly after diagnosis)
Type 2 diabetes	At the time of diagnosis
Follow-up examinations and possible treatment	
Severity of retinopathy	**Frequency of examinations and treatment**
No retinopathy	Every 1–2 years
Mild and moderate no proliferative retinopathy	Every 6–12 months
Severe no proliferative retinopathy	Not less frequently than every 3–6 months
Proliferative retinopathy	Urgent laser therapy
Extrafoveal diabetic macular oedema	Laser therapy
Diabetic macular oedema with foveal involvement	Intravitreal injections (anti-VEGF + optional laser therapy)
Follow-up after ophthalmic procedures in special situations	
After laser treatment	Depending on the condition of the eye
Post vitrectomy	Depending on the condition of the eye
Pregnant women	Depending on the condition of the eye every 1–3 months
In women planning a pregnancy	Prior to pregnancy – then laser treatments

of treating patients with diabetic complications of the visual system.

VII. Treatment of diabetic retinopathy

1. Optimization of glycemic control, blood pressure, and lipid metabolism parameters (fenofibrate, statins). Before intensifying antihyperglycemic therapy, it is essential to assess the presence and severity of retinopathy, as a sudden improvement in metabolic control may lead to retinopathy progression. Although current data suggest the pleiotropic effects of new antihyperglycemic agents, there are still few clinical studies to determine their impact on the prevention and progression of diabetic retinopathy. Aspirin, administered for cardioprotective purposes, is not contraindicated in individuals with retinopathy and does not increase the risk of retinal haemorrhages.
2. The treatment of diabetic macular oedema includes intravitreal administration of anti-VEGF agents (aflibercept 2 mg, aflibercept 8 mg, bevacizumab, faricimab, brolucizumab, and ranibizumab) as well as dexamethasone in the form of an implant. Anti-VEGF injections are administered within drug programs, for which qualification is based on both ophthalmological and diabetological criteria. An important qualifying parameter for the program is the HbA_{1c} value.

For treatment-naïve patients or those previously treated unsuccessfully, therapy is initiated with five doses of bevacizumab.

3. Retinal laser therapy (possible if the eye's optical centres are clear):

- appropriately early conducted retinal laser therapy inhibits the progression of advanced diabetic retinopathy,
- types of retinal laser therapy:
  - » subthreshold (mainly micro pulse) – without tissue coagulation, used in macular oedema without significant thickening and without worsening of visual acuity,
  - » focal – recommended for initial changes in diabetic macular oedema without involvement of the fovea,
  - » grid type – in diffuse macular oedema when first-choice treatment was ineffective,
  - » pan retinal photocoagulation – recommended in severe non-proliferative and proliferative retinopathy.

4. Intravitreal or periocular injections of steroids with antiangiogenic and anti-oedema effects, such as triamcinolone, dexamethasone, or fluocinolone acetonide in a sustained-release form, may be considered first-line treatments when contraindications to anti-VEGF antibodies are identified or when the frequency of monthly visits cannot be maintained.
5. Vitrectomy – indications:

- non-resorbing vitreous haemorrhages despite other treatment methods,
- vitreoretinal traction running vertically towards the macula,
- advanced proliferative retinopathy with complications.

6. In cases of irreversible vision disorders, it is necessary to conduct consultations/rehabilitation for people with poor vision or those who have gone blind.
7. In mild and moderate forms of retinopathy with the presence of hard exudates, sulodexide can be used in a dose of 250 LSU twice a day.

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21. Diabetic Neuropathy: Prevention, Diagnosis, and Treatment

CHAPTER HIGHLIGHTS

- For individuals with type 1 diabetes, maintaining optimal glycemic control from the time of diagnosis is crucial for both primary and secondary prevention of peripheral and autonomic diabetic polyneuropathy of the cardiovascular system. [**A**]
- The diagnosis of diabetic neuropathy, in addition to a detailed medical history, should include an assessment of both small fibre function (pain and/or temperature sensation) and large fibre function (vibration sensation). Each patient should undergo an annual 10 g monofilament test to assess the risk of developing a diabetic foot ulcer. These examinations should be carried out for the first time after 5 years in patients with type 1 diabetes and at the time of diagnosis in patients with type 2 diabetes. [**B**]
- Pregabalin, gabapentin, or duloxetine should be considered as first-line medications for the treatment of neuropathic pain in individuals with diabetes. [**A**]

Distal symmetrical polyneuropathy causes severe symptoms, significantly reduces quality of life, and is a well-established risk factor for the development of diabetic foot disease, including ulcerations and Charcot neuroarthropathy. Neuropathy increases the risk of amputations, fractures, and falls, as well as the costs of treatment and is a predictor of increased mortality risk. Cardiovascular autonomic neuropathy is an independent risk factor for increased mortality in diabetes. Neuropathy can develop as early as the prediabetic state; therefore, diagnostic evaluation should also be considered in individuals with prediabetes who exhibit symptoms of peripheral neuropathy.

I. Clinical classification of neuropathies:

- generalized symmetrical polyneuropathies:
  - » chronic sensorimotor peripheral neuropathy,
  - » autonomic neuropathy,
  - » acute sensory neuropathy,

- focal and multifocal neuropathies:
  - » cranial nerve neuropathies,
  - » spinal nerve neuropathies (thoracic and lumbar),
  - » focal limb neuropathies, including compression syndromes,
  - » proximal motor neuropathy (amyotrophy)

II. Conducting examinations for neuropathy:

- frequency of examinations:
  - » the assessment of symptoms in diabetic neuropathy should be performed at least once a year, for the first time,
  - » in type 1 diabetes – 5 years after the onset of the disease, unless symptoms suggestive of neuropathy occur earlier,
  - » in type 2 diabetes – at the time of disease diagnosis,
- another non-diabetic etiology of peripheral nervous system damage should be considered and possibly ruled out,
- it is advisable to consider periodic measurement of vitamin B_{12} levels in metformin-treated patients at the onset or worsening of neuropathy symptoms,
- in doubtful cases, neurological consultation is indicated.

III. Diagnostic criteria for diabetic neuropathy

Distal symmetrical polyneuropathy

A. Diagnostic methods:

- tactile sensation test with a monofilament of 10 g compression (Semmes-Weinstein 5.07),
- vibration sensory threshold test – using a neurotensiometer or calibrated 128 Hz reed,
- pain sensation test (sterile needle),
- temperature sensation test (test indicator with two ends – metal and plastic),
- examination of tendon reflexes,
- muscle strength testing,
- electroneurography

B. Diagnostic principles:

- subjective symptoms: sensory disturbances, numbness, burning, tingling, pins and needles, spontaneous pain, muscle cramps, mainly in the area of the feet and lower legs, persisting for several months (intensify or mainly occur at night; physical effort does not provoke or intensify the discomfort,
- objective symptoms: weakening or loss of touch, vibration, pain, and temperature sensation, muscle strength weakening, weakening or loss of tendon reflexes (knee, ankle),
- peripheral diabetic neuropathy is considered probable based on the presence of 2 out of 3 following clinical examination elements: subjective symptoms, weakened or absent sensation (touch, vibration, pain and/or temperature) and/or weakened or absent tendon reflexes,
- standardized questionnaires can be used to assess subjective and objective symptoms of neuropathy. For evaluating subjective symptoms, the NSS (Neuropathy Symptom Score) scale can be applied, along with the simple 4-point DNS (Diabetic Neuropathy Symptom) scale, which correlates well with NSS. For assessing both subjective and objective symptoms, the Michigan Neuropathy Screening Instrument (MNSI) can be used due to its documented accuracy and established cutoff points for the Polish population,
- in selected patients, to confirm the diagnosis of neuropathy and for potential differential diagnosis of its etiology, nerve conduction studies (electroneurography) may be necessary. This is particularly indicated in cases of rapid symptom progression, asymmetry, predominant motor neuropathy, or suspected non-diabetic causes,
- in the diagnosis of small fibre neuropathy, when there are doubts in the clinical picture, an assessment of the nerve fibre density in the cornea using confocal microscopy or in a skin biopsy can be additionally used,
- painful polyneuropathy is diagnosed when clinical symptoms indicative of neuropathy and pain are localized in the same area. The DN4 (Douleur Neuropathique en 4 Questions) questionnaire can be used as a screening tool for diagnosing neuropathic pain, with a score of ≥ 4 on a 0–10 scale suggesting neuropathic pain. Pain intensity can be assessed using the visual analogue scale (VAS) on a 0–10 scale. In the painful form, characteristic elements of the physical examination may be normal. In cases of typical symptoms, neuropathy can be diagnosed even in the absence of abnormalities in the physical examination.

Autonomic neuropathy

The function of the autonomic nervous system is indirectly inferred based on the analysis of changes in the function of effector organs under the influence of certain stimuli. Due to the non-specificity

of the occurring clinical symptoms, the diagnosis should be supported by specific tests. Other diseases of the effector organ should be excluded, considering both organic and functional disorders of a different nature, and excluding the influence of the treatment being used.

Clinically, autonomic neuropathy most commonly presents as unawareness of hypoglycaemia, resting tachycardia, orthostatic hypotension, gastroparesis, constipation or diarrhoea, erectile dysfunction, neurogenic bladder, or sweating disorders.

1. Cardiovascular system

Autonomic neuropathy of the cardiovascular system is diagnosed based on tests assessing heart rate variability.

Autonomic neuropathy is considered probable or early if one of the heart rate variability tests is abnormal, and confirmed when the results of two of the following heart rate variability tests are abnormal. A severe (advanced) form of cardiovascular neuropathy is diagnosed when abnormal heart rate variability tests are found, as well as an abnormal blood pressure response to standing:

- tests assessing the parasympathetic system:
  - » change in heart rate while deep breathing,
  - » change in heart rate in response to standing,
  - » change in heart rate in response to the Valsalva manoeuvre,
- tests assessing the sympathetic system: change in blood pressure values in response to standing.

2. Digestive system:

- gastric function disorders – X-ray, radioisotope scintigraphy, breath tests, electrogastrography (EGG), manometry, ultrasonography,
- small intestine function disorders – lack of specific diagnostic tests, exclusion of other causes, manometry, wireless diagnostic capsule – small intestine motility disorders,
- large intestine function disorders – exclusion of other causes (endoscopy), passage after oral administration of contrast agent, manometry, wireless diagnostic capsule,
- gallbladder function disorders – functional ultrasound (USG).

3. Urinary and reproductive systems:

- bladder function disorders – cystometry (assessment of bladder filling before and after urination), sphincter electromyography, uroflowmetry, and urethral pressure profiling,

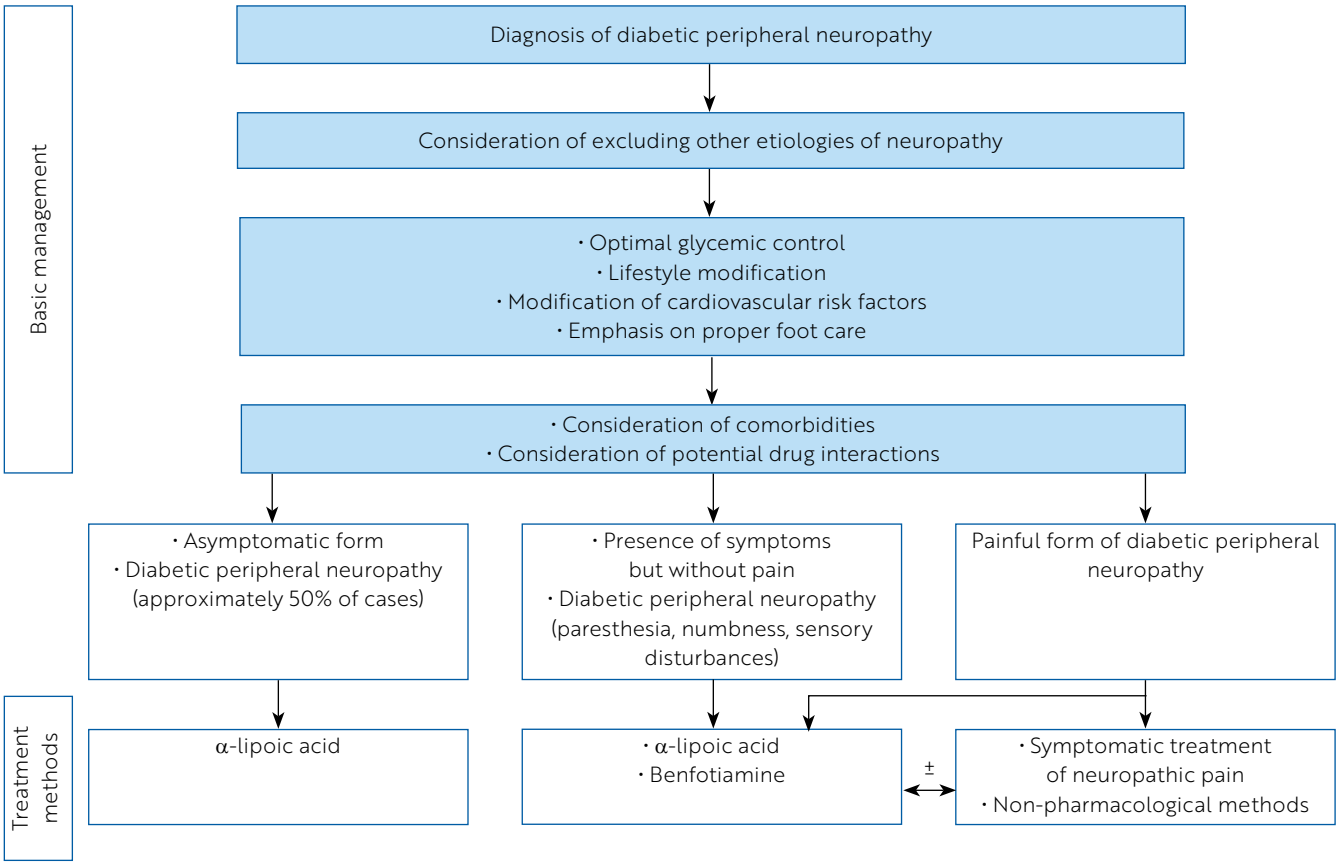

Figure 21.1. Treatment algorithm for peripheral diabetic neuropathy [11]

- erectile dysfunction – questionnaires (the International Index of Erectile Function – IIEF, and its abbreviated 5-question version – IIEF-5), vascular studies (Doppler ultrasound), cavern sonography, hormonal studies, psychological tests, regional assessment of vibration perception threshold, functional studies - monitoring of nocturnal erections.

4. Sweat disorders – simple sweat indicators (e.g., Neuropad), tests requiring complex apparatus (assessment of sudoriferous function using Sudoscan device).
5. Pupil function disorders – pupillometry.

IV. Treatment

Approximately 50% of diabetic neuropathy is asymptomatic. Causal treatment is glycemic control. Optimization of glycemic control should be implemented as soon as possible in individuals with type 1 and type 2 diabetes to prevent and/or delay the development of neuropathy. For patients with neuropathic pain, treatment is absolutely necessary, as it worsens the quality of life and functioning of patients and can lead to depression. There are various therapeutic options for symptomatic pain treatment. Treatment of autonomic neuropathy alleviates symptoms, improves the quality of life, and prognosis of patients, but is often demanding, and effectiveness varies individually. The treatment scheme for diabetic peripheral neuropathy is presented in Figure 21.1.

1. Treatment targeting the pathomechanisms of diabetic neuropathy:
   - optimal glycemic control is crucial in the treatment of diabetic neuropathy, with attention to avoiding hypoglycaemia and large daily glycaemic changes,
   - control of blood pressure, lipid metabolism, cessation of smoking, and alcohol consumption,
   - supportive pharmacotherapy: α-lipoic acid, benfotiamine, ACE.
2. The pharmacological symptomatic treatment of neuropathic pain in diabetic peripheral neuropathy (with the analgesic effect being patient-specific) is presented in Figure 21.1 and Table 21.1.

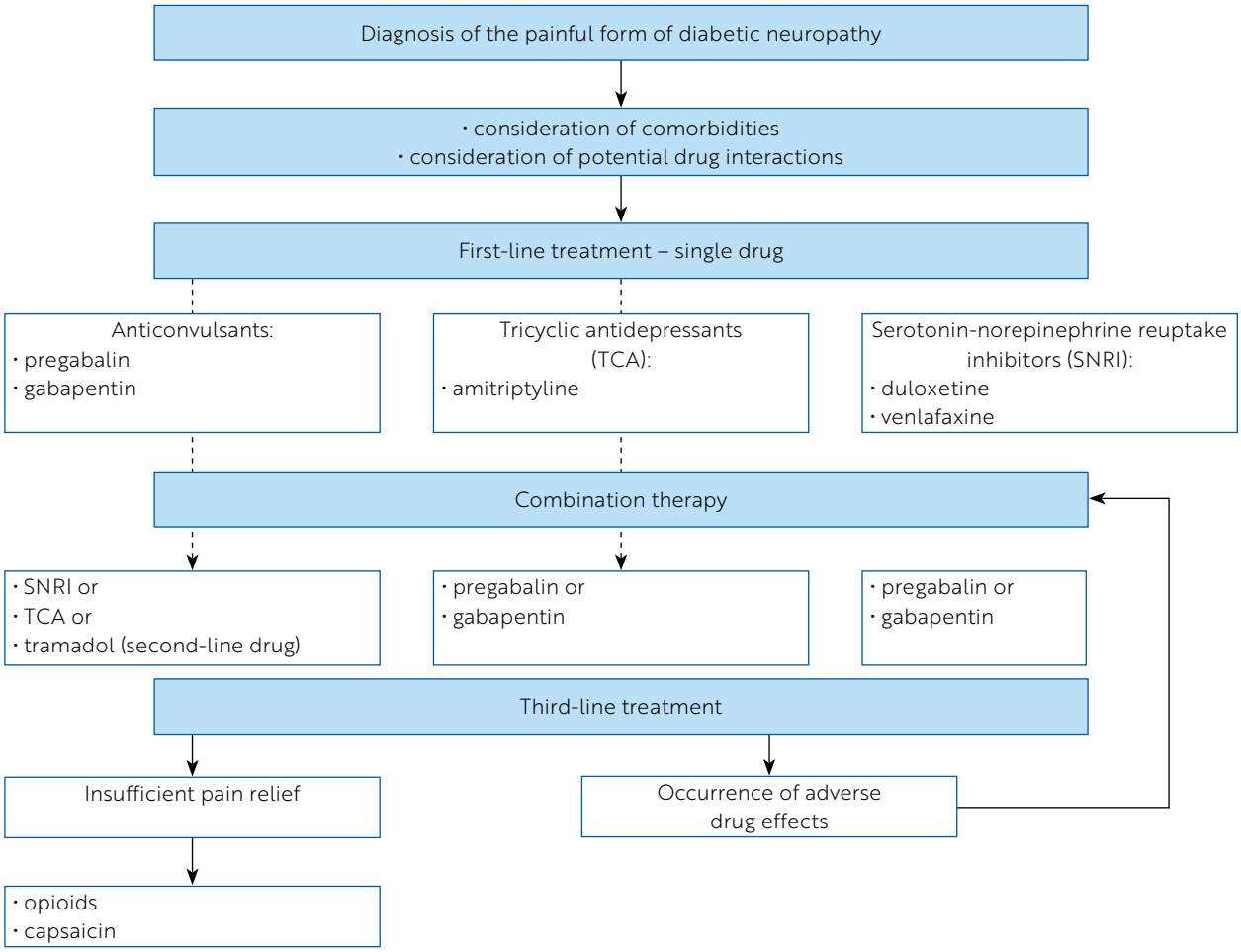

Figure 21.2. Treatment algorithm for symptomatic management of neuropathic pain in peripheral diabetic neuropathy [9]

Table 21.1. Algorithm for the pharmacological symptomatic treatment of neuropathic pain in diabetic peripheral neuropathy

First-line treatment – one of the following medications	Effective doses of drugs
Anticonvulsant drugs	
Pregabalin	300–600 mg/day
Gabapentin	900–3600 mg/day
Selective serotonin and norepinephrine reuptake inhibitors	
Duloxetine	60–120 mg/day
Venlafaxine	75–225 mg/day
Tricyclic antidepressants medications:	
Amitriptyline*	25–100 mg/day
Second-line treatment	**Effective doses of drugs**
Opioid drugs	
Tramadol	200 mg/day
Tapentadol	From 50 mg twice a day, max. 500 mg/day
Topical drugs	
Capsaicin, lidocaine	

The effective drug doses are provided. It is necessary to gradually increase the dose to the maximum tolerable dose if needed. In case of inefficacy of one first-line drug, switching to another preparation or combination therapy is recommended. Chronic use of opioids is not advised. Non-pharmacological methods (physical therapy, acupuncture, neuromodulation techniques) can be applied at any stage.
**In elderly patients and those with cardiovascular diseases, amitriptyline should be initiated at a dose of 10 mg and increased cautiously based on response and tolerance.*

Neuromodulatory methods may have a potentially significant role in the treatment of neuropathic pain, including Frequency Rhythmic Electrical Modulation System (FREMS), Dorsal Root Ganglion Stimulation (DRGS), and Spinal Cord Stimulation (SCS). Studies have demonstrated pain reduction and improved quality of life following the application of these methods in painful neuropathy.

3. Symptomatic treatment of autonomic diabetic neuropathy:

- cardiovascular system:
  - » heart rhythm control disorders – controlled, gradual physical exercise, ACE inhibitors, β-blockers without intrinsic sympathomimetic activity,
  - » orthostatic hypotension – compression clothing on the lower limbs and abdomen, salting food, isometric exercises, mineralocorticoids (fludrocortisone), α_1-adrenomimetics (midodrine),
- digestive system:
  - » gastroparesis – diet modification (frequent, small meals, in severe cases a semi-liquid or liquid diet), prokinetic drugs (cisapride, itopride, erythromycin, trimebutine), drugs inhibiting gastric secretion (H_2 blockers, proton pump inhibitors), antiemetic drugs, surgical treatment, stimulation of gastric bioelectrical activity,
  - » intestinal function disorders – diet modification (consideration of a gluten-free diet, lactose limitation), cholestyramine, clonidine, octreotide, constipating drugs (loperamide), pancreatic enzymes, antibiotics,
- urinary and reproductive systems:
  - » bladder function disorders – avoiding urine retention, regulated, systematic urination, cholinergic receptor agonists (bethanechol), external bladder massage before urination, bladder catheterization (intermittent, permanent),
  - » sexual function disorders in men – psychotherapy, phosphodiesterase type 5 inhibitors (sildenafil, vardenafil, tadalafil), vacuum erection devices, injections into the cavernous bodies (prostaglandin E1), penile prostheses,
  - » sexual function disorders in women – psychotherapy, mechanical sexual organ stimulators, local moisturizing drugs, flibanserin,
- sweat disorders – botulinum toxin, vasodilating medications, moisturizing creams.

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22. Diabetic Foot Disease (DFD)

CHAPTER HIGHLIGHTS
• Maintaining optimal control of glycaemia, lipidaemia, and blood pressure reduces the risk of developing diabetic foot disease. [**A**]
• Treatment of diabetic foot disease should take place within specialized, multidisciplinary clinics. [**B**]
• The gold standard for offloading an uninfected plantar wound of the forefoot and midfoot in a neuropathic foot is a total contact cast or another non-removable orthosis encompassing the foot and lower leg. [**A**]
• Key to the treatment of diabetic foot disease, in addition to maintaining optimal glycemic control, are surgical debridement of the wound, offloading, systemic antibiotic therapy in case of infection, and vascular interventions in ischemic foot. [**A**]

Diabetic foot disease includes the presence of at least one of the following pathologies in a person diagnosed with diabetes: peripheral polyneuropathy, peripheral arterial disease (lower limb ischemia), infection, ulceration, Charcot neuroarthropathy, or amputation.

In regional diabetes centres, including provincial and university-affiliated facilities, it is recommended to establish multidisciplinary diabetic foot clinics, also referred to as reference clinics. Additionally, at diabetes clinics, there should be the establishment of basic diabetic foot clinics dedicated to the ongoing management of therapies initially formulated within the multidisciplinary settings. The structure and tasks should be in accordance with the Ministry of Health's Ambulatory Care Support Program for Diabetic Foot Syndrome (http://www.mz.gov.pl/health-and-prevention/health-programs/list-of-programs/program-of-ambulatory-support-treatment-of-diabetic-foot-syndrome/)

I. Definition

Diabetic foot is defined as an infection and/or ulceration and/or destruction of deep foot tissues (e.g., bones) caused by peripheral nerve damage and/or vascular impairment of varying severity. Based on this definition, diabetic foot is classified into neuropathic, ischemic, and mixed (neuropathic-ischemic) types.

The diagnosis of diabetic foot syndrome includes the assessment of peripheral polyneuropathy, lower limb blood circulation disorders, deformities, and other risk factors for foot damage. If protective pain sensation is lost, a physician should examine the patient's feet during every visit.

II. Risk factors for the development of diabetic foot disease

The most important risk factors for the development of DFD include:

- peripheral neuropathy and/or signs of lower limb ischemia,
- no patient awareness,
- long-term, poorly managed diabetes,
- improper foot hygiene,
- inappropriate footwear,
- presence of calluses,
- foot deformity,
- increased pressure on the plantar side of the foot,
- tobacco smoking.

Factors favouring ulcer recurrence:

- previous amputations,
- history of ulceration,
- Charcot neuroarthropathy

III. Prevention:

- systematic foot examination; annual screening for sensory disturbances (physical examination using a 10 g monofilament and a 128 Hz tuning fork; if a monofilament or tuning fork is not available, screening for sensory loss can be performed by lightly touching the patient's toes with an index finger for 2–3 seconds) and ischemia (assessment of pulse on the dorsalis pedis artery and posterior tibial artery; if the pulse on the dorsalis pedis/posterior tibial artery is not palpable, an ankle-brachial index measurement is recommended). Further ischemia diagnostics should also be considered in consultation with a vascular surgeon or angiologist for all patients; the frequency of foot examinations based on the assessment of ulceration risk is presented in Table 22.1,
- regular podiatric care (removal of calluses and hyperkeratosis),
- assessment of the patient's footwear and existing deformities, as well as knowledge concerning the risk of ulceration,
- systematic education of patients, their families, and caregivers on ulcer prevention principles, with particular emphasis on proper footwear selection,
- treatment/elimination of other risk factors, such as smoking, overweight, hypertension, lipid disorders, diabetic metabolic regulation,
- early detection and treatment of limb ischemia,
- exercise walking may be recommended exclusively for patients without plantar surface ulceration using properly fitted footwear. Patients with plantar ulcers should perform offloading exercises.

IV. Clinical classification of foot ulceration

The PEDIS classification [P – perfusion (circulation), E – extent (size), D – depth, I – infection, S – sensation] is recommended, considering both infection and ischemic factors (Table 22.2) as well as the SINBAD classification (Table 22.3).

V. Infections in diabetic foot

1. The diagnosis of infection is primarily based on clinical presentation (presence of at least two classic subjective and objective signs of infection), rather than solely on the results of microbiological and laboratory tests.
2. Assessment of the severity of the infection (refer to the PEDIS classification).
3. Microbiological testing (with antibiogram) and its interpretation (colonization, contamination, infection):

- it is recommended to collect a tissue sample after wound debridement and rinsing with

Table 22.1. Frequency of preventive foot examinations according to risk (risk stratification system according to the International Diabetic Foot Working Group)

Category	Wound risk	Features	Frequency of testing
0	Very low	Preserved sensation, no ischemia	Once a year
1	Low	Sensory disturbance or ischemia found	Once every 6–12 months
2	Moderate	Identified sensory disturbance and ischemia, or identified sensory disturbance + foot deformity, or stated ischemia + foot deformity	Once every 3–6 months
3	High	Identified sensory disturbance or ischemia and one of the following: • a history of ulceration • a history of amputation • end-stage renal failure	Once every 1–3 months

Table 22.2. PEDIS classification

	Grade			
	1	2	3	4
Vascularization	Features of a normal blood supply: palpable pulse on the arteries of the feet or ABI > 0.9	Clinical signs of circulatory impairment: the presence of chromic lag, ABI < 0.9, $TcpO_2$ 30–60 mm Hg	Critical ischemia: rest pain, ABI < 0.4, $TcpO_2$ < 30 mm Hg	–
Size	The dimension of the wound is determined in square centimetres			
Drilling	Superficial ulceration not exceeding the dermis	Wound may involve all soft tissues	Penetration of infection into bone: visible on X-ray, features of osteolysis or bone palpable with probe	–
Severity of infection	No clinical signs of infection	The infection involves the skin and subcutaneous tissue The area involved in the inflammation does not exceed 2 cm from the border of the ulceration	Topical intensification of inflammatory features The border exceeds 2 cm, but there are no features of generalized infection	Features of generalized infection: fever > 38°C, pulse > 90/min, respiratory rate > 20/min, leucocytosis > 12 thousand or < 4 thousand
Sensory neuropathy	No features of sensory neuropathy in basic tests: monofilament and camertone or neurotip examination	Presence of sensory neuropathy		

Table 22.3. SINBAD classifications

Category	Definition	Score
Location	Forefoot Midfoot/rear of the foot (heel area)	0 1
Ischemia	Blood supply to the foot normal – palpable pulse at least on one artery Clinical features of ischemia	0 1
Neuropathy	Retained sensation. No feeling	0 1
Infection	No Present	0 1
Area	< 1 cm^2 ≥ 1 cm^2	0 1
Depth	Ulceration limited to the skin and subcutaneous tissue The ulceration involves muscles, tendons or deeper structures	0 1
Total		6

a sterile solution; aspirate collection – a swab should only be performed when no other options are available – it is not recommended as the results are less reliable,

- necessary when there is a clinically infected wound,
- interpretation of cultures in infection assessment can be challenging – clinical presentation should be primarily considered,
- blood culture is recommended only in justified cases,
- for clinically uninfected wounds, microbiological examination is not indicated; in cases of mild infection without prior antibiotic use, empirical antibiotic therapy may be initiated without culture.

4. Examination for osteomyelitis (should be performed in every case of infected ulceration, especially those with a prolonged duration):
- probe to bone test with a metal instrument,
- X-ray of the foot bones (every 3–6 weeks); the preferred next imaging method is magnetic resonance imaging, and SPECT, PET, or scintigraphy with labelled leukocytes,
- bone biopsy or culture from bone fragments and histopathological examination (recommended); bone biopsy is necessary if osteomyelitis diagnosis is uncertain, or pathogen identification is required,
- laboratory tests – ESR > 70 mm/hr. increases the probability of osteomyelitis; lower values suggest a lower risk; CRP and leucocytosis measurements may also be helpful; normal laboratory test results do not fully rule out osteomyelitis.

5. The primary criterion for dressing selection is the nature of the wound – dry or exudative.
6. Guidelines for antibiotic therapy:

- use only in cases of confirmed infections (not prophylactically),
- do not delay the initiation of therapy,
- initially, use an antibiotic that covers the most common flora (staphylococci and streptococci),
- duration of antibiotic use – until clinical symptoms of infection subside (not until the wound heals):
  - » soft tissue infection (without bone infection) 1–2 weeks,
  - » antibiotic therapy extended to 3–4 weeks if the infection is extensive and improving but slowly, or if ischemia is present,
  - » in cases of osteomyelitis, the duration of antibiotic therapy is the same as for soft tissue infections if the infected bone has been radically removed, 3 weeks if a minor amputation was performed and infected fragments remain, and 6 weeks in cases of osteomyelitis without bone resection or amputation.

To confirm remission of osteomyelitis, an assessment should be conducted after a minimum of 6 months of observation following the completion of antibiotic therapy.

Extension of antibiotic therapy should also be considered in cases where the severity of infection decreases, but due to the extent of the surgical procedure within the foot, the improvement occurs more slowly than expected:

- route of administration:
  - » intravenous – for PEDIS grade 4 infections and in selected cases of grade 3 (MRSA infection, *Pseudomonas aeruginosa*), intolerance to oral antibiotics.,
  - » oral – for PEDIS grades 2 and 3 infections and after improvement in grade 4,
  - » topical – consider using a gentamicin-soaked collagen sponge (garamycin sponge) as adjunctive to systemic antibiotic therapy if the pathogen is sensitive to gentamicin,
  - » intra-arterial – not recommended.

7. Empirical antibiotic therapy based on clinical presentation and microbiological data.

A. Mild Infections – usually Gram-positive cocci

- MSSA *Staphylococci* – cloxacillin,
- *Streptococci* – amoxicillin, cephalexin,

In case of β-lactam antibiotic intolerance – clindamycin, trimethoprim-sulfamethoxazole, doxycycline.

B. Recent antibiotic exposure

Infection may be caused by both Gram-positive and Gram-negative bacteria. Recommended treatment – amoxicillin/clavulanate, ampicillin/sulbactam, or trimethoprim-sulfamethoxazole.

C. High risk of MRSA infection (prior MRSA infection or colonization, prolonged hospitalization, ICU admission, recent hospitalization, recent antibiotic use, invasive procedures, HIV infection, admission from nursing homes, open wounds, haemodialysis, presence of central venous access).

Glycopeptides – only in cases of MRSA isolation from peripheral blood.

For local infection with negative blood cultures, glycopeptides (vancomycin, teicoplanin – due to poor penetration into the foot, only 3% of the therapeutic dose) should be replaced with:

- ceftaroline,
- doxycycline,
- trimethoprim-sulfamethoxazole,
- linezolid,
- clindamycin,
- dalbavancin,
- daptomycin,
- fusidic acid (not available in Poland in oral or IV form).

D. Moderate or severe infections of mixed Gram-positive and Gram-negative etiology (no prior antibiotic use):

- amoxicillin/clavulanate,
- ampicillin/sulbactam,
- 2nd and 3rd generation cephalosporins (cefuroxime, cefotaxime, ceftriaxone).

E. Moderate or severe infections of mixed Gram-Positive and Gram-negative etiology (prior antibiotic use):

- ticarcillin/clavulanate,
- piperacillin/tazobactam,
- 2nd and 3rd generation cephalosporins (cefuroxime, cefotaxime, ceftriaxone),
- carbapenems (ertapenem).

F. Persistent infections of mixed Gram-positive, Gram-negative, and *Pseudomonas aeruginosa* etiology:

- ticarcillin/clavulanate,
- piperacillin/tazobactam,
- penicillinase-resistant semi-synthetic penicillin (cloxacillin) + ceftazidime,
- carbapenems (meropenem/imipenem),
- fosfomycin IV.

G. Ischemic limbs/necrosis/gas gangrene formation:

- amoxicillin/clavulanate,
- ampicillin/sulbactam,

- ticarcillin/clavulanate,
- piperacillin/tazobactam,
- carbapenems (ertapenem or meropenem/imipenem),
- 3rd generation cephalosporins (cefuroxime, cefotaxime, ceftriaxone) + clindamycin or metronidazole.

H. Risk of multi-drug-resistant Gram-negative bacilli
- carbapenem (ertapenem, meropenem, imipenem) + aminoglycoside (amikacin) or colistin,
- carbapenem + IV fosfomycin,
- colistin + IV fosfomycin.

I. *Enterococcus faecalis* infection (if susceptible):
- ampicillin IV,
- amoxicillin PO, IV.

If β-lactam antibiotic intolerance or resistance:
- vancomycin,
- teicoplanin,
- daptomycin,
- linezolid PO, IV.

J. *Enterococcus faecium* infection:
- vancomycin,
- teicoplanin,
- daptomycin,
- linezolid PO, IV.

Important Note. According to the latest IDSA, FDA, National Institute of Drugs, and the President of the Office for Registration of Medicinal Products guidelines (May 26, 2023), based on the European Medicines Agency (EMA) recommendations, fluoroquinolone antibiotics (ciprofloxacin, levofloxacin, moxifloxacin) should not be used in empirical therapy due to the risk of long-term and potentially irreversible adverse effects.

V. Multidisciplinary Treatment of Diabetic Foot Disease

Treatment of Diabetic Foot Disease (DFD) should be conducted within the framework of specialized, multidisciplinary clinics. This concept encompasses an organizational structure that allows for patient access to required specialists who possess knowledge and experience in diabetic foot treatment and form a team in constant communication. The treatment of DFD includes:
- metabolic control of diabetes, considering the general principles of its treatment,
- offloading – the preferred method of offloading a neuropathic foot with a non-infected ulcer located on the plantar surface of the forefoot and midfoot is non-removable offloading, which can only be recommended and applied by properly trained personnel, preferably extending to the knee, but if this is not possible or not accepted by the patient, it may extend to the ankle; a temporary offloading shoe for the forefoot or heel (with a compensatory shoe for the healthy limb), therapeutic insoles, crutches, a wheelchair, specialized footwear, and restriction of walking – including at home; in other locations (e.g., heel), in the presence of infection and/or limb ischemia, and in situations where experienced personnel are not available, the first and subsequent choices are removable offloading devices (foot-ankle orthoses extending to the knee); when making decisions regarding the choice of offloading method for the limb, the patient's condition and mobility, coexisting diseases, patient preference, and team training should be considered; in many patients (especially in cases of loss of protective pain sensation, ischemia, and existing deformities), the use of appropriate, individually fitted shoe insoles is recommended to correct excessive plantar pressure forces in order to prevent ulceration or ulcer recurrence,
- in case of infection: antibiotic therapy (oral or intravenous): see above,
- surgical procedures – removal of necrotic tissues, drainage, incision; tenotomy of toe flexors may be considered if their deformation causes recurring ulcers, as well as lengthening of the Achilles tendon and resection of the metatarsal head if ulceration does not heal despite offloading,
- endovascular procedures and conventional vascular surgery, hybrid procedures (diabetic foot characterized by a predominance of ischemic factor) – patients with a low (< 0.5) ankle–brachial index (ABI), $TcPO_2$ values < 25 mm Hg and/or a history of intermittent claudication should be referred for further urgent vascular diagnostics, and then to a vascular surgeon or angiologist; imaging diagnostics and revascularization should also be considered – even when the results of the above tests are normal – if there is no progress in wound healing within 4 weeks; it should be noted that many patients with diabetes may have lower limb ischemia without typical pain symptoms; the goal of revascularization should be to restore blood flow at least to one artery, preferably the one supplying the anatomical area of ulceration,

- regular wound debridement depending on local condition,
- conventional dressings and therapy providing an appropriate wound environment – the use of TLC-NOSF technology dressings in uninfected neuropathic-ischemic etiology wounds (but without critical/significant ischemia), not healing despite optimal standard treatment, should be considered,
- other – hyperbaric chamber meeting required standards (ischemic wounds, not healing despite standard procedures), negative pressure therapy (should be considered especially in the case of postoperative wounds in patients for whom ischemia and infection do not constitute a significant contraindication), drugs improving circulation (ischemic foot or with a predominance of vascular factor): low molecular weight heparin preparations (acute ischemic states, critical ischemia), acetylsalicylic acid, exercise walking; the use of preparations from autologous leukocytes, platelet-rich fibrin (ulcers without or with minor ischemia), local oxygen therapy, and dressings from human placenta as adjunctive therapies for the treatment of uninfected ulcers may also be considered; sulodexide treatment may also be considered.

The use of "artificial skin" grafts, growth factors, ozone therapy, and autologous platelet gel is not recommended. In justified cases, the use of Lucilia sericata larvae bred in sterile conditions in specialized laboratories may be considered for wound debridement.

Every patient with DFS should be educated on the prevention of ulcers.

VI. CHARCOT NEUROOSTEOARTHROPATHY (CHARCOT FOOT)

1. Diagnosis

The diagnosis is based on the patient's medical history and clinical presentation (most often unilateral swelling, redness, increased warmth of the foot, especially if there is no ulceration, in patients with features of diabetic polyneuropathy), after excluding other causes, particularly deep vein thrombosis, gout, and abnormalities on imaging studies. If these are not visible on a standard radiograph (weight-bearing position), an MRI should be performed, or if unavailable, a CT scan. In the absence of these methods, the patient should be treated as having probable neuroosteoarthropathy.

2. Treatment:

- active phase – round-the-clock offloading reaching the knee (lower levels are not recommended); bisphosphonate or calcitonin therapy is not recommended, and vitamin D and calcium supplementation should follow general principles; offloading should be maintained until the process stabilizes and enters the inactive phase; monitoring of the activity process through foot surface temperature measurements and comparison between both feet (no clear cutoff point) and radiological imaging indicating consolidation may be considered; the return to full limb loading should be very gradual,
- inactive phase – education, foot hygiene, specialized orthopaedic footwear with therapeutic insoles to correct deformities, orthopaedic surgical procedures for correction of deformations (ostectomy, arthrodesis); multidisciplinary specialist team management is recommended.

VII. Hospitalization – indications

For emergency admission:

- PEDIS grade 4 infection,
- PEDIS grade 3 infection, if intravenous antibiotic therapy is necessary,
- any case of critical ischemia – emergency intervention unit for urgent revascularization,
- admission to a department capable of performing urgent vascular imaging (CT angiography or MR angiography), followed by urgent consultation of the patient for revascularization qualification.

For elective admission:

- no improvement after two months of outpatient treatment,
- preparation for planned surgical procedures (minor amputation, skin graft, limited bone resections, revascularization procedures),
- orthopaedic correction of deformities in the course of Charcot neuroosteopathy.

VIII. Amputation

Assessment of limb perfusion is necessary before any amputation.

1. "Major" amputation (above the ankle) should be considered when:

- life-threatening inflammation, extensive necrosis (absolute indication),
- debilitating pain resistant to treatment, especially as a result of ischemia (relative indication),

- loss of foot load-bearing functions (relative indication).

2. "Minor" amputation (below the ankle) should be considered when:

- necrosis,
- inflammation of the distal phalangeal bones of the toes (to avoid chronic antibiotic therapy – accelerates healing),
- inflammation within the metatarsophalangeal joints to perform their resection as a limb-sparing bone procedure,
- in the case of dry necrosis, it is recommended to wait for autoamputation while continuously monitoring for signs of infection.

3. An indication for amputation may also be a chronically treated wound in cases of the patient's deteriorating condition and lack of treatment progress, taking into account the patient's preferences.
4. The choice of amputation level depends on vascular status, reconstructive, and rehabilitative possibilities. It is recommended to perform the most conservative amputation possible.

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23. Children and Adolescents: Standards of Care in Diabetes

CHAPTER HIGHLIGHTS
· From the moment of diagnosis, a care plan utilizing appropriate educational tools should be implemented to achieve individual therapeutic goals for children and adolescents with diabetes. [**A**]
· For children and adolescents with diabetes, the goal should be to maintain Time in Range (TIR) ≥ 80% and Coefficient of Variation (CV) < 36%, with HbA_{1c}/GMI values ≤ 6.5%, while minimizing episodes of hypoglycaemia and maintaining good quality of life. [**B**]
· During disease remission and when using automated insulin delivery systems, it is advisable to narrow the target range to 70–140 mg/dl and CV < 33%. [**E**]
· Children and adolescents with diabetes and their families should receive specialized psychological care from the moment of diagnosis. [**A**]
· Continuous glucose monitoring systems should be used by children and adolescents with diabetes from the time of diagnosis. [**A**]
· Blood glucose should be interpreted at least eight times daily: fasting and before meals, before sleep, before, during, and after exercise, and when feeling unwell, as needed 1–2 hours post-meal and during the night. [**A**]
· Using continuous glucose monitoring in children and adolescents improves diabetes metabolic balance (increases TIR, lowers HbA_{1c} levels), reduces the risk of acute and chronic complications, and extends life expectancy. [**A**]
· Children and adolescents with type 1 diabetes should be treated with intensive insulin therapy from the initiation of insulin treatment (excluding the remission period) – the preferred method is therapy using automated insulin delivery systems. If these systems cannot be used, systems with an automatic insulin suspension function in anticipation of hypoglycaemia are preferred. [**A**]

This chapter outlines differences in general recommendations due to the specificities of developmental age.

I. Diagnosis and forms of diabetes in developmental age

1. The same tests used for diagnosing diabetes in adults are applicable to children and adolescents. Without clear hyperglycaemia, the diagnosis requires two abnormal test results from the same sample or two separate samples. HbA_{1c} < 6.5% does not exclude diabetes diagnosed with glucose tests. The role of HbA_{1c} alone in diagnosing type 1 diabetes in children is unclear.
2. Type 1 diabetes with autoimmune pathogenesis is the most common.
3. Screening tests (OGTT or HbA_{1c}) for type 2 diabetes should be performed in children at the onset of puberty or after the age of 10 who have a BMI ≥ 85th percentile for age and sex, and other risk factors for developing type 2 diabetes. If results are normal, they should be repeated at least every three years. Annual screenings are necessary if BMI increases, the cardiometabolic risk profile worsens, there is a family history of type 2 diabetes, and/or there are signs of prediabetes. Type 2 diabetes in children and adolescents is characterized by earlier development and faster progression of chronic complications than in adults.
4. It should be noted that in Poland, monogenic diabetes is the second most common form of

diabetes in the paediatric population. Indications for testing for monogenic diabetes are presented in Chapter 1.

5. The number of children with glucose tolerance disorders or cystic fibrosis-related diabetes is increasing. Diabetes is usually asymptomatic. Children over 10 years of age with cystic fibrosis should undergo an annual OGTT with glucose measurement fasting, and at 30, 60, 90, and 120 minutes.
6. Initial diagnosis of hyperglycaemia or revision of a diabetes diagnosis includes the detection of antibodies against glutamic acid decarboxylase (anti-GAD), islet cell antibodies (ICA), insulin (insulin autoantibodies – IAA), tyrosine phosphatases (insulinoma-associated autoantigen 2 – IA-2), and zinc transporter 8 (ZnT8) (testing should be performed in a reference laboratory).

It is also recommended to determine these antibodies in individuals with a family history of type 1 diabetes. Currently, the introduction of population-based screening for type 1 diabetes is being considered in Poland, as in other countries.

Detecting diabetes in the preclinical stage, combined with monitoring for disease progression, allows for:

- significant reduction of hyperglycaemia consequences (including diabetic ketoacidosis, central nervous system damage),
- gentler introduction of insulin therapy,
- lengthening of clinical remission,
- participation in research projects aimed at preventing the progression of diabetes to the clinical stage.

It is currently considered that the optimal age for a single screening test is 3 years. It is recommended to conduct screenings at the ages of 2 and 6, and optionally at 10 years.

The presence of two or more positive antibody titers indicates an active autoimmune process of β-cell apoptosis in the pancreas and allows for the diagnosis of stage 1 (preclinical) type 1 diabetes. Stage 2 is diagnosed with the addition of dysglycaemia, which is:

- IFG (impaired fasting blood glucose) or
- IGT (impaired glucose tolerance) or
- HbA_{1c}: 5.7–6.4% or a 10% increase from its value.

Due to the significant risk of progressing to stage 3 type 1 diabetes, patients in preclinical stages require health education on a healthy lifestyle (maintaining a proper body weight and engaging in regular physical activity prolongs the preclinical phase) and glycemic value assessment. In children in the preclinical phase of the disease, monitoring the progression depends on the child's age and the number of positive autoantibodies. (Consensus Guidance for Monitoring Individuals with Islet Autoantibody–Positive Pre-Stage 3 Type 1 Diabetes. https://diabetesjournals.org/care/article/47/8/1276/156880/Consensus-Guidance-for-Monitoring-Individuals-With)

7. Keep in mind that a patient may have a mixed etiology of diabetes.

II. Goals of Diabetes Treatment

1. Prevention of acute and chronic complications of diabetes.
2. Achievement and maintenance of proper, harmonious physical development: growth and body mass, including composition (percentile values), as well as the progression of puberty, appropriate to age and gender, while ensuring comfort for the child and their family.
3. Target values for parameters to reduce the risk of vascular complications:

- aim for TIR ≥ 80%, CV < 36%, and HbA_{1c} ≤ 6.5%, while minimizing hypoglycaemia episodes and maintaining a good quality of life; During remission and when using automated insulin delivery systems, consider narrowing the target range to 70–140 mg/dl and CV < 33%,
- total cholesterol concentration < 170 mg/dl (< 4.4 mmol/l), LDL cholesterol < 100 mg/dl (< 2.6 mmol/l), triglycerides < 100 mg/dl (< 1.1 mmol/l).
- blood pressure value < 90th percentile for age, gender, and height (from age 13 < 120/80 mm Hg).
- BMI < 85th percentile for age and gender,
- physical activity of moderate or high intensity for at least one hour daily,
- sleep duration: children aged 5–13 years a minimum of 9 hours and aged 14–17 years a minimum of 8 hours per day,
- no tobacco uses.

III. Diabetes treatment

1. Pharmacotherapy:

Type 1 diabetes — insulin therapy:

- the method of insulin therapy should be tailored to the individual needs of the patient and accepted by the person with diabetes and their caregivers,
- the preferred method is functional intensive insulin therapy (IIT) which involves constant adaptation of insulin doses to current glycaemic

values and their trends, the amount of carbohydrates consumed (considering fat and protein content in meals), and physical and emotional activity, carried out as either:
  - » continuous subcutaneous insulin infusion (CSII) with a personal insulin pump, or
  - » multiple daily injections (MDI) using a pen injector with needles ≤ 6 mm in length,
- idications and contraindications for CSII — see the thematic chapter,
- for patients requiring intensive insulin therapy, the standard should be the use of automated insulin delivery (AID) systems. If these systems cannot be used, consideration should be given to insulin delivery systems that automatically suspend insulin administration in anticipation of hypoglycaemia, provided these therapy methods are accepted by the patient and their parents/caregivers and there are no contraindications (guidelines of PTEiDD and the Pediatric Section of Poland Diabetes on insulin therapy using hybrid closed-loop systems in children and adolescents with diabetes in Poland – https://doi.org/10.5114/pedm.2024.144041),
- in CSII and MDI, the use of the bolus calculator function from the start of therapy is indicated, as it increases glycemic stability and reduces the risk of hypoglycaemia and hyperglycaemia; regular verification and modification of bolus calculator settings are important,
- the choice of rapid-acting or ultra-rapid-acting insulin analogues and long-acting or ultra-long-acting insulin analogues should be tailored to the individual needs of the patient, considering pharmacological differences between formulations and approved indications. When using AID systems, ultra-rapidacting analogues increase time in range (TIR). In MDI therapy, ultra-long-acting analogues reduce the risk of hypoglycaemia, allow for less rigid adherence to insulin dosing times, and generally do not require dose reduction in the case of physical activity (see Chapter 7),
- in the paediatric population, daily insulin requirements are highly variable; the highest is during puberty but should not exceed 1.5 U/kg body weight/day; high insulin requirements can often be associated with lack of physical activity, excessive carbohydrate intake, obesity, or coexisting disease; in cases of obesity, the addition of a GLP-1 receptor agonist may be considered; for patients with concomitant insulin resistance, the addition of metformin can be considered.
- in the functional IIT method, the size of the basal dose (20–50% of the daily dose) and its profile depend on the child's age and the type of personal insulin pump; in the case of AID systems, the size of the basal dose depends on the algorithm used,
- rapid-acting and short-acting insulin is preferably administered before a meal, respectively 15–20 minutes and 20–30 minutes, and ultra-rapid-acting analogue 2–10 minutes before a meal; in very young children, due to the impossibility of planning the time and size of the meal, it is worth considering splitting the dose and administering half before the meal and half during or after the meal; administering the entire dose after the meal should only be done exceptionally,
- it is important to systematically rotate the insulin injection sites, while avoiding administering insulin in areas of hypertrophy or atrophy of subcutaneous tissue,
- for patients treated with CSII who have low insulin requirements, diluting the insulin is permissible.

Type 2 diabetes — In this age group, the following can be used: metformin, insulin, GLP-1 receptor agonists, and SGLT-2 inhibitors (age restrictions according to the Summary of Product Characteristics).

For newly diagnosed diabetes with:
- no symptoms of the disease, HbA_{1c} < 8.5%, and no ketoacidosis, pharmacotherapy in children can begin with metformin (gradually increased to 2 g/day or tolerated dose),
- symptoms of the disease and/or HbA_{1c} ≥ 8.5% and no ketoacidosis, treatment starts with metformin and basal insulin (at a dose of 0.25–0.5 U/kg body weight/day),
- ketoacidosis present – initial treatment as in type 1 diabetes (intravenous insulin).

After stabilizing acute metabolic disorders and initial normalization of glycaemia, insulin treatment should be withdrawn (usually within 2–6 weeks).

In patients with longer disease duration without sufficient glycemic control (HbA_{1c} ≥ 6.5%) and no normalization of body weight despite using metformin, a second hypoglycaemic drug (GLP-1 receptor agonist and/or SGLT-2 inhibitor) should be added. If therapy is ineffective or the use of GLP-1 receptor agonists and/or SGLT-2 inhibitors is not possible, basal insulin should be introduced.

Bariatric treatment is permissible in selected cases.

Monogenic diabetes or diabetes associated with genetic syndromes – treatment depends on

the type of disease (use of sulfonylurea derivatives is off-label).

Diabetes in cystic fibrosis – see Chapter 1.

2. Nutrition for children and adolescents with diabetes

The basic principles of healthy eating for children with diabetes are the same as for their peers without diabetes. It is recommended to maintain a proper caloric balance, with carbohydrates optimally comprising 45% of daily caloric intake. Simple sugars should be limited to 10% of daily caloric intake, and a portion of vegetables should be included in every meal. Estimating the amount of carbohydrates consumed in meals is essential, particularly for proper insulin dosing and preparation for physical activity (currently, counting grams of carbohydrates is preferred over carbohydrate exchanges). Adequate fluid intake should also be emphasized.

3. Self-monitoring:

- glucose monitoring should be conducted through self-measurements using continuous glucose monitoring systems (CGM) and its analysis; CGM is recommended for every child and adolescent from the onset of the disease,
- if CGM is not possible or accepted, glucose measurements should be performed with a glucometer,
- the frequency of glucose value interpretation is individualized, with functional IIT at least 8 times daily; glucose should be assessed fasting and before meals, 1–2 hours after a meal, before sleep, before, during, and after exercise; night-time glucose profiles should also be evaluated; in case of feeling unwell, glucose should be measured immediately.

CGM use requires diabetes education in terms of correct interpretation of current results, therapy modification according to glucose concentration dynamics (trend arrows), retrospective analysis of results according to TIR recommendations (see: Chapter 4.). With CGM, education should be expanded to include correct sensor calibration principles (if required), proper selection, and programming of alarm limits and notifications. If CGM glucose concentration values are not in line with clinical symptoms, glucose should be measured with a glucometer, and in the case of hyperglycaemia, ketonemia/ketonuria should also be assessed.

The use of CGM systems enables more effective adjustment of insulin doses to glucose trends, thus increasing glucose stability, reducing hypoglycaemia incidents, improving metabolic balance, enhancing the quality of life for patients and their caregivers, and reducing the risk of cardiovascular complications. Only consistent CGM use is therapeutically effective (at least 70% of the time).

For patients with hypoglycaemia unawareness or frequent hypoglycaemia, CGM use is necessary, optimally – automated insulin delivery systems or insulin pumps integrated with CGM with an automatic insulin suspension feature for hypoglycaemia prediction.

Measuring blood β-hydroxybutyrate concentration with strip tests is a more sensitive indicator of ketonemia than urine ketone testing.

4. Therapeutic education:

- it is a key element in diabetes treatment and should always involve the child and their caregivers,
- patients and/or their parents/caregivers need education on the principles of diabetes self-management, including modern technologies in diabetes care, and regular re-education according to the patient's individual needs; everyone involved in the child's care must be educated,
- educational methods and programs should be diversified and adapted to the child's age, intellectual capabilities, and the educational roles of parents/caregivers,
- in adolescents and young adults, special attention should be paid to prevention of acute and chronic complications of diabetes, contraception, pregnancy, risky behaviours, and addictions,
- the process of acquiring self-management skills should be gradual; too early or too late a transfer of responsibility to children and adolescents with diabetes is associated with therapy failure,
- workshops and camps for children, adolescents, and young adults with diabetes are a beneficial and effective educational tool,
- members of the diabetes team caring for patients < 18 years of age at camps/colonies without parents should provide intensive medical care, including night shifts; legal and organizational support from the administrative units caring for the child with diabetes is expected,
- conducting diabetes education and its continuation is the duty of the entire diabetes team led by a specialist physician, with a special role for the diabetes educator.

5. Psychological care:

- continuous psychological care for children, adolescents, and young adults with diabetes and

their families from the onset of the disease is essential,
- subclinical and clinical depressive syndromes, eating disorders including anorexia nervosa (especially in girls during puberty), and other non-specific eating disorders (ED-NOS) are often observed,
- care should be provided by an experienced psychologist specialized in developmental age diabetes issues, in collaboration with a child psychiatrist,
- screening for depressive disorders, eating disorders, and diabetes-related stress should be performed in all patients over the age of 12 every 1–2 years and in any patient with unsatisfactory metabolic control of the disease; diabetes-related stress should also be assessed in parents/caregivers.

6. Additional remarks:
- inclusion of the entire family in the treatment process of diabetes in children and adolescents is necessary; setting therapeutic goals together is recommended.
- encouraging patients to be independent and take responsibility for their treatment, appropriate to their age, intellectual development, and emotional maturity, is necessary.
- properly developing children > 10 years old should be able to independently measure glucose with CGM and glucometer and interpret results, administer insulin with an injector, change infusion sets for insulin pumps, and CGM sensors.
- children > 13 years old should independently conduct daily self-monitoring of diabetes under parental supervision.

In cases of existing or suspected social problems, collaboration with a social worker is necessary.

IV. Coexisting diseases with type 1 diabetes

Common conditions include:
- autoimmune thyroiditis, celiac disease; typically presenting with scant or no symptoms such as glucose level fluctuations, or growth and sexual maturation issues,
- IgA deficiency.

Certain chronic diseases (e.g., diseases requiring systemic corticosteroid therapy, epilepsy, Asperger's syndrome, mental or intellectual disorders) may impose additional requirements on diabetes therapy.

V. Acute and chronic complications of diabetes (refer to thematic chapters):

1. Acute complications:
- for blood glucose ≤ 70 mg/dl (3.9 mmol/l) or when clinical symptoms of hypoglycaemia are present (without severe consciousness disorders), administer oral glucose at approximately 0.3 g/kg body weight, with the dose dependent on the blood glucose levels and active insulin (maximum dose usually does not exceed 15 g of glucose for a child weighing ≥ 50 kg); re-measure blood glucose after 15 minutes; with AID, consider treating hypoglycaemia with a smaller amount of glucose (0.15 g/kg body weight, usually up to 8 g),
- blood glucose < 54 mg/dl (3.0 mmol/l) is indicative of clinically significant hypoglycaemia,
- in the case of CGM use, clinically significant hypoglycaemia is diagnosed when blood glucose < 54 mg/dl persists for more than 15 minutes,
- severe hypoglycaemia in small children is identified by consciousness disorders and/or seizures (require assistance from others even in the treatment of mild hypoglycaemia),
- severe hypoglycaemia management is detailed in Chapter 15,
- biochemical criteria for acute hyperglycaemic states in children and adolescents are in Table 23.1,
- Figure 23.1 presents the management principles of diabetic ketoacidosis (DKA) in children; it is emphasized that rehydration can be carried out using 0.45% to 0.9% NaCl or, at a later stage, possibly a balanced electrolyte solution,
- management in hyperglycaemic hyperosmolar state involves:
  - **fluid therapy:** rapid infusion of 0.9% NaCl at ≥ 20 ml/kg body weight/hour, subsequent fluid portions given until peripheral perfusion improves, then replace fluid deficits over 24–48 hours with 0.45–0.75% NaCl; optimal sodium level reduction rate – 0.5 mmol/l/hour, blood glucose – 75–100 mg/dl/hour; if blood glucose lowers by > 100 mg/dl/hour in the initial hours of rehydration, consider adding a 2.5–5% glucose solution,
  - **insulin therapy:** include insulin when blood glucose does not decrease by at least 50 mg/dl/hour with fluids alone; initial insulin dose is 0.025–0.05 U/kg body weight/hour, then adjust the dose to decrease blood glucose by 50–75 mg/dl/hour,

Table 23.1. Biochemical criteria for the diagnosis of acute hyperglycaemic conditions in children and adolescents with diabetes

Parameter	DKA*			Hyperglycaemic-hyperemic state	Hypermolal DKA
	Light	Mild	Severe		
Plasma glucose levels [mg/dl]	≥ 200	≥ 200	≥ 200	> 600	> 600
pH of venous blood	< 7.3	< 7.2	< 7.1	> 7.25 arterial > 7.3	< 7.3
Bicarbonate concentration [mmol/l]	< 18	< 10	< 5	> 15	< 18
Ketosis β-hydroxybutyrate [mmol/l]	≥ 3	≥ 3	≥ 3	No or minor	≥ 3
Ketonuria	Moderate or high	Moderate or high	Moderate or high	No or minor	Moderate or high
Effective plasma osmolality [mOsm/kg/H_2O]	< 320	< 320	< 320	> 320	> 320

**All three biochemical criteria are required for the diagnosis of DKA: 1) hyperglycaemia ≥ 200 mg/dl, 2) venous blood pH < 7.3 or bicarbonate < 18 mmol/l, 3) ketonemia or ketonuria.*
DKA – diabetic ketoacidosis

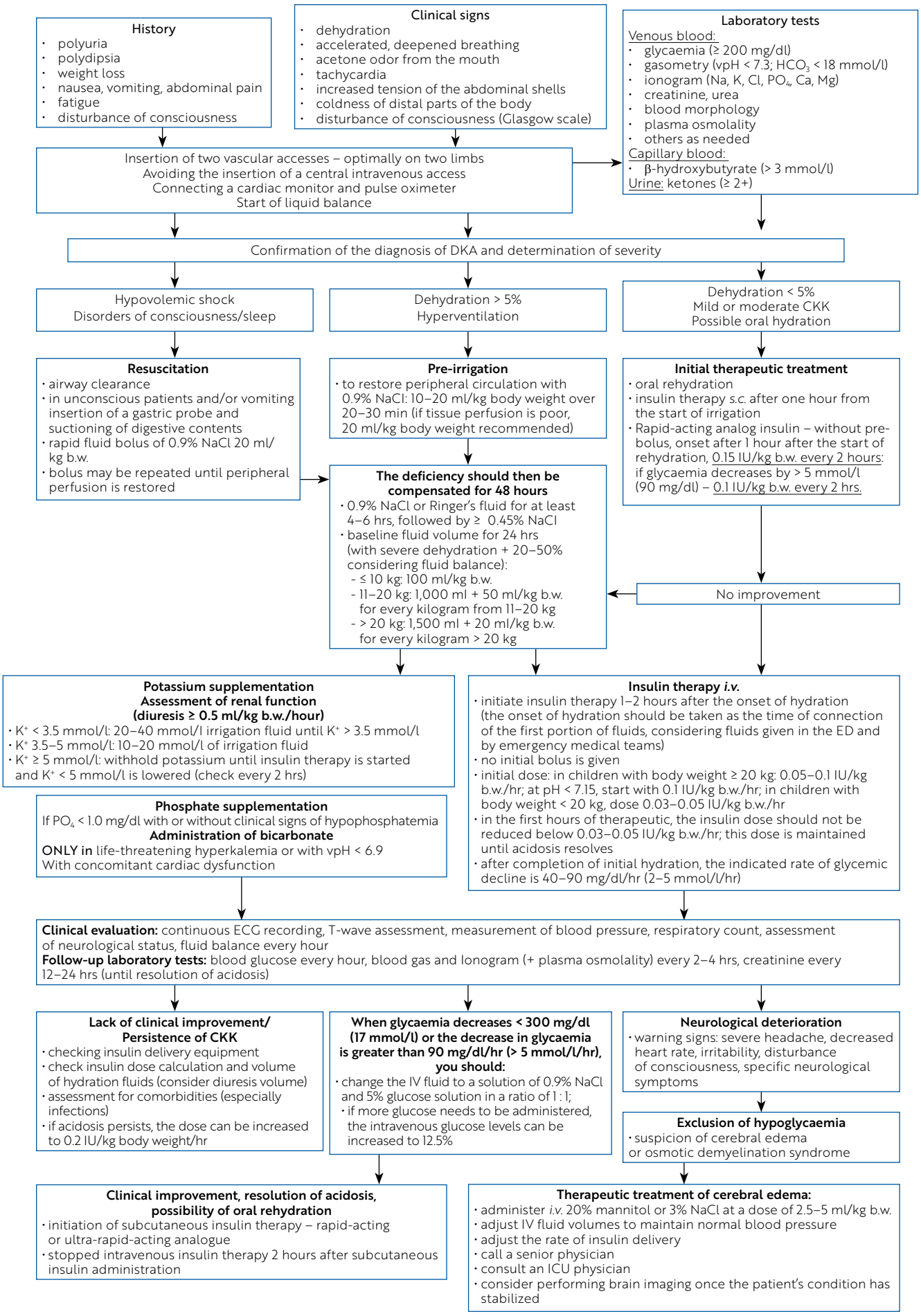
  - » **electrolytes:** deficiencies in sodium, potassium, phosphorus, and magnesium are greater than in DKA; begin potassium supplementation once renal function and urine output are stable; intravenous administration of 1 : 1 potassium phosphate and potassium chloride allow for adequate phosphorus supplementation; phosphorus administration can cause hypocalcaemia; consider magnesium supplementation if hypomagnesemia is detected,
- each centre treating children with diabetes should have a written DKA protocol, including local criteria for ICU admission, reflecting the diabetes department's capabilities, team training, and ICU availability,
- idications for intensive care within diabetes departments or ICUs include:
  - » severe DKA (pH < 7.1) with prolonged symptom duration, circulatory disorders, reduced consciousness,
  - » icreased risk of cerebral oedema (age < 5 years, rapidly developing acidosis, low pCO_2 levels, high blood urea nitrogen levels),
  - » hyperosmolar DKA.

2. Chronic complications:

- regular examinations are necessary for complication prevention (refer to Table 23.2),
- upon diagnosing any chronic complication, screening for other disorders such as diabetic kidney disease, retinopathy, neuropathy, and macroangiopathy is essential,
- for persistent albuminuria above normal levels, ACE inhibitors or AT1 receptor antagonists are indicated to slow progression; effectiveness requires monitoring albuminuria levels,
- to normalize blood pressure, ACE inhibitors or AT1 receptor antagonists are recommended; therapy effectiveness should be continuously monitored, targeting nocturnal blood pressure reduction as recorded during ambulatory blood pressure monitoring (ABPM),
- for lipid metabolism disorders, i.e., when LDL-C > 100 mg/dl (2.6 mmol/l), improved glycemic control and lifestyle modifications are required:
- for children > 8 years old, if previous lifestyle changes have not positively influenced the plasma lipid profile, or when other atherosclerosis risk factors are present with persistent LDL levels > 130 mg/dl, consider the possibility of using statins, and for LDL > 159 mg/dl (4.1 mmol/l), genetic testing for familial hypercholesterolemia is recommended.

VI. Management during procedures under sedation or general anaesthesia in children with diabetes

1. Collaboration between anaesthesiology, surgery, and diabetes teams is essential. Guidelines for perioperative management in children and adolescents with diabetes should be available in the hospital.
2. Preoperative metabolic control assessment is recommended before elective surgery. If HbA_{1c} > 8.5% and/or TIR < 40%, reschedule the procedure until glycemic balance is achieved (in emergencies, manage immediately before the procedure in the paediatric diabetes department).
3. Management depends mainly on the procedure type:



Rycina 23.1. Management of diabetic ketoacidosis (DKA) in children

Table 23.2. Recommendations for diabetes care for children and adolescents with diabetes

Therapeutic education of a child with diabetes and his parents/ guardians	At diagnosis and during the course of the disease; depending on the doctor's assessment or educational nurse
Nutrition education for children with diabetes and their parents/guardians	At diagnosis and during the course of the disease; depending on the doctor's assessment or educational nurse/dietitian
Psychological care of a child with diabetes and his/her parents/ guardians	At diagnosis and during the course of the disease, depending on the assessment of the doctor or educational nurse or psychologist and the needs reported by the patient
Type of diabetes diagnosis	At diagnosis and at revision of diagnosis: clinical picture, family history, assessment of insulin secretion, determination of antipancreatic antibodies, determination of insulin sensitivity*, genetic testing*
HbA_{1c}	3–4 times a year; may be determined less frequently in patients using CGM regularly
Total cholesterol, HDL-C, LDL-C, non-HDL-C, serum triglycerides	First evaluation after stabilization of blood glucose after the diagnosis of diabetes, followed by: · in type 1 diabetes > 10 years of life with normal values, an unbroken family history of cardiovascular disease and no other risk factors besides diabetes – at least every 3 years · in type 2 diabetes – every year
Abdominal ultrasound	At the diagnosis of diabetes
Weight and height monitoring	At each visit according to age- and gender-specific centile grids
Monitoring maturation according to Tanner scale	At the doctor's decision, at least once a year; evaluation of menstrual regularity
Blood pressure test	At each visit; in children < 7 years of age at least twice a year, in children > 10 years of age 24-hour ambulatory blood pressure monitoring (ABPM) – every 2 years or in case of elevated blood pressure values in casual measurements
Celiac disease testing	According to the ESPGHN guidelines for diagnosing celiac disease, screening tests should be performed at the time of diabetes diagnosis and then every 2 years in the absence of disease symptoms
Thyroid function assessment study/ diagnosis of disorders	At the time of onset: TSH, fT_4, anti-TPO and anti-TG (ultrasound if antibodies and/or thyroid dysfunction are positive), then every 2 years (at the doctor's discretion): TSH and anti-TPO, anti-TG
Investigations for chronic complications: creatinine concentration (calculation of eGFR), albuminuria, general urine examination, ophthalmologist consultation	Perform after glycemic stabilization, then: · in type 1 diabetes over 10 years of age or over 5 years of diabetes duration every 2 years · in type 2 diabetes – every year In the case of abnormal results, the frequency of subsequent examinations individualized according to needs
Liver steatosis test: ALT, AST, GGTP, abdominal ultrasound	In type 2 diabetes, after glycemic stabilization, and every year thereafter
Specialist consultations	According to general paediatric indications and with the revision of the diagnosis

**As needed.*

- minor procedure – lasts up to 2 hours, with a return to typical eating within 2–4 hours after completion,
- major procedure – lasts more than 2 hours, with no return to normal meal intake within 4 hours, planned hospital stay after the procedure over 24 hours.

4. During the procedure:

- blood glucose monitoring at least hourly until 4 hours post-procedure is necessary,
- CGM systems can be used if there are no contraindications,
- target blood glucose levels are 90–180 mg/dl (5–10 mmol/l); if post-procedure ICU stay is needed, maintain blood glucose levels at 140–180 mg/dl (7.8–10 mmol/l).

5. **Major procedure under general anaesthesia:**

- Preoperative day admission: perform laboratory tests (including blood glucose, serum sodium and potassium levels, blood gases, and if blood glucose > 250 mg/dl, assess ketonemia or ketonuria); consider evening intravenous insulin therapy or modifying the basal insulin dose,

- schedule the procedure for the morning,
- on the day of the procedure: start intravenous insulin therapy at least 2 hours before the procedure – dose dependent on blood glucose levels (see Table 23.3),
- approximately 2 hours before the procedure, intravenous fluid therapy should be initiated with 0.9% NaCl and 5% glucose, or 0.9% NaCl if blood glucose exceeds 250 mg/dl (14 mmol/l), at a rate of 4 ml/kg/h for body weight below 10 kg, 40 ml/h plus 2 ml/h per kilogram for body weight between 10 and 20 kg, and 60 ml/h plus 1 ml/h per kilogram for body weight over 20 kg, with a recommended maximum infusion rate of 80–100 ml/h,
- for significant blood glucose fluctuations and longer surgical procedures, monitor sodium and potassium levels perioperatively,
- maintain intravenous insulin and glucose-enriched fluid therapy until the patient awakens and can eat orally,
- for procedures with a high risk of infectious complications or ICU stays, maintain intravenous insulin therapy longer postoperatively.

6. **Minor procedure under general anaesthesia:**

- hospital admission on the day of the procedure is permissible, with necessary lab tests performed,
- maintain subcutaneous insulin therapy or apply intravenous insulin (same protocol as for major procedures),
- if the procedure is in the morning, consider reducing the evening dose of long-acting insulin analogue by 20–30% or reducing the basal rate in CSII to 70–90% if nighttime/morning blood glucose levels were low in the preceding days,
- on the day of the procedure, if using subcutaneous insulin: for MDI, administer the full dose of long-acting insulin (or reduced by 20–30% if recent low blood glucose before noon) or ultralong-acting insulin (without dose reduction); for CSII, maintain typical basal insulin delivery, and if low blood glucose levels are a tendency in the morning, reduce the dose to 70–90%.
- If blood glucose ≤ 70 mg/dl (3.9 mmol/l), administer an intravenous bolus of 10% glucose (2 ml/kg body weight of the patient) and check blood glucose after 15 minutes.
- If blood glucose > 180 mg/dl (10 mmol/l), consider administering a correction bolus calculated for a target blood glucose of 150 mg/dl.
- If blood glucose > 250 mg/dl for more than 2 hours, in addition to a subcutaneous correction bolus, assess ketonemia or ketonuria and consider starting intravenous insulin therapy.
- Start administering intravenous 0.9% NaCl with 5% glucose 1-2 hours before the procedure (or 0.9% NaCl if blood glucose > 250 mg/dl).

7. **Procedures in patients treated with continuous subcutaneous insulin infusion (CSII) via a personal insulin pump (PIP) – general remarks:**

- During intravenous insulin therapy, after disconnecting the infusion set from the body, remember to turn off insulin delivery from the PIP.
- Use of PIP during a minor procedure is possible, provided that the infusion set insertion is not in the procedure area and the anaesthesiologist accepts CSII and understands PIP operation basics.
- Protect the PIP subcutaneous insertion from damage during the procedure.

Table 23.3. Intravenous insulin therapy (solution: 1 unit of human crystalline insulin/1 ml of 0.9% NaCl) in major procedures in children and adolescents with diabetes (based on ISPAD Clinical Practice Consensus Guidelines, 2022)

Blood glucose level mg/dl [mmol/l]*	Insulin solution flow rate of 1 unit/ml (ml/kg/hour)
≤ 70** [≤ 3.9]	0 (+ 10% intravenous glucose)
71–89 [4.0–5.0]	0–0.01
90–109 [5.0–6.0]	Up to 0.02 (approximately 0.01-0.02)
110–143 [6.1–7.9]	0.025 (“base flow”)
144–215 [8.0–11.9]	0.05
216–270 [12.0–14.9]	0.075
> 270 [> 15.0]	0.1

Monitor capillary blood glucose: hourly, after changing insulin dose every 30 minutes, if blood glucose < 80 mg/dl (5 mmol/l) – every 15 minutes; when blood glucose drops to 90–110 mg/dl (5.0–6.0), reduce insulin flow by 50%.

***If glucose levels are ≤ 70 mg/dl (3.9 mmol/l), give an intravenous bolus of 10% glucose (2 ml/kg of the patient's body weight) and check the glycaemia after 15 minutes, if the glycaemia is still low – repeat the bolus of 10% glucose; if the glycaemia is still ≤ 70 mg/dl (3.9 mmol/l) after another bolus of glucose, you can additionally stop the intravenous insulin infusion, but only for 10–15 minutes.*

- A break in subcutaneous insulin infusion (in case of hypoglycaemia) should not exceed 30 minutes.
- Subcutaneous correction boluses should not be given more frequently than every 2 hours.
- When using CGM systems during procedures, the following should be ensured:
  - » verify that the devices used during the procedure will not interfere with CGM readings,
  - » avoid placing the sensor in the procedure/examination area,
  - » secure the sensor to prevent dislodgement during the procedure,
  - » provide the procedural team with continuous access to glucose concentration readings from the CGM.
- Currently, there is no evidence that advanced hybrid closed-loop systems can be safely used in the perioperative period. Some paediatric diabetology centers, based on their own experience, continue using these systems with their full functionality during certain minor procedures while adhering to the recommendations for using insulin pumps and CGM during the procedure.

VII. Recommendations for diabetes care for children and adolescents with diabetes (Table 22.1)

1. General recommendations:

- Every new case of diabetes should involve hospitalization at a specialized paediatric diabetes ward, followed by regular care at a paediatric diabetes clinic until transition to an adult diabetes clinic (transition principles in Annex 1):
  - » ensure 24-hour access to diabetes information for children and adolescents with diabetes and their caregivers,
  - » consider hospitalization with any disease decompensation (persistent hyperglycaemia, glucose fluctuations, recurring hypoglycaemia),
  - » during every hospitalization and clinic visit, analyse and interpret data from insulin delivery devices and glucose monitoring devices in close cooperation with the patient and their caregivers.

2. Therapeutic team:

- hospital care – for 10 paediatric diabetes beds: 2 full-time physicians (paediatric diabetologists or pediatric endocrinology and diabetology specialists, or in their absence, paediatricians, or endocrinologists with paediatric diabetes experience), 2 full-time nurses or diabetes educators, a full-time dietitian and psychologist, and a social worker on a 1/4-time basis. Intensive supervision wards require a dedicated nurse,
- outpatient care – a team covering 300 children and adolescents: 1 full-time paediatric diabetologist or pediatric endocrinology and diabetology specialist (or paediatricians or endocrinologists with paediatric diabetes experience), 1–2 full-time nurses or diabetes educators, a 1/2-time dietitian, and a 1/2-time psychologist.

The therapeutic team must collaborate closely with a child psychiatrist, social worker, and IT specialist, who may be part of the diabetes team.

3. Outpatient consultations:

- unlimited diabetes visits recommended every 6–8 weeks, at least 4 times a year,
- some outpatient visits can be replaced with video consultations or teleconsultations, provided that it is possible to remotely retrieve and transmit the following data to the clinic:
  - » from glucose monitoring devices,
  - » from insulin delivery devices or applications serving as electronic self-monitoring diaries,
- personal clinic visits should occur at least once every 6 months despite teleconsultations,
- advise clinic visits for patients with poorly controlled diabetes or additional health issues,
- recommended visit duration: 30 minutes for data analysis,
- educational, dietary, and psychological consultations should be separate from medical consultations and can also be conducted electronically,
- additionally, the therapeutic team oversees educational materials and activities for children with diabetes in educational institutions and camps/workshops.

4. Clinic and ward equipment:

- equipment: insulin pens, personal insulin pumps, glucometers, continuous glucose monitoring devices, blood pressure Holter monitors, ophthalmoscopes, monofilaments, food scales, and a computer system for data reading and printing,
- facilities and teaching aids for diabetes education, dietary counselling, and psychological care,
- ward: at least 1 intensive medical supervision station per 10 diabetes beds equipped with a pulse oximeter, EKG monitor, oxygen access, and an ultrasound machine for vascular flow assessment.

VIII. Child with diabetes in educational and care facilities

1. Collaboration among the diabetes treatment team, educational staff, school nurse, and family aims to ensure the child's safety at school and prevent stigmatization of children with diabetes:
- after diagnosis, provide educational staff with written information about diabetes, emergency care, and contact numbers for parents, doctor, and educational nurse,
- inform school staff about the child's need to have a mobile device with apps for CGM, insulin pumps, integrated systems, and therapy support (e.g., for carb counting),
- train educational staff in diabetes self-care,
- the nurse/staff responsible for caring for a child with diabetes at school should be trained in the use of a glucometer, CGM system, insulin pen or personal insulin pump, and glucagon administration,
- ensure that the facility has glucose and glucagon supplied by caregivers,
- diabetes is not a reason for individualized education or exemption from any activities (e.g., physical education, school trips).

2. Responsibilities of educational staff:
- immediate provision of diabetic first aid in life-threatening conditions,
- help children with newly diagnosed diabetes return to and integrate with the school environment quickly and safely,
- understand basic diabetes self-care,
- enable self-monitoring at educational facilities for all age groups; younger children may require staff supervision,
- allow children to use glucose monitoring and insulin administration devices during school activities, including tests and exams,
- work closely with the diabetes treatment team and child's caregivers.

IX. Travel:

- the child with diabetes and their caregivers should inform trip organizers about the condition, treatment, mealtimes, emergency care, and provide contact numbers for the diabetes care team,
- for international trips, prepare a certificate of illness in English,
- secure insulin, glucagon, glucose, glucometer with test strips, insulin pens, spare equipment for insulin pumps, and CGM for the journey in carry-on luggage.

X. Physical activity, sports participation

1. Children and adolescents with diabetes:
- should be encouraged to achieve at least 60 minutes of moderate to intense physical activity daily,
- should regularly participate in physical education classes,
- can participate in sports, including competitive, like non-diabetic children.

2. The safe blood glucose range to start physical activity is 90–250 mg/dl (up to 270 mg/dl per ISPAD), and during exercise, strive for 90–180 mg/dl.
3. Management depends on:
- type, intensity, and duration of planned physical activity.
- method of therapy and blood glucose self-monitoring.
- ability to plan physical activity in advance.

4. Physical activity and sports guidelines are presented in Chapter 7 and Annex 6.

XI. Career choice:

- emphasize education for youth with diabetes to achieve the best possible education,
- the diabetes care team's role is to assist young people with diabetes in choosing a career by assessing their health status, presence of complications, intellectual and psychological abilities.

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24. Management of Diabetes in Pregnancy

CHAPTER HIGHLIGHTS

- Planning pregnancies in women with diabetes reduces adverse events for mother and child and should be part of standard diabetes care for reproductive-aged women. [**A**]
- Contraception using barrier methods or hormonal contraceptives should be utilized by women with diabetes as part of pregnancy planning to prevent developmental defects, starting from adolescence. [**A**]
- In Poland, universal screening for hyperglycaemia in pregnancy is in place, with recognition criteria according to WHO guidelines. [**A**] Screening is recommended at the first pregnancy visit and between weeks 24–28.
- Satisfactory glycemic control can often be achieved in many women with gestational diabetes through behavioural management, and insulin pharmacotherapy should be introduced if therapeutic goals are not met. [**A**]
- General principles of diabetes treatment in pregnancy
  - Hyperglycaemia in pregnancy increases risks for the mother and foetus; thus, optimization of glycemic control is essential in both pregestational diabetes and hyperglycaemia first detected during pregnancy. [**A**]
  - Self-monitoring of glucose is recommended as a primary way of assessing metabolic control in all types of pregnancy-complicating diabetes. Target glucose levels for self-monitoring with a glucometer are fasting and before meals: 70–90 mg/dl (3.9–5.0 mmol/l); 1-hour post-meal: 110–140 mg/dl (6.1–7.8 mmol/l), 2-hour post-meal: 100–120 mg/dl (5.5–6.7 mmol/l), overnight 2:00–4:00 am: 70–90 mg/dl (3.9–5.0 mmol/l). [**A**]
  - Continuous Glucose Monitoring (CGM) systems and achieved target glucose levels can help reach treatment goals in patients with pregestational diabetes. [**B**]
  - All pregnant women with pregestational diabetes are advised to use CGM, with type 1 diabetes women preferring integrated pump therapy systems with the highest level of automation.
  - Consider CGM systems for all pregnant women with hyperglycaemia, especially those treated with insulin therapy or with unstable glucose levels, to achieve better glycemic control.
  - HbA_{1c} measurement is a tool for assessing glycemic control in women with pregestational diabetes. The recommended glucose levels should be as close to normal safe levels as possible, aiming for an HbA_{1c} < 6.5% (48 mmol/mol) when planning pregnancy and in the first trimester, and < 6.0% (42 mmol/mol) thereafter. [**B**]
  - In addition to good glycemic management, proper nutrition and concurrent conditions and medications must be considered. [**B**]
  - Insulin is the only antihyperglycemic medication recommended during pregnancy. Current knowledge does not support the use of other glucose-lowering drugs, whether oral or injectable. [**A**]
  - Metformin use is only permitted if it provides the recommended metabolic balance in women with type 2 diabetes and polycystic ovary syndrome (PCOS) and insulin resistance in the preconception period. It should be discontinued by the end of the first trimester at the latest.
  - Due to metformin crossing the placenta and the lack of definitive long-term observational results in children exposed to metformin in utero, insulin remains the pharmacological treatment of choice for hyperglycaemia in pregnancy if dietary therapy is ineffective. Recent meta-analysis showed that metformin exposure in pregnancy with GDM resulted in a portion of newborns with lower birth weight and accelerated postnatal growth, leading to higher BMI in childhood. [**B**]
- Patients after GDM should be screened for diabetes before subsequent pregnancies and treated if diagnosed to reduce the risk of developmental defects in offspring. [**E**]

Pregnancy planning in all women with diabetes significantly impacts the course of the disease, reducing the occurrence of adverse events in both the mother and the foetus/newborn. In addition to focusing on achieving glycemic goals, standard preconception care should emphasize proper nutrition, diabetes education, and screening for coexisting diseases and complications of diabetes. Early detection of glucose intolerance in women with obesity of reproductive age is recommended. It is recommended to perform a 75 g OGTT before planning pregnancy in women without a diagnosed diabetes. Pregnancy should be planned in women with obesity.

Diabetes in pregnancy can occur as:

1) pregestational diabetes mellitus (PGDM) — when a woman already suffering from diabetes (regardless of the type) becomes pregnant,
2) hyperglycaemia first diagnosed during pregnancy.

I. Contraception

Women planning pregnancy should be informed that the risk of pregnancy complications increases with metabolic imbalance, presence of organ complications, and the duration of diabetes.

Pregnancy in a woman with poorly controlled diabetes exceeds the risk associated with any contraceptive method used.

Patients should be informed that diabetes per se is not a contraindication to hormonal contraception. Patients should be assessed for standard contraindications to hormonal contraception and should be able to choose their preferred effective method of contraception, being aware of the risk associated with unplanned pregnancy. In patients with diabetes lasting more than 20 years or with microvascular complications (nephropathy, retinopathy, neuropathy), the use of intrauterine devices or progestogen-only preparations is recommended.

The use of estrogen-progestogen preparations containing less than 35 µg of ethinylestradiol, preferably 15 and 20 µg, which have a minor impact on carbohydrate and lipid metabolism, is recommended. The preferred progestogen component is levonorgestrel or norethisterone due to their weakest prothrombotic effect. The intrauterine device with a progestogen inserts (IUDG) is a particularly recommended method of contraception for obese women over 35 years of age and in the case of vascular complications.

II. Model of care for pregnant women with diabetes

1. All women with diabetes during pregnancy planning, during pregnancy, and during the postpartum period should remain under the care of a diabetological-obstetric (perinatological) team experienced in this field. Women with type 2 diabetes receiving oral medications already in the pregnancy planning period require insulin therapy to achieve proper glycemic control. The use of metformin is only allowed in women with type 2 diabetes in the preconception period in therapeutic doses in situations where it ensures recommended metabolic control. After conception, it should be discontinued until the end of the first trimester of pregnancy.
2. SGLT-2 inhibitors, GLP-1 receptor agonists, and GIP/GLP-1 receptor agonists currently do not have studies allowing for their use during pregnancy and should not be used during pregnancy planning and in the reproductive period if the patient does not use contraception.
3. Every doctor caring for a patient with type 2 diabetes or obesity should regularly discuss procreation plans with her and inform about the necessity of pregnancy planning due to the presence of complex risk factors for obstetric failure in this population of women, as well as due to often used antihypertensive drugs and statins (necessity to modify treatment).

The goal of such management is to:

- optimize diabetes treatment,
- assess and possibly treat chronic complications of diabetes,
- diabetic education, including dietary,
- recommendation to quit smoking,
- thyroid function diagnostics (excluding hypothyroidism) - the upper normal ranges for TSH should be considered as values: 2.5 µIU/ml in the first trimester of pregnancy and 3 µIU/ml in the second and third trimesters of pregnancy,
- during pregnancy, visits to a diabetologist should take place at least once a month, in justified cases every 2–3 weeks; this is due to, among other things, changing insulin requirements and the need to monitor body weight, kidney function, vision, and blood pressure values,
- in women with pregestational diabetes, regardless of the type, an ophthalmological check should be carried out before pregnancy, or at the latest in the first trimester of pregnancy,

then repeated in each trimester; routine vision checks are not performed in women with GDM,
- in the case of gestational hypertension, treatment should be initiated at blood pressure values > 140/90 mm Hg,
- in women with diabetes and chronic hypertension before pregnancy or with renal complications, the goal is to maintain systolic pressure < 135 mm Hg and diastolic pressure < 85 mm Hg (methyldopa is the first-line drug in pregnancy),
- in women with pre-gestational diabetes, it is recommended to use acetylsalicylic acid at a dose of 1 mg/kg body weight (100–150 mg/day) from the 12th to the 36th week of pregnancy (to prevent preeclampsia; initiation between the 12th and 16th weeks of pregnancy). The decision to implement this approach is made by the obstetrician.

4. Pregnancy is not recommended for women with diabetes in the following clinical situations:
- nephropathy manifested by a creatinine clearance < 40 ml/min,
- proliferative retinopathy not responding to treatment,
- advanced ischemic heart disease not responding to treatment,
- hypertrophic cardiomyopathy or severe impairment of left ventricular function (LVEF < 30%, NYHA III/IV),
- history of peripartum cardiomyopathy with any residual impairment of left ventricular function,
- autonomic neuropathy affecting the heart's conduction system or the gastrointestinal tract.

The final decision regarding procreation belongs to the patient; however, she must be informed by specialists in the field about the health and life risks associated with pregnancy in these cases.

It does not seem that pregnancy is associated with a postpartum worsening of the course of chronic complications of diabetes. A woman with diabetes may freely plan the number of offspring as long as the contraindications listed above are not present.

III. Criteria for diagnosis and classification of hyperglycaemia first recognized in pregnancy.

All pregnant women should be screened for glucose tolerance disorders as soon as possible after pregnancy is confirmed. Pregnant women at risk should undergo an OGTT (described in Chapter 1) at the first visit, while others should have a fasting glucose test. If abnormal glucose values are not

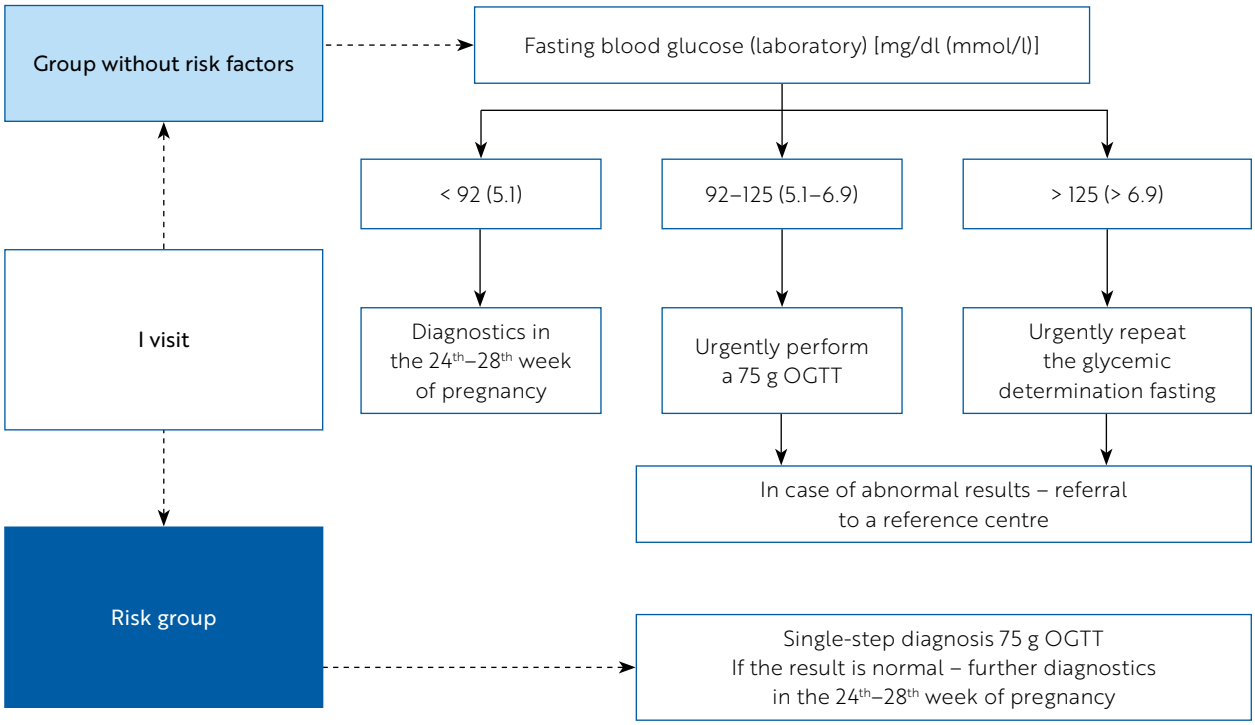

Figure 24.1. Schematic for the diagnosis of carbohydrate metabolism disorders in pregnant women

NOTE: A single fasting blood glucose in a pregnant woman in the first trimester of pregnancy > 92 mg/dl, and < 125 mg/dl cannot be the basis for the diagnosis of hyperglycaemia in pregnancy.
OGTT – oral glucose tolerance test

found (see Figure 24.1), the diagnostic test should be repeated between the 24th and 28th week of pregnancy or when the first symptoms suggesting diabetes occur. Diagnosis in the group without risk factors and with normal glucose in the first examination of pregnancy should be conducted between the 24th and 28th week of pregnancy and is a one-step process, consisting of performing an OGTT.

Hyperglycaemia first recognized during pregnancy should be diagnosed and classified according to WHO recommendations:

- diabetes in pregnancy – when any of the following conditions are met:
  - fasting glucose ≥ 126 mg/dl (7.0 mmol/l) or
  - glucose in the 2nd hour of OGTT ≥ 200 mg/dl (11.1 mmol/l) or
  - random glucose ≥ 200 mg/dl (11.1 mmol/l), accompanied by clinical symptoms of hyperglycaemia.
- gestational diabetes (GDM) — when at least one of the criteria listed in Table 24.1 is met.

After delivery, glucose levels normalize in most women; however, all should be screened for glucose tolerance disorders, as having diabetes during pregnancy is a risk factor for overt diabetes in later years. An OGTT is recommended 6–12 weeks postpartum, followed by an annual screening test. Before planning another pregnancy, a glucose tolerance test (OGTT) should be performed. Women with a history of gestational diabetes should be considered a high-risk group for diabetes and cardiovascular diseases (management: see Chapter 2).

IV. Multidisciplinary, integrated management in pre-pregnancy diabetes and hyperglycaemia during pregnancy

Hyperglycaemia during pregnancy increases the risk of obstetric complications for the pregnant woman and the developing foetus and affects the child's further development. Therefore, therapy should aim to achieve glycemic values found in healthy pregnant women. At the current stage of knowledge, the following self-monitoring of blood glucose (SMBG) targets are considered optimal during pregnancy regardless of the type of diabetes:

- fasting and before meals: 70–90 mg/dl (3.9–5.0 mmol/l),
- glucose in the 1st hour after starting a meal: 110–140 mg/dl (6.1–7.8 mmol/l), in the 2nd hour after starting a meal: 100–120 mg/dl (5.5–6.7 mmol/l), with values between 2.00–4.00 AM ranging from 70 to 90 mg/dl (3.9–5.0 mmol/l).

Pregnant women should perform self-monitoring of blood glucose after receiving appropriate training from a nurse experienced in diabetes care. The frequency and timing of glucose measurements should depend on the severity of carbohydrate metabolism disorders and the type of treatment used.

Women with type 1 diabetes, as well as women with type 2 diabetes and gestational diabetes treated with insulin, are advised to use CGM.

It is recommended that for pregnant women with type 1 diabetes, CGM glucose values > 140 mg/dl (7.8 mmol/l) should account for less than 25% of daily measurements, values between 63–140 mg/dl (3.5–7.8 mmol/l) should be > 70% of measurements, values < 63 mg/dl (3.5 mmol/l) should be less than 4%, and values < 54 mg/dl (3.0 mmol/l) should be less than 1% of measurements. For pregnant women with type 2 diabetes and gestational diabetes, more than 90% of measurements should be within the target range of 63–140 mg/dl (3.5–7.8 mmol/l).

The effectiveness and safety of AID systems during pregnancy have been proven, particularly with CamAPS and 780G. Recommended glucose target settings for automated systems: during the planning phase: target 100 mg/dl (5.5 mmol/l) in 780G, 90 mg/dl (5.0 mmol/l) in MyLoop; during pregnancy: target 100 mg/dl (5.5 mmol/l) in 780G, 80 mg/dl (4.4 mmol/l) in MyLoop; and during breastfeeding: target 120 mg/dl (6.7 mmol/l) in 780G, 110–120 mg/dl (6.1–6.7 mmol/l) in MyLoop.

HbA_{1c} levels in women with pregestational diabetes should be measured every 6 weeks, aiming for values < 6.5% (< 48 mmol/mol) in the first trimester and < 6.0% (< 42 mmol/mol) in subsequent trimesters. If these targets cannot be achieved without significant hypoglycaemic episodes, more flexible targets should be considered based on clinical experience and individualized care. However, HbA_{1c} values should not exceed 7%. There is insufficient evidence to support the use of HbA_{1c} as a monitoring tool for metabolic control in gestational diabetes.

Table 24.1. Criteria for the diagnosis of gestational diabetes mellitus based on the results of the oral glucose load test according to IADPSG 2010 and WHO 2013

Plasma glucose levels		
	[mg/dl]	[mmol/l]
Fasting	92–125	5.1–6.9
60th minute	≥ 180	≥ 10.0
120th minute	153–199	8.5–11.0

HbA_{1c} should be measured at the time of gestational diabetes diagnosis.

1. Recommendations for proper nutrition in pregnancy:
- 40–50% carbohydrates (about 180 g of carbohydrates/day) – preference for low glycemic index carbohydrates in the diet,
- 30% protein (1.3 g/kg body weight/day),
- 20–30% fats (including < 10% saturated fats),
- the number of calories should depend on body weight, height, physical activity, and age – the average daily caloric requirement is about 30 kcal/kg of appropriate body weight, i.e., 1500–2400 kcal,
- for overweight patients, a diet of 25–30 kcal/kg body weight is recommended,
- due to the very restrictive target glycemic values, pregnant women should consume consistent amounts of carbohydrates in meals at constant times to adjust insulin doses and avoid both hyperglycaemia and hypoglycaemia,
- control of weight gain during pregnancy is necessary, as excessive weight gain in pregnant women with diabetes is associated with excessive foetal growth (see Table 24.2),
- fasting urine ketone testing may be useful for identifying women who severely restrict carbohydrates in their diet to control blood glucose levels,
- the use of artificial sweeteners is permitted, except for saccharin, which crosses the placenta and its impact on the foetus has not been fully understood (see Chapter 6.),
- during the pregnancy planning period, it is recommended to implement supplementation with folic acid (min. 0.4 mg/day) for at least 6 weeks before becoming pregnant and to continue until the 12th week of pregnancy.

Table 24.2. Recommendations for weight gain during pregnancy

Pre-pregnancy body mass index (BMI) [kg/m²]	Recommended weight gain [kg]	Recommended weight gain in the second and third trimester [kg/week]
< 18.5	12.5–18.0	0.51 (0.44–0.58)
18.5–24.8	11.5–16.0	0.42 (0.35–0.50)
25.0–29.9	7.0–11.5	0.28 (0.23–0.33)
≥ 30	5.0–9.0	0.22 (0.17–0.27)
Assuming weight gain in the first trimester of pregnancy 0.5–2.0 kg		

2. Physical exertion – unless contraindicated, moderate-intensity aerobic physical activity is recommended.
3. Insulin therapy.

In pre-pregnancy diabetes:
- human insulins have long been used in pregnancies complicated by diabetes, and their safety has been proven; the safety of using insulin analogues lispro, glargine, and ultra-rapid-acting aspart has been demonstrated in a series of observational studies, and insulin aspart, detemir, and degludec also in randomized trials; none of the studies have shown insulin analogues to cross the placenta,
- intensive insulin therapy using multiple injections, or a personal insulin pump is recommended; if possible, this treatment should be conducted in diabetes centres with experience in treating diabetes in pregnancy, Intensive insulin therapy using multiple daily injections or a personal insulin pump, preferably with automation in combination with a CGM system, is recommended. This treatment should be carried out in diabetology centres experienced in managing diabetes during pregnancy,
- therapy using pumps is best initiated at the planning stage or in early pregnancy (up to the 12th week); exceptionally later in a patient who cannot achieve satisfactory metabolic balance by multiple injections,
- in early pregnancy, insulin sensitivity may slightly increase, and thus, incidents of hypoglycaemia may occur at the previously used insulin dose,
- from the 16th week of pregnancy, insulin resistance increases, which requires regular, adequate increases in insulin dose according to demand.

Insulin therapy in hyperglycaemia diagnosed during pregnancy:
- after exhausting all possibilities of behavioural therapy, the initiation of insulin therapy is recommended,
- the recommended method is intensive insulin therapy using multiple injections or a personal insulin pump,
- due to increasing insulin resistance, around the 16th week of pregnancy, the demand for insulin begins to significantly increase, and for this reason, the total daily insulin requirement increases by about 5% weekly until the 36th week of pregnancy; usually, this leads to a doubling of the daily dose of insulin compared to pre-pregnancy requirements,

- the demand for insulin sharply decreases after delivery, and most women with hyperglycaemia in pregnancy can discontinue insulin while maintaining glycemic control.

4. Oral antihyperglycemic drugs are currently not recommended for the treatment of diabetes in pregnancy. For women using oral antihyperglycemic drugs, it is recommended to start insulin therapy during pregnancy planning or as soon as pregnancy is diagnosed.

Metformin does not have a teratogenic effect on the foetus. Although many beneficial effects have been shown during pregnancy for patients with GDM (less weight gain, a lower percentage of newborns with excessive growth), its use is **not recommended for pregnant women** due to the lack of long-term data on children's development. It is currently recommended to discontinue metformin in women treated for PCOS no later than the end of the first trimester.

If the patient refuses insulin therapy and wants to use metformin, it should not be unconditionally used in pregnant women with hypertension, pre-eclampsia, or in the case of foetuses with intrauterine growth restriction, due to the possibility of further growth restriction or acidosis under conditions of placental insufficiency.

5. Education system

- clinical issues – sessions are conducted by a doctor, nurse, dietitian knowledgeable in personal insulin pump therapy,
- technical issues related to the operation of a personal insulin pump – sessions are conducted by a nurse or doctor who has a training certificate in technical training, or an employee of the company producing personal insulin pumps,
- the education program is implemented according to the training card, which is documentation of the treatment course, also using digital techniques,
- implementation of therapy is possible when the patient has mastered clinical and technical knowledge concerning CSII at a basic level (understanding the principles of therapy, technical operation relating to the main functions of the pump).

6. Breastfeeding should be widely promoted and recommended for women with pre-pregnancy diabetes and hyperglycaemia during pregnancy, unless there are other contraindications.
7. Oral medications and lactation – available literary and clinical data show that metformin passes into human milk in very small amounts and does not exceed 1% of the maternal concentration; women with type 2 diabetes can therefore safely use metformin during lactation; the safety of using other antihyperglycemic drugs has not been sufficiently studied.

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25. Older Adults: Diabetes in People over 65 Years of Age

CHAPTER HIGHLIGHTS
• When initiating diabetes therapy in individuals over the age of 65, therapeutic goals should be individually assessed depending on the patient's health status, diabetes complications, cognitive abilities, and socio-economic conditions. [**B**]
• One of the main goals of diabetes treatment in individuals over the age of 65 is to achieve good metabolic control and prevent hypoglycaemia by individualizing therapeutic goals and avoiding medications that are associated with a high risk of hypoglycaemia. [**B**]
• In individuals over the age of 65 without significant complications, the therapeutic goal may be similar to that in the younger adult population. [**C**]
• In intensifying treatment, target values for glycaemia, blood pressure, and lipids should be considered, considering the specifics of the age group and coexisting conditions. [**B**]

I. The prevalence of diabetes in the population over the age of 65 reaches 25–30%.

II. Symptoms of hyperglycaemia in patients over the age of 65 may be less severe than in younger individuals, which can delay the diagnosis of the disease.

III. In elderly patients with diabetes, life expectancy is significantly shorter; therefore, when determining the treatment approach, it should be remembered that preventing complications that develop after several or more years of illness is less important than in younger people.

IV. Goals of diabetes treatment in individuals over the age of 65

- The paramount goal of treating older individuals with diabetes is to improve or at least maintain the current quality of life, with a crucial focus on avoiding hypoglycaemia while simultaneously reducing the symptoms of hyperglycaemia.
- If a person with diabetes over the age of 65 does not have significant complications and comorbid diseases, while pursuing general treatment goals, one should aim for gradual diabetes control, adopting a target HbA_{1c} value of ≤ 7%, provided that this does not increase the risk of hypoglycaemia.
- For elderly patients with long-standing diabetes and significant complications of macroangiopathy (history of heart attack or stroke), the target HbA_{1c} value is 8.0–8.5%.
- Conducting diagnostic tests for diabetes complications, preventing their progression, and recommending appropriate treatment.
- Treating comorbid diseases to reduce functional impairment and improve the quality of life.

V. Physical activity

After initially determining the individual risk and capacity of the patient, it is recommended to encourage outdoor physical activity that starts slowly and ends slowly, avoiding exercises that are straining and holding breath, with attention to the risk of injury, especially the risk of developing diabetic foot syndrome.

VI. Dietary recommendations

There are no specific recommendations related to age, and diet modification is less effective due to established eating habits.

VII. Oral antihyperglycemic drugs, injectable GLP-1 and GIP/GLP-1 receptor agonists

The use of antihyperglycemic drugs in individuals over the age of 65 should follow the principles presented in Chapter 11. Drug groups with a low risk of hypoglycaemia should be preferred:

- metformin – special caution should be exercised in patients with an eGFR of < 45 ml/min/1.73 m^2,
- DPP-4 inhibitors, SGLT-2 inhibitors, GLP-1 receptor agonists, GIP/GLP-1 receptor agonists, PPAR-γ agonists – there are no specific contraindications for use in individuals over the age of 65; these drugs may be particularly beneficial in this age group due to the negligible risk of hypoglycaemia; PPAR-γ agonists should not be used in individuals with heart failure and a high risk of fractures,
- sulfonylurea derivatives – the use of this group of drugs should be particularly cautious in elderly individuals with diabetes due to the risk of hypoglycaemia. This group of drugs should not be used in individuals with frailty syndrome.

VIII. Insulin therapy:

- there are no specific indications or contraindications for insulin therapy in older adults,
- one should not delay starting insulin if indicated, preferring simple models of insulin therapy (see Chapter 12),
- when starting or modifying insulin therapy, choose preparations that have the lowest risk of hypoglycaemia,
- age over 65 is not a contraindication for the use of intensive insulin therapy,
- in individuals with type 1 diabetes and in those with type 2 diabetes using insulin, the preferred method of glucose level control is the use of CGM systems,
- if an individual over the age of 65 has frailty syndrome, cognitive impairments, or difficulties in implementing the insulin therapy scheme, efforts should be made to simplify it, using non-insulin drugs (see Chapters 11 and 12),
- in some elderly patients (> 80 years), administering small doses of short-acting insulin preparations or rapid-acting analogues before main meals may be effective, without the simultaneous use of long-acting (basal) insulin,
- in situations where the volume of the meal is unpredictable (e.g., patients with lack of appetite, advanced dementia), it may be advisable to administer a rapid-acting insulin analogue immediately after the meal in a dose adjusted to it.

IX. Diabetic education

- Diabetic education should include both patients and their caregivers.

X. Antihypertensive treatment

- Age does not constitute a criterion for the choice of a specific class of antihypertensive drugs.
- The benefits of antihypertensive treatment in individuals over the age of 65 are comparable to those obtained in younger individuals.

XI. Lipid-lowering treatment:

- Despite the lack of objective data, it should be assumed that the benefits of lipid-lowering treatment both in primary and secondary prevention observed in younger individuals also apply to patients over the age of 65.

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26. Diabetes Care before Surgery

Prepared in collaboration with Prof. Wojciech Szczeklik, MD, PhD and Dorota Studzińska, MD, PhD.

CHAPTER HIGHLIGHTS
· Elective surgical procedures in individuals with diabetes should be postponed when the HbA_{1c} exceeds 8.5%. [**B**]
· In individuals treated with insulin, insulin therapy must not be discontinued before surgery. In most individuals with well-controlled type 2 diabetes, non-insulin medications can be continued until the day of surgery, except for SGLT2 inhibitors, which should be stopped three days before surgery. [**B**]
· In individuals with diabetes in critical condition, receiving parenteral nutrition, insulin treatment administered intravenously in a dose dependent on glycaemia is recommended. [**C**]
· Glycemic monitoring in diabetic individuals in the perioperative period reduces the risk of complications and death. [**B**]
· Recommended target glycemic values in the perioperative period are 100–180 mg/dl. [**C**]

I. Examinations that should be performed before a planned surgical procedure:

- daily glycemic profile – 7 measurements within a day and around 3:00 AM if treated with insulin; not necessary if the patient is using a continuous glucose monitoring system,
- HbA_{1c} value,
- blood morphology,
- serum concentrations: creatinine, electrolytes (Na^+, K^+), aminotransferase activities (AST, ALT),
- INR, APTT indexes,
- acid-base balance (blood gas analysis) in case of suspected disturbances,
- general urine test,
- resting EKG (see Note 1),

NOTE 1: In patients at high and very high cardiovascular risk, as well as when planning extensive procedures (e.g., surgeries on abdominal or iliac vessels, cardiac surgeries), expanded non-invasive diagnostics should be performed (e.g., exercise testing, echocardiography, Holter ECG monitoring). According to the current ESC guidelines, expanded diagnostics primarily concern patients undergoing high-risk procedures or those with multiple severe comorbidities.

NOTE 2: A surgical procedure in the so-called one-day system can be conducted in diabetic pa-

tients with good metabolic control, treated with intensive insulin therapy, and in patients with type 2 diabetes, where there is no need for periodic insulin treatment in the perioperative period. Withholding an antihyperglycemic drug on the day of the procedure will not cause an increase in glycaemia > 180 mg/dl (10 mmol/l).

II. Management in the period before a planned surgical procedure

1. A patient with diabetes requiring periodic insulin treatment should be admitted to the hospital 1–2 days before a planned surgical procedure, depending on the clinical situation.
2. A planned procedure should be postponed in a patient with inadequate metabolic control, defined as persistent blood glucose levels > 250 mg/dl (13.9 mmol/l) in the daily profile, HbA_{1c} > 8.5%, and/or the presence of glucosuria accompanied by acetonuria and/or ketonemia.
3. If a patient with type 2 diabetes treated with two or three antihyperglycemic drugs will not be consuming meals on the day of the procedure or will undergo a large operation with an increased risk of hemodynamic instability, it is recommended to discontinue current therapy and apply periodic insulin treatment.
4. The recommended model for periodic insulin treatment is multiple injections (basal bolus).
5. Daily insulin dose – 0.3–0.7 IU/kg body weight; 50–60% of the daily dose — short-acting (rapid-acting) insulin administered before main meals according to the scheme: 50–20–30% of the daily dose of short-acting (rapid-acting) insulin.
6. 40–50% of the total daily insulin dose—so-called basal insulin: a long-acting analogue administered once daily, usually in the evening, or an intermediate-acting insulin (NPH) given in two injections—at 7:00–8:00 AM (40%) and 10:00–11:00 PM (60%). A well-trained and metabolically stable patient with diabetes undergoing intensive insulin therapy independently adjusts insulin doses according to current needs. Therefore, in the hospital, they should not be deprived of this ability or subjected to rigid, non-adjustable dosing regimens.
7. Individuals treated with a personal insulin pump should maintain their current therapy until the day of surgery and, in justified cases, throughout the entire hospitalization period.
8. If preparation for surgery requires a strict diet on the day (days) preceding the operation, instead of a meal, it is recommended to use a 500 ml intravenous infusion of a 10% glucose solution with 12 IU of short-acting (rapid-acting) insulin and 10 mmol of KCl. The potassium dose should be modified depending on the concentration of potassium in the blood.
9. Achieving glycemic control: in the perioperative period, blood glucose levels should be monitored and should be maintained within the safe range of 100–180 mg/dl (5.6–10.0 mmol/l).
10. Notify the surgical-anesthesiological team of complications that increase the surgical risk (heart or kidney diseases, neuropathy, proliferative retinopathy).
11. The principles of using antihyperglycemic drugs in the perioperative period are presented in Table 26.3.

NOTE 3: Periodic insulin therapy is not required for patients undergoing low-risk surgeries with a short, expected duration (e.g., tooth extraction, abscess incision, minor ambulatory amputation, cataract surgery, arthroscopy, or colonoscopy under anaesthesia), provided that the preparation for the procedure does not require a change in the usual dietary regimen. If food intake needs to be withheld for more than 12 hours due to the surgical procedure, an intravenous infusion of glucose solution with insulin and potassium is recommended [500 ml of 10% glucose solution with 12 units of short-acting (rapid-acting) insulin and 10 mmol of KCl], administered at a rate of 100–150 ml/hour. The insulin and potassium doses should be adjusted based on blood glucose and potassium levels.

III. Management on the day of surgical procedure:

1. An intravenous infusion of glucose, insulin, and potassium under glycemic control should be applied:

- algorithm 1 – for individuals with absolute insulin deficiency, a separate continuous intravenous insulin infusion is recommended (solution concentration: 1 IU of short-acting/rapid-acting insulin in 1 ml of 0.9% NaCl) and a glucose solution (5–10%) using infusion pumps; to balance 1 g of exogenous glucose, 0.2–0.3 IU of insulin is needed; if during the procedure the glycemic value increases by 30–50 mg/dl above 180 mg/dl, the insulin infusion rate should be increased by 1–2 IU/hour; in case of glycaemia exceeding 250 mg/dl (13.9 mmol/l), the intravenous glucose solution should be stopped and resumed only after lowering the blood glucose concentration to

180 mg/dl (10 mmol/l); at the same time, it is recommended to increase the rate of intravenous insulin infusion; this procedure should be continued until oral feeding is resumed; during the intravenous insulin infusion, glycemic control every hour is recommended, and after stabilizing glycaemia in the next 3 measurements every 2 hours,

- algorithm 2 – for patients with type 2 diabetes with preserved insulin secretion, an optional glucose, insulin, and potassium solution may be given (500 ml of 10% glucose containing 12–16 IU of short-acting insulin and 10–20 mmol of potassium chloride), the dose of potassium should be modified depending on the concentration of potassium in the blood:
  - » consider using a higher dose of insulin (≥ 16 IU) for obese individuals, in cases of severe infection, during cardiac surgery procedures, for patients operated in hypothermia, or when the baseline glucose concentration is > 180 mg/dl (10.0 mmol/l),
  - » consider using a lower dose of insulin (< 12 IU) for lean individuals, as well as for those who were taking small doses of insulin or non-insulin antihyperglycemic drugs before the procedure.

2. The intravenous infusion of glucose, insulin, and potassium should be started at 8:00 AM and continued continuously at a rate of 80 ml/hour until normal eating is resumed.
3. During the intravenous infusion of glucose, insulin, and potassium, blood glucose levels should be monitored at least every 2 hours and maintained within the range of 100–180 mg/dl (5.6–10.0 mmol/l):

- if the plasma blood glucose concentration decreases or remains at the lower recommended values, the insulin dose should be reduced by 2–4 IU,
- it is recommended to increase the insulin dose in the drip by 2 IU for every 30 mg/dl (1.6 mmol/l) of plasma blood glucose concentration > 180 mg/dl (> 10 mmol/l).

4. If there is a possibility of constant supervision of the operated patient with diabetes, Algorithm 1 should be preferred.

IV. Postoperative management

1. Treatment with multiple insulin injections or via a personal insulin pump should be started with the patient's resumption of oral feeding and maintained (in the case of periodic insulin therapy) until the end of hospitalization. If a long-acting or ultra-long-acting analogue is used in insulin therapy, administration should continue on the day before the operation and after the operation at a dose reduced to 80% compared to that used before the operation.
2. In the case of individuals with type 2 diabetes who used non-insulin drugs before the procedure with good glycemic effect, it is possible to return to their use with the commencement of normal eating, provided there are no clinical contraindications.

NOTE 4: In patients with diabetes previously treated with insulin who are undergoing surgery for acute or chronic inflammatory conditions, the possibility of daily reduced insulin requirements should be considered.

NOTE 5: In glycaemic control during the perioperative period, the use of CGM systems reduces the risk of hypoglycaemia.

NOTE 6: The recommendations for management during the perioperative period regarding the use of non-insulin antihyperglycaemic medications are presented in Table 26.3.

V. Management related to low-risk procedures with an expected duration of less than 2 hours.

In the case of low-risk procedures with an expected duration of less than 2 hours performed under general anaesthesia or sedation, the patient who

Table 26.1. Principles of 10 and 5% glucose solution and insulin infusion according to glycaemia

Glycaemia	10% glucose solution [ml/hr]	5% glucose solution* [ml/hr]	Insulin [IU/hr]
< 90 mg/dl	50	100	Stop the infusion for 15–30 minutes
< 5.0 mmol/l			
90–119 mg/dl	50	100	0.5–2
5.0–6.7 mmol/l			
120–180 mg/dl	50	100	2–3
6.7–10 mmol/l			

**A 5% solution is preferred when better hydration and/or higher plasma osmolality is needed.*

is well metabolically balanced should be admitted to the hospital in the morning of the day of the procedure or in the afternoon of the day before the procedure. Subcutaneous insulin therapy can be maintained, or alternatively, the algorithm for so-called major procedures (see Table 26.2) can be applied.

VI. Immediate and urgent surgery.

In patients with diabetes, it is sometimes necessary to perform surgical procedures on an urgent or immediate basis.

In these cases, it is necessary to exclude the possibility of peritoneal symptoms as a result of

Table 26.2. Subcutaneous insulin therapy for small procedures under general anaesthesia or sedation

Base-bolus therapy	Base: NPH insulin – 50% of the morning dose, long-acting analogue – 100% of the morning dose
	Intravenous fluids should be started: patients with normal glycaemia can initially be given glucose-free fluids. Then fluids containing 5–10% glucose in such amounts as to prevent hypoglycaemia
	Treatment in the morning hours: • bolus – only as a possible corrective dose • initiation of intravenous fluids
	Treatment in the afternoon: • bolus – if the patient can eat breakfast, the usual dose of rapid-acting analogue or 50% of the dose of short-acting insulin, possibly an additional corrective dose • start intravenous fluids 2 hours before the procedure or no later than noon
Therapy with a personal insulin pump	Can only be continued if the anaesthesiologist accepts this method of therapy and can administer it
	Continuation of insulin therapy at the base dose programmed in the OPI (base) appropriate for the time of day (modification of the base is usually not necessary)
	Hypoglycaemia: discontinue administration of the base (for a maximum of 30 minutes)
	Hyperglycaemia: correction bolus
	Start intravenous fluids 2 hours before the procedure
Hybrid closed loop therapy	It is recommended to continue therapy

Table 26.3. Perioperative recommendations for non-insulin antihyperglycemic medications

Medication used before planned surgery	Day before surgery	Day of surgery	After surgery	Notes
Sulfonylurea	Administer	Withhold	Administer when oral feeding resumes	Withhold during temporary insulin therapy
Metformin	Administer	Withhold	Administer when oral feeding resumes	If iodinated contrast agent is required, withhold metformin for at least 24 hours before the procedure Do not administer if eGFR < 45 ml/min/1.73 m²
Pioglitazone	Withhold	Withhold	Administer when oral feeding resumes	
Gliptin	Administer	Withhold or administer	Administer when oral feeding resumes	
SGLT2 inhibitor	Withhold	Withhold	Administer when oral feeding resumes	Half-life is 12–14 hours, justifying withholding the drug 3 days before surgery
Oral GLP-1 receptor agonist	Administer	Withhold	Administer when normal oral feeding resumes	
Injectable GLP-1 receptor agonist	Administer*	Withhold	Administer when normal oral feeding resumes	*Omit one dose of weekly GLP-1 RA
Dual GIP/GLP-1 receptor agonist	Withhold	Withhold	Administer when normal oral feeding resumes	

ketoacidosis accompanying the metabolic disorders of diabetes. Therefore, when symptoms of the so-called acute abdomen occur with accompanying diabetic acidosis (acetone in the urine and indicators of metabolic acidosis in the blood gas analysis), immediate action should be taken to correct the acid-base balance disorders.

In the case of ketoacidosis (when BE < –12; pH < 7.3) or hyperglycaemic-hyperosmolar state, prior metabolic compensation is required, in accordance with generally accepted principles. If the surgical procedure cannot be postponed, the treatment of metabolic disorders should be conducted simultaneously with surgical actions.

If there are no indicators of acute diabetic complications and the patient has taken their morning dose of insulin, an intravenous insulin infusion should be used during the procedure according to the above scheme.

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27. Vaccination

CHAPTER HIGHLIGHTS
• Every child with diabetes should be vaccinated according to the current immunization schedule (PSO). [**C**]
• The vaccination schedule for adults includes recommended vaccinations for patients based on their age. [**C**]
• Annual influenza vaccination is recommended for children over 6 months of age and adults. [**C**]
• All individuals with diabetes are advised to be vaccinated against hepatitis B (HBV) and COVID-19. [**C**]

Children and adolescents

Every child with diabetes should be vaccinated according to the current immunization schedule (PSO). The vaccination schedule for children and adolescents is updated annually and is available on the Ministry of Health website. It includes mandatory, recommended, and recommended free vaccinations. All children born after January 1, 2017, should be routinely vaccinated against invasive Streptococcus pneumoniae (pneumococcal) strains. For children who were not vaccinated at the recommended time according to the immunization schedule, a catch-up vaccination should be administered as soon as possible, which is mandatory until the child turns five years old. Children with diabetes born before February 1, 2017, as unvaccinated individuals in a high-risk group, must be vaccinated until they turn 19 years old. For children and adolescents, preventing human papillomavirus (HPV) infection is also essential, particularly in the context of reducing the future risk of cancers, including reproductive organ cancers, male genital cancers, vulvar and anal cancers, as well as head and neck cancers. Currently, Poland has a Universal HPV Vaccination Program, which from September 1, 2024, will be available for girls and boys from the age of nine until they turn 14, including in schools. Other children up to the age of 18 can be vaccinated for free after obtaining an e-prescription from a doctor. Other recommended vaccinations include vaccinations against COVID-19, meningococcal infections, influenza, chickenpox, hepatitis A, and tick-borne encephalitis.

Adults

The immunization schedule for adults, which includes recommended vaccinations based on age, is also available on the Ministry of Health website. For individuals with diabetes, the need for immunization against hepatitis B (HBV), pneumococcal pneumonia, and human papillomavirus (HPV) should be emphasized. It is also important to note that diabetes increases the risk of infections and severe respiratory illnesses, including influenza, pneumococcal pneumonia (including invasive pneumococcal disease), whooping cough, COVID-19, and respiratory syncytial virus (RSV) infections. On the other hand, acute infections increase the risk of metabolic decompensation of diabetes. Chickenpox/shingles infections are also dangerous for people with diabetes due to the risk of postherpetic neuralgia.

Hepatitis B (HBV)

Unvaccinated individuals should be identified and vaccinated at any age according to the 0, 1, 6-month schedule. If previously vaccinated individuals have an anti-HBs antibody titer of < 10 IU/l, revaccination with 1–3 doses are recommended. If a protective antibody level is not achieved after three vaccine doses (measured 4–12 weeks after the last dose), further vaccinations are discontinued.

Pneumococcal pneumonia

Pneumococcal vaccination is recommended for all adults with diabetes, and it is currently provided free of charge in Poland for patients over the age of 65.

Human papillomavirus (HPV)

HPV vaccination is recommended for young adults aged 19–26 years. For individuals aged 27–49 years, the decision is made on a case-by-case basis after discussing the benefits of vaccination with a doctor.

Influenza

Studies confirm an increased risk of hospitalization and death from influenza among individuals with diabetes. According to available data, influenza vaccination significantly reduces the risk of death and hospitalization in diabetic patients. Annual influenza vaccination is recommended for all children over six months and adults. Standard vaccines are free for children up to 18 years and individuals 65+. For adults aged 18–64 years, the vaccine is available with 50% reimbursement.

COVID-19

Due to the increased risk of severe COVID-19 infection and death in individuals with diabetes,

Table 27.1. Adult vaccination schedule (based on the latest recommendations from the Ministry of Health)

Type of vaccination	Age (years)				
	19–26	27–49	50–59	60–64	≥ 65
Influenza	Annually during the infection season (optimally at the beginning of the season)				
Diphtheria, tetanus, pertussis	Every 10 years				
Varicella (chickenpox)	2 doses – for individuals who have not had chickenpox and have not been vaccinated				
Measles, mumps, rubella (MMR)	2 doses – for individuals who have not had measles or rubella and have not been vaccinated				
COVID-19	Depending on vaccination history and current recommendations				
Hepatitis B (HBV)	3 doses for individuals not previously vaccinated				
Human papillomavirus (HPV)	3 doses	3 doses (individual decision)			
Pneumococcal disease			1 dose	1 dose	1 dose
Shingles (herpes zoster)			2 doses every 6 months		
Respiratory syncytial virus (RSV)				1 dose	
Vaccinations recommended for individuals with additional risk factors (medical, occupational, or lifestyle-related)					
Tick-borne encephalitis	3 doses + booster doses every 3–5 years				
Hepatitis A	2 doses – for individuals who have not been previously vaccinated				
Meningococcal disease	1–2 doses				

Routine, mandatory, and recommended vaccinations before travelling to endemic regions, according to the Ministry of Health recommendations from September 16, 2010 (Journal of Laws 2010, No. 180, item 1215), CDC (Centers for Disease Control and Prevention, USA), WHO (World Health Organization), and NHS (National Health Service, UK). A medical examination is required before each vaccination..

booster vaccinations against COVID-19 are recommended, tailored to the current epidemiological situation.

Diphtheria, tetanus, whooping cough (pertussis)

Vaccination against diphtheria, tetanus, and pertussis is recommended for all adults, including individuals with diabetes. A booster dose should be administered every 10 years. If the vaccination history is unknown, a 0, 1, 6-month schedule should be followed.

Respiratory syncytial virus (RSV)

The CDC recommends that adults with diabetes aged 60 and older receive a single dose of the RSV vaccine. However, in Poland, this vaccine is not reimbursed.

Chickenpox/shingles

Unvaccinated individuals, especially those over the age of 50, should be vaccinated against chickenpox (2 doses at a 6-week interval) due to the risk of prolonged postherpetic neuralgia.

Other vaccinations

For unvaccinated individuals, vaccinations against rubella, mumps, and measles are also recommended, as contracting any of these diseases can cause severe metabolic decompensation of diabetes.

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28. Professional Activity for People with Diabetes

Written in collaboration with Andrzej Marcinkiewicz, MD, Ph.
and Prof. Jolanta Walusiak-Skorupa, MD, PhD (Prof. J. Nofer Institute of Occupational Medicine, Łódź, Poland)

Having diabetes cannot be a reason for discrimination or unequal treatment. Occupational restrictions should be imposed only after careful analysis of the individual situation and health condition.

The role of a diabetologist in maintaining the professional activity of a person with diabetes, in addition to providing effective therapy, includes:

- health education aimed at raising awareness of health issues and understanding the limitations resulting from potential diabetes complications,
- assisting in providing an objective opinion on health predispositions for work by offering information to a physician authorized to make occupational health decisions.

In assessing health status for occupational purposes, the key factor for the physician's decision should be the attitude of the person with diabetes. Every person with diabetes, regardless of type and treatment method, must actively participate in managing their disease.

The determination of health predispositions for performing occupational tasks or driving is made by a physician authorized to conduct occupational health or driver examinations. Due to the incidental nature of contact with the patient (often during a single visit), to issue a decision based on an individualized health assessment, it is advisable for the person with diabetes to present an opinion from their treating physician.

As part of consultations for occupational health assessments, the diabetologist should:

- assess the patient's knowledge of their disease, treatment, and possible complications on a scale: high, sufficient, or insufficient;
- assess glycemic control skills on a scale: good, acceptable, or low;
- evaluate the patient's awareness of hypoglycaemia, their ability to prevent it and respond appropriately, on a scale: good or insufficient;
- confirm or rule out the presence of prodromal symptoms of hypoglycaemia;
- determine the risk of hypoglycaemia on a scale: low, acceptable, or high;
- indicate the presence of chronic diabetes complications affecting vision, the nervous system, and the cardiovascular system;
- take into account the ability and consistency in using continuous glucose monitoring (CGM);
- include additional remarks on chronic diabetes complications and the patient's overall health status that are relevant to assessing risks to public safety.

Occupational restrictions for individuals with diabetes are justified by:

- the possibility of a hypoglycaemic episode and associated impairment of consciousness;
- the potential development of long-term diabetes complications that may hinder job performance.

Contraindications for driving and for working in specific occupations are outlined in Annex 2.

Individuals with advanced chronic diabetes complications cannot perform tasks where damage to a particular organ, as part of diabetes complications, could impact workplace safety. However, this should not prevent them from taking on other types of work where the specific complication does not pose a significant risk. At the same time, the nature and intensity of work should not hinder metabolic control of diabetes, which is essential for preventing the progression of complications.

A diabetology consultation for driver or occupational health assessments should conclude with a structured opinion in the form of standardized consultation forms, samples of which are provided in Annex 2.

Health requirements for a person with diabetes should be divided into two categories based on the type of occupational tasks performed or the specific job position.

The first (higher) category includes tasks and positions that require full psychomotor efficiency and involve exposure to adverse psychosocial factors, where performance affects both the safety of the worker and those around them (co-workers, individuals nearby, or those impacted by their

work, such as road users or customers in large retail stores). More stringent health requirements apply particularly in cases where consciousness disturbances, potentially caused by severe hypoglycaemia, may occur.

Professions requiring the highest category of health requirements, where diabetes must be given special consideration, include those related to public safety, such as:

- professional vehicle operation (passenger transport, freight transport, train operation, taxi driving);
- uniformed and emergency services: armed forces (land forces, navy, air force), police, fire department, municipal guards, emergency services, maritime services, prison services, licensed security personnel;
- civil aviation professions: pilots, aviation engineers, flight crew, air traffic controllers;
- high-risk occupations (working at heights, operating machinery in motion, working with furnaces, high-temperature environments, incineration plants, metallurgy, mining, high-traffic areas, and other high-accident-risk environments).

The second (lower) category of health requirements includes tasks and job positions with harmful or strenuous factors that may negatively affect diabetes management. In this category, rather than absolute contraindications, certain occupations or positions may be deemed inadvisable. Decisions on employment or job continuation for individuals with diabetes in the following positions require additional scrutiny and individual assessment:

- roles requiring significant physical effort, especially static work (e.g., mining, metallurgy);
- shift and night work;
- jobs involving exposure to carbon disulfide and pesticides—dichlorophenoxyacetic acid compounds (e.g., dichlorprop, mecoprop).

A diabetologist should serve as an advisor for young individuals with diabetes, as extra care is needed when selecting a profession. In this case, consideration should be given not only to the individual's current health status but also to the natural history of diabetes, which at different stages may impose health-related limitations that can hinder both vocational training and long-term professional work.

Annex 3 contains the "Rights and Responsibilities of Employers and Employees" document, aimed at strengthening the sense of responsibility of people with diabetes, reinforcing their position as employees, and preventing their exclusion from the job market.

29. Diabetic Care in Penitentiary Institutions

Individuals with diabetes who are incarcerated in penitentiary institutions (prisons, detention centers, reformatories) should be guaranteed access to the same level of medical care, including diabetic care, that is offered to the general population of patients.

The staff of the institution should be informed about the inmate's disease, as well as trained in recognizing states of hyperglycaemia and hypoglycaemia and how to act in case they occur or in other emergency situations.

30. Treatment of Obesity in People with Diabetes

Type 2 diabetes is, in most cases, a direct consequence of overweight or obesity, which affects 80% of individuals with this type of diabetes. Obesity is also observed in approximately 10–15% of people with type 1 diabetes.

Effective obesity treatment leads to improved metabolic control of diabetes and better outcomes in managing other obesity-related conditions, primarily hypertension, dyslipidemia, MASLD, heart failure, musculoskeletal disorders, and mental health conditions.

At every visit, each patient with diabetes should have their body weight, waist circumference, and body mass index (BMI) assessed, along with classification into overweight or obesity categories. If overweight is identified (BMI 25–29.9 kg/m^2), preventive measures should be implemented to avoid the development of obesity (BMI ≥ 30 kg/m^2). If obesity is confirmed, treatment must be initiated without delay.

30.1. Non-Pharmacological Treatment and Pharmacotherapy

CHAPTER HIGHLIGHTS

- Every patient with diabetes and obesity should be advised on both non-pharmacological and pharmacological treatment options. [**A**]
- In patients with diabetes and a BMI ≥ 27 kg/m², pharmacotherapy with GLP-1 receptor agonists or dual GIP/GLP-1 receptor agonists should be considered, considering their anti-hyperglycaemic effects. [**A**]

Non-pharmacological treatment, or behavioural therapy, is an essential component of obesity management. From the beginning of treatment, patients should receive guidance on optimal nutrition and physical activity, tailored to their age and fitness level while considering personal preferences. Additionally, the presence of potential mental health disorders should be evaluated to determine if further therapy is needed. Therapeutic education should be continuous and reinforced at every medical visit, ideally with the involvement of the entire healthcare team. Detailed recommendations on behavioural therapy are provided in Chapters 6–8.

Pharmacological treatment of obesity in people with diabetes involves the use of GLP-1 receptor agonists or dual GIP/GLP-1 receptor agonists. For most patients, these medications can achieve >10% body weight reduction while simultaneously improving metabolic control and outcomes in comorbid conditions. This may necessitate adjustments in pharmacotherapy, such as reducing insulin or antihypertensive medication doses.

It is particularly important to emphasize that dulaglutide, liraglutide, and semaglutide reduce cardiovascular and renal risks in individuals with type 2 diabetes, while semaglutide also exerts similar benefits in individuals with obesity who do not have diabetes.

Regarding weight management, the mechanism of action of GLP-1 and GIP receptor agonists primarily involves appetite suppression and reduced calorie intake. Therefore, patients must be aware of the importance of maintaining a nutritionally balanced diet to prevent the loss of lean (muscle) mass. Adequate protein intake and consistent physical activity should be maintained throughout incretin-based pharmacotherapy for obesity. The most effective method for assessing muscle mass is body composition analysis.

If obesity treatment proves successful – defined as halting the progressive increase in body weight – pharmacotherapy should not be discontinued and should instead be considered a long-term intervention.

30.2. Metabolic Surgery

CHAPTER HIGHLIGHTS

- Metabolic surgery should be considered in individuals with type 2 diabetes and a BMI > 35 kg/m², particularly when conservative obesity treatments have been ineffective, especially in the presence of comorbidities and unsatisfactory glycemic control despite behavioural therapy and anti-hyperglycaemic medications. [**A**]
- Every individual after surgical treatment for diabetes should remain permanently under the care of a diabetologist and a general surgeon and should receive constant supplementation with vitamins and micronutrients to prevent their deficiencies. [**C**]

Metabolic surgery is an effective method for treating obesity and associated conditions, particularly type 2 diabetes. A multidisciplinary approach allows for the proper qualification of patients for metabolic surgery procedures and the selection of the appropriate technique.

I. Qualification for metabolic surgery procedures

1. A metabolic surgery procedure should be considered for every patient with type 2 diabetes and a body mass index (BMI) > 35 kg/m², especially when additional comorbid conditions such as hypertension and dyslipidemia are

present. Qualification for metabolic surgery procedures should be considered when type 2 diabetes and obesity do not adequately respond to pharmacological and behavioural therapy.

2. Qualification for a metabolic surgery procedure is recommended for every patient with a BMI > 40 kg/m² and type 2 diabetes.
3. Considering the preferences of patients with type 2 diabetes, surgical treatment of obesity may also be considered in patients with class I obesity (BMI 30.0–34.9 kg/m²), who do not achieve stable weight reduction and improved control of comorbidities with non-surgical methods, i.e., primarily pharmacotherapy using GLP-1 receptor analogues and GIP/GLP-1.
4. Patients between the ages of 18 and 65 are qualified for metabolic surgery procedures for type 2 diabetes. The upper age limit may be extended to 70 years in justified cases, provided that the individually considered risk of the surgical procedure is less than the potential benefits that can be achieved from the operation.

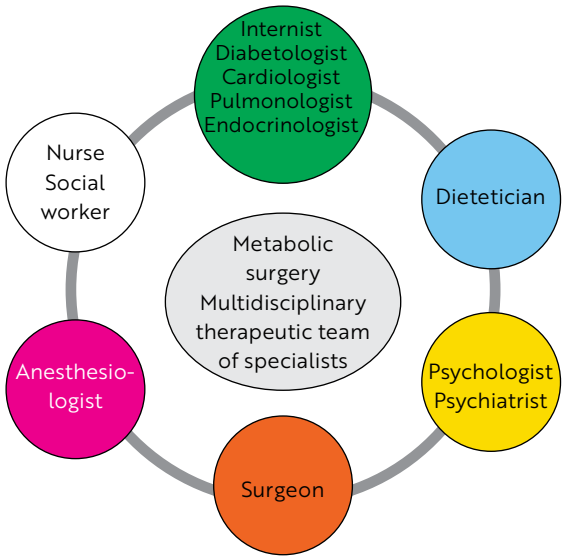

Figure 30.1. Multidisciplinary qualification for metabolic surgery

5. Qualification for bariatric surgery should be performed by a team of physicians, including at least a diabetologist and a general surgeon with extensive experience in metabolic surgery. It is recommended that the multidisciplinary team of specialists involved in the qualification process also include a cardiologist, pulmonologist, psychologist/psychiatrist, anaesthesiologist, and dietitian, as well as a nurse and social worker (Figure 30.1, Table 30.1).

II. Types of procedures in metabolic surgery

1. It is recommended that patients be qualified for surgical procedures performed using minimally invasive techniques (laparoscopy).
2. Considering the available study results in patients with type 2 diabetes, it is recommended to primarily qualify for the laparoscopic gastric bypass (laparoscopic Roux-en-Y gastric bypass), laparoscopic loop gastric bypass (mini gastric bypass), laparoscopic sleeve gastrectomy, laparoscopic biliopancreatic diversion, and the laparoscopic duodeno-ileal bypass with single anastomosis (single anastomosis duodeno-ileal bypass – SADI).
3. The decision on the type of procedure to be performed should be made after a surgical consultation and individual consideration of the advantages and disadvantages of each of the aforementioned methods of metabolic surgery.
4. It is recommended that before deciding on a metabolic surgery procedure, patients familiarize themselves with the informed consent forms prepared by the Association of Polish Surgeons.

III. Complications associated with metabolic surgery in type 2 diabetes.

Within 30 days of the operation, mortality related to the performance of a metabolic surgery procedure is associated with a calculated risk of

Table 30.1. Auxiliary tests and consultations before the planned procedure in the field of metabolic surgery

Laboratory tests	Blood group Blood morphology, serum levels of sodium, potassium, creatinine, TSH and cortisol Coagulation system parameters Fasting blood glucose and glycated haemoglobin (HbA_{1c})
Endoscopic and imaging tests	Gastroscopy Abdominal ultrasound
Specialist consultations	Cardiology (with EKG and echocardiography) Pulmonology (with chest X-ray, spirometry and possibly polysomnography) Laryngology Endocrinology (in case of abnormal serum TSH or cortisol levels)

0.1–0.3% mortality, which is identical to the risk of mortality for laparoscopic cholecystectomy and is considered low. Among the most common complications after metabolic surgery procedures include leakage along the suture line (3.1%), infection of the operated site (2.3%), respiratory system complications (2.3%), gastrointestinal bleeding (1.7%).

IV. Assessment of the outcomes of metabolic surgery in type 2 diabetes

Type 2 diabetes resolves in 40–95% of patients, depending on the duration of the disease, the degree of initial obesity, and the type of surgical procedure performed. The following method is recommended for assessing the outcomes of surgical treatment of type 2 diabetes:

1. Remission of the disease and comorbidities. Remission of the disease can be declared after the discontinuation of pharmacotherapy when:
- HbA_{1c} is < 6.5%,
- the patient does not experience episodes of hypoglycaemia,
- total cholesterol level is < 4 mmol/l, LDL cholesterol < 2 mmol/l,
- triglyceride level is < 2.2 mmol/l,
- blood pressure values are < 140/90 mm Hg,
- weight loss is > 15% compared to the state at the time of qualification for surgery.

2. Improvement in disease course.

An improvement in the course of the disease after a metabolic surgery procedure can be declared when after reducing the doses of medications taken before the operation:

- HbA_{1c} value is reduced by > 20%,
- LDL cholesterol level is < 2.6 mmol/l,
- blood pressure values are < 140/90 mm Hg.

V. Recommendations after surgical treatment of type 2 diabetes

1. Every patient after surgical treatment for diabetes should remain permanently under the care of a diabetologist and a general surgeon.
2. Constant supplementation with vitamins and micronutrients is necessary to prevent their deficiencies.

VI. Pregnancy and metabolic surgery procedures

1. There are no contraindications to becoming pregnant for women after metabolic surgery procedures after 24 months from the date of the bariatric surgery.
2. Constant contact with the diabetologist managing the patient is recommended before becoming pregnant and during pregnancy.

VII. Contraindications for qualifying patients with type 2 diabetes for metabolic surgery procedures

1. Absolute contraindications:
- refusal by the patient of surgical treatment for type 2 diabetes,
- alcohol or drug addiction (qualification for surgical treatment of obesity can be considered in the case of at least one year of documented abstinence),
- psychiatric illnesses that are uncontrollable despite treatment and pharmacotherapy,
- high cardiovascular risk associated with the procedure,
- endocrinological diseases that are the underlying cause of obesity (e.g., Cushing's syndrome),
- inability to participate in constant, long-term postoperative control,
- the period of 24 months preceding the planned pregnancy, breastfeeding.

2. Relative contraindications:
- weight gain in the period immediately preceding the operation indicating lack of cooperation with the patient,
- active peptic ulcer disease – requires treatment before the surgical procedure; in the case of patients with asymptomatic *Helicobacter pylori* infection, eradication before surgery is recommended but not necessary,
- in the case of patients treated for cancer in the past, an oncological consultation documenting the effective cure of the cancer is necessary.

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31. Specific Situations and Diseases Occurring in Individuals with Diabetes

Developed in collaboration with Prof. Renata Górska, MD, PhD.

I. Shift work

Shift work can be associated both with an increased risk of developing diabetes and with poorer glycemic control. It necessitates periodic changes to the timing of oral antihyperglycemic drugs or insulin administration.

1. For people with diabetes who work shifts, intensive self-monitoring is necessary, especially when work hours change. [E]
2. For individuals with diabetes working shifts, antihyperglycaemic medications with a low risk of hypoglycaemia and greater dosing flexibility are preferred. For those treated with long-acting insulin, formulations that provide a stable basal concentration throughout the day should be chosen [E].
3. People with diabetes, especially type 1, treated with insulin should have the ability to modify insulin doses (intensive functional insulin therapy method).

II. Changing time zones

Travel is not contraindicated for individuals with diabetes. People with diabetes, particularly type 1 and type 2 patients treated with insulin, should prepare for travel by considering factors such as duration, mode of transport, time zone changes (taking into account the direction of travel — east or west), and the climate of the destination country. A rapid time zone change (air travel) may present a particular challenge for individuals with diabetes.

1. Individuals with diabetes, particularly type 1 patients treated with insulin, should exercise special caution during the body's adjustment to a new time zone (this period is considered to last as many days as the number of hours of time difference). During this period, frequent blood glucose monitoring is essential.
2. Long-acting insulin analogues that provide stable basal insulin levels throughout the day can be administered at the same dose and time according to the new time zone. These should be preferred, especially for individuals who travel frequently [E].
3. If a patient is treated with NPH insulin or a long-acting insulin analogue that does not provide stable levels throughout the day, adjustments are needed when traveling by plane:
- when traveling west (prolonged day), the usual dose of long-acting insulin should be administered in the evening according to the new local time. Any hyperglycaemia resulting from in-flight meals, for example, can be corrected with additional doses of short-acting insulin/rapid-acting analogues,
- when traveling east (shortened day), a reduction in the evening dose of long-acting insulin may be necessary [E].
4. Individuals using an insulin pump do not need to adjust the pump clock or modify insulin doses if the time change is within 2 hours. However, if the time change is greater and the planned stay in the new time zone is long, it is recommended to gradually shift the basal infusion schedule by 2 hours per day.

III. Glucocorticoid therapy

Many medications have diabetogenic effects. The diabetogenic action of glucocorticoids seems particularly significant, both because of the strength of the diabetogenic effect and the frequency of use of these drugs. Glucocorticoids primarily cause an increase in postprandial glycaemia.

1. Replacement doses of glucocorticoids (hydrocortisone at a dose of up to 20 mg/day) and inhaled glucocorticoids do not have a significant impact on carbohydrate metabolism.
2. The following factors contribute to the increased risk of steroid-induced diabetes: older age, obesity, impaired glucose tolerance, use of high doses of glucocorticoids, and concurrent use of other diabetogenic drugs.
3. In the treatment of glucocorticoid-induced diabetes, insulin administered in a model of intensive insulin therapy is preferred (short-acting/rapid-acting insulin preparations can also be administered before meals if fasting and pre-meal glycamia are acceptable). For steroid-induced diabetes, no superiority of any insulin preparation or its analogue over others has been proven.
4. In individuals with type 2 diabetes treated with oral antihyperglycemic drugs, who require temporary use of glucocorticoids, especially in high doses, periodic treatment with insulin in a model of intensive insulin therapy is recommended.
5. In individuals with type 2 diabetes, when using combination therapy with basal insulin (NPH insulin, long-acting insulin analogue), it is usually necessary to add short-acting/rapid-acting insulin before meals.
6. In individuals with diabetes treated with insulin, the use of glucocorticoids is associated with increased insulin requirements, mainly during the day.

IV. Periodontal diseases

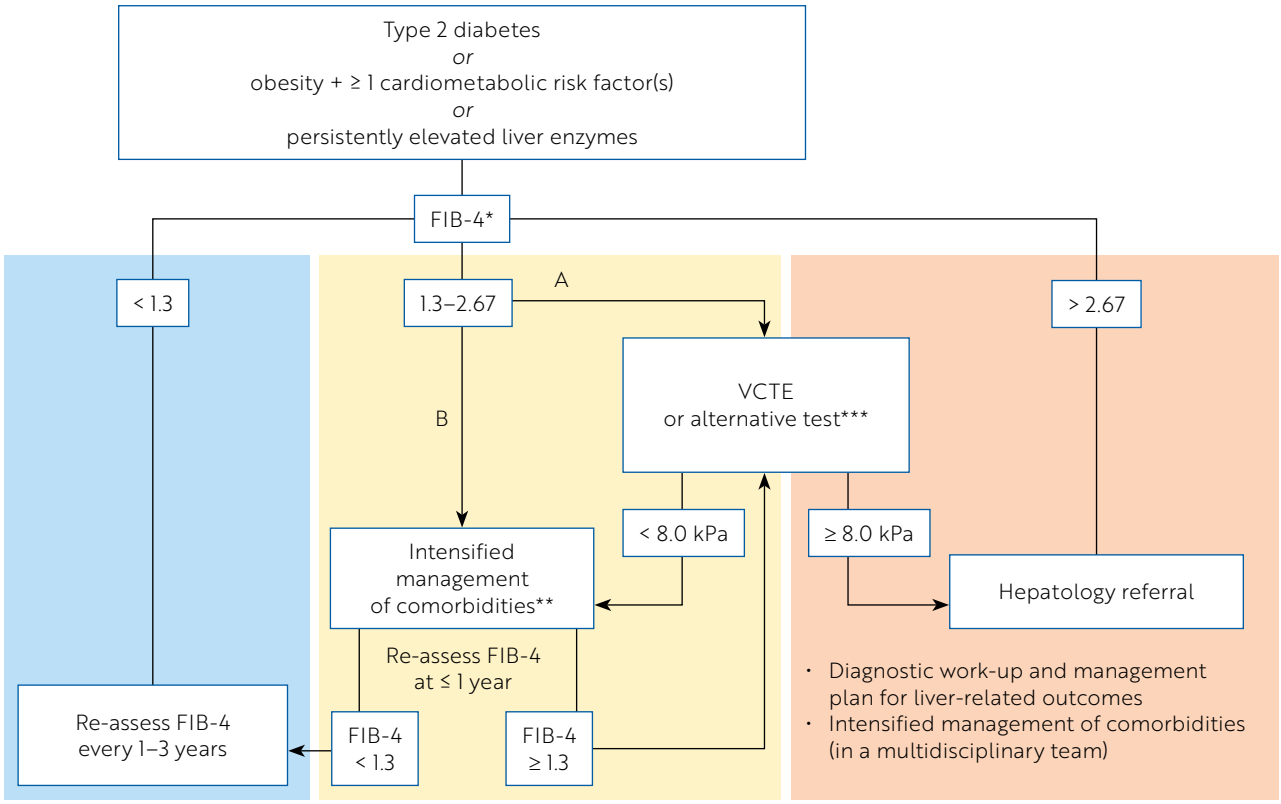
Periodontal diseases and other oral diseases occur more frequently in people with diabetes. Periodontal disease adversely affects the metabolic control of diabetes and increases the risk of its complications. Treatment of periodontal diseases improves the metabolic control of diabetes.

1. Every person with diabetes should undergo an interview and physical examination focused on oral diseases.
2. Every person with diabetes should have a dental examination once a year.

V. Metabolic dysfunction-associated steatotic liver disease (MASLD)

MASLD is the new name for a condition previously referred to as non-alcoholic fatty liver disease (NAFLD). It is diagnosed in women who consume less than 140 g of alcohol per week and in men consuming less than 210 g per week, provided they meet at least one of the criteria listed below. Alcohol consumption between 140–350 g/week (women) or 210–420 g/week (men) allows for the diagnosis of metabolic and alcohol-associated liver disease (MetALD) in individuals meeting at least one of these criteria.

1. MASLD can be diagnosed in an individual with hepatic steatosis (confirmed by imaging or biopsy) who meets at least one of the following criteria [E]:



**FIB-4 thresolds valid for age ≤ 65 years (for age > 65 years: lower FIB-4 cut-off is 2.0).*
***e.g. lifestyle intervention, treatment of comorbidities (e.g. GLP1-RA), bariatric procedures*
****e.g. MRE, SWE, ELF, with adapted thresolds.*
A and B are options, depending on medical history, clinical context and local resorces.

Figure 31.1. Proposed strategy for assessing the risk of fibrosis progression and liver-related endpoints in individuals with MASLD according to EASL-EASD-EASO [3]

- » in the white population, BMI ≥ 25 kg/m² or a waist circumference > 94 cm in men (80 cm in women),
- » presence of diabetes or prediabetes,
- » blood pressure ≥ 130/85 mmHg or use of antihypertensive medications,
- » triglyceride levels ≥ 150 mg/dl (1.7 mmol/l) or use of lipid-lowering therapy,
- » HDL-C levels ≥ 40 mg/dl (1.0 mmol/l) in men or ≥ 50 mg/dl (1.3 mmol/l) in women, or use of lipid-lowering therapy.

2. MASLD is expected to be present in most individuals with diabetes. About half of these individuals develop liver fibrosis, which is associated with an increased risk of cirrhosis, gastrointestinal cancers (including hepatocellular carcinoma), cardiovascular and renal complications, and mortality. The recommended screening tool for this condition is the FIB-4 index (a calculator is available, for example, on the website of the Polish Society of Gastroenterology). A FIB-4 index below 1.3 indicates a low risk of liver fibrosis, while a value above 2.67 indicates a high risk. In cases of high or intermediate risk (1.3–2.67), confirmation through fibro elastography or other methods such as MRI or liver biopsy may be necessary [B]. Figure 31.1.
3. Currently, there is no specific treatment for MASLD in Poland. Recommended management includes behavioural interventions (diet and physical activity) and pharmacological therapy (GLP-1 receptor agonists or dual GIP/GLP-1 receptor agonists, SGLT-2 inhibitors, pioglitazone, and metformin). Assessment and modification of other cardiovascular risk factors, including statin therapy, are also recommended.

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Annex 1.

Recommendations for Transitioning a Person with Type 1 Diabetes from Paediatric to Adult Care or in the Case of Changing Diabetes Clinics

A. The transition from paediatric to adult diabetes care is a critical moment in the life of a young person with type 1 diabetes. Transitioning is a continuous process that includes three stages: the pre-transition period (in the paediatric centre), the transfer, and the post-transition period (in the adult care centre). The primary principle in transitioning to adult diabetes care should be maintaining continuity of medical care, which means avoiding any significant gap between leaving the paediatric clinic and starting treatment in the adult clinic. To ensure a smooth process, the following recommendations should be observed:

1. The moment of transferring care for a person with diabetes from a paediatric clinic to an adult diabetes clinic should be determined individually so that this process does not disrupt the course of therapy. Depending on the emotional development of the individual, his family and educational situation, and other circumstances, the optimal time to transfer care is between the ages of 18-21.
2. The individual should be prepared by the paediatric diabetologist for the transition to adult care for at least one year. During this time, it is advisable to perform control tests for chronic complications of the disease and co-morbidities.
3. At the last visit to the paediatric diabetes clinic, no later than 6 months before the transition, the patient should be referred to an adult diabetes clinic in a coordinated manner, which specifically means:
   - determining the adult diabetes clinic to which the patient will be transferred.
   - providing the person with diabetes with a Diabetes Care Information Card,
   - issuing a referral to the adult diabetes clinic.
4. The individuals should be under adult care no later than 6 months after concluding paediatric care.
5. During the first visits to the adult care clinic, it is important to support the young person with diabetes in adjusting to the new system of care. In the first year, appointments should take place at least every 3–4 months to ensure a smooth transition.
6. Psychological support for young people with diabetes may be particularly beneficial during the transition process.
7. Creating regional networks of cooperating paediatric and adult diabetes clinics, with established principles for consistent communication and patient transfers, is recommended
8. In the case of a large number of transitioning patients, it is advisable to establish a transition care coordinator role in both paediatric and adult clinics. This coordinator would manage the referral and patient intake process, schedule appointments, ensure efficient information flow, and handle other related tasks.
9. Establishing separate clinic days for patients transitioning to adult care is not necessary but may be helpful, e.g., for organizational reasons. In planning the work of the adult clinic, it should be considered that the visits of patients transitioning from paediatric care, especially if they are treated with a personal insulin pump (PI) including automated insulin delivery systems (AID), are significantly more time-consuming.
10. A list of adult diabetes clinics dedicated to young adults with type 1 diabetes is available on the PTD website: https://ptdiab.pl/wiecej/lista-poradni-dla-mlodych-doroslych-z-cukrzyca-typu-1.

B. In cases where it is necessary to change the diabetes clinic (paediatric or adult), such as due to a change of residence, it is recommended to direct the patient to another diabetes clinic where they can receive appropriate care. It is required to complete the Diabetes Care Information Card during the final visit at the clinic.

Prepared by the team: Aleksandra Araszkiewicz, Leszek Czupryniak, Andrzej Gawrecki, Przemysława Jarosz-Chobot, Tomasz Klupa, Małgorzata Myśliwiec, Agnieszka Szadkowska, Bogumił Wolnik, Dorota Zozulińska-Ziółkiewicz

DIABETES CARE INFORMATION CARD

PATIENT'S PERSONAL INFORMATION:

Name and surname:.....

PESEL (National ID number): | | | | | | | | | | | |

Diagnosis: Type 1/Type 2 Diabetes..... Date of diagnosis (MM/YYYY): .....

1. Current Diabetes Therapy

A. Insulin therapy: YES/NO

CSII – Pump: .....

(Date of last reimbursed pump issuance: DD/MM/YYYY .....

Prescription validity (until which month):

- Infusion sets: .....
- Reservoirs: .....

Insulin: .....

HCL (HYBRID CLOSED LOOP): YES/NO ..... App:

Data from CSII/HCL therapy report:

- Average daily insulin dose (units): .....
- Average daily bolus dose (units): .....
- Average daily basal dose (units): .....
- Carb ratio (g/unit) or (units/WW): .....
- Insulin sensitivity factor (1 unit -mg/dl/unit):.....
- Target glucose level (mg/dl): .....

Multiple daily injections (MDI):

Basal insulin: ..... **Dose (units):** .....

Mealtime insulin: .....

Carb ratio (g/unit) or (units/WW): .....

Insulin sensitivity factor (1 unit - mg/dl/unit): .....

Target glucose level (mg/dl): .....

B. Other antihyperglycemic medications (name, dosage):

.....

2. Glucose Monitoring

Continuous glucose monitoring system (CGM): YES/NO in accordance with the indications: (system name)

.....

Prescription validity:

- Sensors (until which month): .....
- Transmitter (issue date): .....

Data from CGM system report: .....

Glucose meter: YES/NO

Data from glucose meter application report: .....

3. HbA_{1c} Levels

Over the past two years: ..... %

Most recent result (date: .....): .....%

4. Number of clinic visits in the past 12 months:.....

5. Acute Diabetes Complications in the Past 5 Years

Number of hospitalizations due to:

- Diabetic ketoacidosis: .....
- Severe hypoglycaemia: .....

Severe hypoglycaemia in the last 12 months without hospitalization (dates): .....

6. Diabetes Complications

Diagnosis		Severity/Comments/Treatment
Eye complications (last consultation date: .....)	YES/NO	
Diabetic kidney disease	YES/NO	
Somatic neuropathy	YES/NO	
Autonomic neuropathy	YES/NO	
Subcutaneous tissue atrophy	YES/NO	
Subcutaneous tissue hypertrophy	YES/NO	

7. Comorbidities

Diagnosis		Date of diagnosis	Current treatment/Comments
Autoimmune thyroiditis	YES/NO		
Celiac disease	YES/NO		
Hypertension	YES/NO		
Hyperlipidaemia	YES/NO		
Obesity	YES/NO		

8. **Psychological consultation in the past 12 months:** YES/NO
   Result:

9. **Education Level:** Very good/Satisfactory/Requires re-education

Attachments:
Hospital treatment information card: YES/NO
Results of follow-up tests from the past 12 months: YES/NO

Patient Declaration
I, the undersigned, declare that I have received the diabetes care information card from the diabetes clinic.

Date of receipt: .....

Patient's signature: ..... Doctor's signature: .....

Annex 2.

Medical Assessment Procedures for Drivers and Workers with Carbohydrate Intolerance and Diabetes

I. Driver Assessments

1. The medical assessment procedure for drivers with diabetes is regulated by Annex No. 8 to the decree of the Minister of Health dated December 5, 2022, regarding medical examinations of people applying for the right to drive vehicles and drivers (Official Gazette of 2022, item 2503) entitled "Detailed conditions for medical examination in the scope of diabetes."
2. Based on the medical examination, additional test results, and conclusions from consultations, the physician authorised to conduct driver assessments evaluates the risk to road safety and includes this in the medical certificate.
3. In accordance with points 4.1, 6.a, and 8 of the aforementioned annexes, **an opinion must be obtained from a diabetology specialist or another physician treating diabetes**, confirming the absence of other health-related contraindications to driving. This applies to individuals:

- applying for or holding a driver's license of categories C1, C1+E, C, C+E, D1, D1+E, D, D+E, or a tram driving permit
- performing road transport within the meaning of the Road Transport Act regulations,
- driving a priority vehicle or transporting monetary values,
- driving instructors and examiners,
- applying for or holding a driver's license of categories AM, A1, A2, A, B1, B, B+E, or T – in the case of recurrent severe hypoglycaemia.

4. The physician authorized to conduct driver assessments may also request a diabetological consultation in cases of diagnostic or certification uncertainty.
5. **The diabetological consultation for driver examinations**, to be considered by the certifying doctor, **must end with the issuance of an opinion in the form of a diabetological consultation card,** according to the template specified in Annex No. 8 to the aforementioned regulation of the Minister of Health dated December 5, 2022.
6. The diabetologist or another doctor treating diabetes, while filling out the consultation card, should assess the ability of the person with diabetes to drive a vehicle, which in consequence may have the following impact on the final medical decision issued by the doctor authorized to examine drivers:

- **no health contraindications** to driving motor vehicles:
  - » **without time restrictions** related to carbohydrate metabolism disorders,
  - » **with time restrictions** based on the diagnosed carbohydrate metabolism disorders (corresponding to low or moderate risk to road safety).
- **health contraindications** to driving motor vehicles resulting from diagnosed carbohydrate metabolism disorders:
  - » **relative contraindications** – with a specified follow-up period after which the patient may reapply for certification (corresponding to high risk to road safety, with the possibility of re-assessment).,
  - » **absolute contraindications** – prohibiting driving due to a high risk to road safety, without the option for re-assessment

7. For drivers applying for or holding a driver's license of categories AM, A1, A2, A, B1, B, B+E, or T:

- absolute contraindications: **lack of hypoglycaemia awareness**, defined as an inability to perceive or respond to pathologically low blood glucose levels, or failure to respond to alerts from a Continuous Glucose Monitoring (CGM) device, which may lead to severe hypoglycaemia and impaired consciousness. A relative health contraindication is recurrent severe hypoglycaemia (i.e., at least two cases of severe hypoglycaemia in the last 12 months),
- relative contraindications: recurrent severe hypoglycaemia (at least two incidents within the last 12 months).

8. For individuals with diabetes using CGM, the authorised physician may determine that there are no contraindications to driving vehicles in categories AM, A1, A2, A, B1, B, B+E, or T, provided a diabetology consultation confirms:

- consistent use of CGM in diabetes self-monitoring,
- at least sufficient patient knowledge regarding diabetes self-monitoring, including the interpretation of CGM readings,
- appropriate response to CGM device alerts,

- regular diabetological care (at least 2 visits to diabetic care per year, at regular intervals of every 6 months).

9. In cases of recurrent severe hypoglycaemia in individuals applying for or holding a driver's license of categories AM, A1, A2, A, B1, B, B+E, or T, the doctor authorized to conduct driver examinations may decide there are no health contraindications to driving vehicles, provided that a diabetological opinion indicates that:

- at least 3 months have passed since the last incident of severe hypoglycaemia during waking hours,
- diabetes is managed to the degree that ensures road safety,
- CGM is consistently used in diabetes self-monitoring, including mandatory use while driving,
- the patient has at least sufficient knowledge about diabetes self-monitoring, including the interpretation of CGM readings,
- a correct response to CGM device alerts is noted,
- regular medical check-ups are conducted at least 2 times a year, at regular 6-month intervals – subject to point 14.

10. For drivers applying for or holding a driver's license of categories C1, C1+E, C, C+E, D1, D1+E, D, D+E, or a tram driving permit, those performing road transport or driving a priority vehicle or transporting monetary values, as well as driving instructors and examiners, an absolute contraindication to driving is:

- any case of severe hypoglycaemia during waking hours,
- unawareness of hypoglycaemia during waking hours, defined in Annex No. 8 to the aforementioned decree of the Minister of Health dated December 5, 2022, as not feeling pathologically low blood glucose values, being a significant complication due to the frequent occurrence of hypoglycaemia episodes,
- other diabetes-related complications that exclude the possibility of driving.

The condition for obtaining a positive opinion on the ability to drive vehicles is:

- regular blood glucose monitoring, at least four times a day for those taking insulin more than once a day; in other treatment models, once a day and at times of the day related to driving – recorded in a way that allows for the assessment of diabetes management,
- documentation of diabetes management control by the treating physician,
- demonstration by the examinee of full awareness of the risk of hypoglycaemia during waking hours.

11. The completed diabetological consultation card should be passed on by the specialist diabetologist (or another doctor treating the diabetes) to the doctor authorized to examine drivers through the patient. In the case of a negative opinion regarding the ability to drive, it is recommended that the consulting doctor convey this information directly to the certifying doctor who referred the patient for the consultation.
12. During the consultation, the driver must be informed about the absolute necessity of undergoing a reassessment of their health predisposition to drive in the event of an episode of severe hypoglycaemia during waking hours, even if not related to driving.
13. The appropriate doctor to conduct the diabetological consultation is a doctor specialized in diabetology or a doctor with another specialization who is treating the diabetes of the consulted patient.
14. In the following cases, it should be considered to send information to the relevant territorial communication department or local government unit about the necessity of performing a new medical examination for the patient to verify their health predispositions to drive - on a form referring to Art. 75 sec. 1 point 5 of the Act of January 5, 2011, on drivers (Official Journal of 2024, item 1210, page 147):

- when there are rational indications that the patient drives a vehicle in a period shorter than 3 months from the last episode of severe hypoglycaemia,
- when a person with diabetes declaring consistent use of CGM does not show up for scheduled medical check-ups (especially in the case of severe hypoglycaemia episodes during waking hours) and all available forms of notifying the patient about the need for check-ups have proven ineffective,
- after each incident of severe hypoglycaemia.

15. Every patient treated with insulin who has received a certificate of no diabetological contraindications to driving mechanical vehicles should be obliged to check glycaemia (glucometer/CGM) each time before starting to drive. A person with diabetes should not start driving with glycaemia < 100 mg/dl (5.6 mmol/l), unless the diabetologist determines a different glycemic threshold that enables driving.

16. During driving, glycemic control should occur no less frequently than every 2 hours, and in case of a drop in glycaemia < 100 mg/dl, driving should be stopped, and an appropriate portion of carbohydrates consumed. Driving can be continued only after achieving normalization blood glucose level and reversing the downward trend. In cases of higher risk of hypoglycaemia, the necessity of using a Continuous Glucose Monitoring (CGM) system while driving should be indicated.

II. Worker Examinations

1. The assessment procedure for workers and individuals starting work is regulated by the decree of the Minister of Health dated May 30, 1996, on conducting medical examinations of workers, the scope of preventive health care over workers, and medical certificates issued for purposes provided in the Labor Code (Journal of Laws of 2023, item 607).
2. The doctor conducting the preventive examination of workers may expand its scope to include a diabetological consultation and additional tests if it is deemed necessary for the correct assessment of the health status of the person being admitted to work or the employee.
3. **A diabetological consultation for preventive examinations**, to constitute a valuable opinion allowing for an objective decision based on an individual assessment of the patient, **should contain key information for assessing health predispositions to work under specific conditions and occupational requirements.** For this purpose, the use of a diabetological consultation card is recommended.
4. Based on the medical examination, the results of additional tests, and the conclusions from the consultations, the doctor authorized to conduct preventive examinations of workers issues a medical certificate about the absence or existence of medical contraindications to perform or take up work at a specific position.
5. **Absolute contraindications to work in positions associated with higher health requirements include:**

- recurrent, severe hypoglycaemia or even one medically unexplained incident of severe hypoglycaemia in the past during waking hours (a drop in blood glucose levels leading to consciousness disturbances and the need for professional medical help),
- unawareness of hypoglycaemia during waking hours that is unlikely to improve, resulting from chronic complications of diabetes in the form of autonomic neuropathy, which impairs the ability to feel increasing hypoglycaemia and, as a result, the lack of response by the person with diabetes to the drop in glycaemia,
- advanced complications from the visual organ, most often in the form of diabetic retinopathy or cataract with impaired vision,
- other advanced chronic complications of diabetes,
- opinion of a diabetologist or a doctor with another specialization treating diabetes in the consulted patient, stating a high risk of hypoglycaemia, not feeling prodromal symptoms of hypoglycaemia during waking hours.

6. **Relative health contraindications to jobs requiring higher health requirements may be declared by the doctor authorized to conduct preventive examinations of workers in cases of conditions that are likely to improve:**

- lack of metabolic control of the disease (HbA_{1c} ≥ 8%),
- lack of self-monitoring of glycaemia or low ability to control it,
- insufficient patient knowledge concerning diabetes, hypoglycaemia, and ways to prevent it,
- non-compliance with medical recommendations. In such cases, the next examination should take place within 1–3 months.

Written in collaboration with Andrzej Marcinkiewicz, MD, Ph. and Prof. Jolanta Walusiak-Skorupa, MD, PhD
(Prof. J. Nofer Institute of Occupational Medicine, Łódź, Poland)

Stamp of the health care facility or medical practice

DIABETOLOGY CONSULTATION CARD FOR DRIVER EXAMINATIONS

(Annex No. 8 to the Regulation of the Minister of Health dated 29 August 2019, amended 5 December 2022, on medical examinations for individuals applying for driving licences and drivers, Official Gazette of 2022, item 2503)

Personal data of the patient

Full name of the patient: .....

PESEL number (National ID number): | | | | | | | | | | | |

If no PESEL assigned, ID Document Name and Number: | |

Address of residence: City: ..... Postal code: | | | - | | | |

Street: ..... House/apartment number: .....

Driver applicant ☐ Driver ☐

Diabetes Information:

Date of diagnosis: | |

Type of diabetes: | |

Attending physician: | |

Healthcare Entity Conducting Medical Activities: | |

Diabetes Clinic: | |

Patient's knowledge of their disease, treatment, and complications: high ☐ satisfactory ☐ insufficient ☐

Ability to control blood glucose levels: good ☐ acceptable ☐ poor ☐

Awareness of hypoglycaemia, ability to prevent and counteract: good ☐ insufficient ☐

Presence of prodromal symptoms of hypoglycaemia: yes ☐ no ☐

Risk of hypoglycaemia: low ☐ acceptable ☐ high ☐

Presence of chronic complications of diabetes ☐ no chronic complications of diabetes ☐
If present, specify affected systems: Visual system ☐ nervous system ☐ cardiovascular system ☐

Comments on chronic complications of diabetes:

.....

Assessment of driving ability:

.....

Other comments:

For individuals using Continuous Glucose Monitoring (CGM), 3 questions must be answered:

1. Consistent use of CGM: Yes ☐ No ☐
2. Good understanding of and response to CGM alerts: Yes ☐ No ☐
3. Regular clinic visits (at least every 6 months) with data readings from the pump and CGM: Yes ☐ No ☐

Other comments:

.....

..... (Date of the opinion)

..... (Signature, name and surname, medical license number of specialist in the field of diabetology or other physician treating diabetes)

Stamp of the health care facility or medical practice

DIABETOLOGY CONSULTATION CARD FOR PREVENTIVE EXAMINATIONS – Documentation of diabetes control by the attending physician for the purpose of assessing health predisposition to work.

(compiled by A. Marcinkiewicz, D. Szosland)

PERSONAL DATA OF THE PATIENT

Full name of the patient: .....

PESEL number (National ID number): ☐☐☐☐☐☐☐☐☐☐☐

If no PESEL assigned, ID Document Name and Number: ☐

Diabetes Information:

Date of diagnosis: ☐ Type of diabetes: ☐

Attending physician: ☐ Primary care physician ☐ Diabetes clinic physician

Patient's knowledge of their disease, treatment, and complications: high ☐ satisfactory ☐ insufficient ☐

Ability to control blood glucose levels: good ☐ acceptable ☐ poor ☐

Awareness of hypoglycaemia, ability to prevent and counteract: good ☐ insufficient ☐

Presence of prodromal symptoms of hypoglycaemia: yes ☐ no ☐

Risk of hypoglycaemia: low ☐ acceptable ☐ high ☐

Risk of hypoglycaemia: low ☐ acceptable ☐ high ☐

Presence of chronic complications of diabetes ☐ no chronic complications of diabetes ☐
If present, specify affected systems: Visual system ☐ nervous system ☐ cardiovascular system ☐

Comments on chronic complications of diabetes:

.....

Other comments:

.....

For individuals using Continuous Glucose Monitoring (CGM), 3 questions must be answered:

1. Consistent use of CGM: Yes ☐ No ☐
2. Good understanding of and response to CGM alerts: Yes ☐ No ☐
3. Regular clinic visits (at least every 6 months) with data readings from the pump and CGM: Yes ☐ No ☐

Other comments:

.....

..... (Date of the opinion)

..... (Signature, name and surname, medical license number of specialist in the field of diabetology or other physician treating diabetes)

....., on .....
(location) (date)

Name and address of the referring entity:

.....

.....

.....

.....

Full name, address, and identification details
of the individual concerned by the notification:

.....

.....

.....

.....

Name of the relevant local transportation department
or local government unit:*:

.....

.....

.....

.....

NOTIFICATION

Pursuant to Article 75(1)(5) of the Act of 5 January 2011 on Driving Licences
(Official Gazette of 2024, item 1210), we hereby notify that:

Mr/Ms.....

has serious and justified health-related concerns which, if the individual holds a driving licence or a permit to operate a tram, require an urgent and necessary evaluation of their health fitness for driving and verification of their medical certification

.....
(Signature of the notifying person)

Notes:

*The territorial jurisdiction applies to the individual being reported.

Annex 3.

Charter of Rights and Responsibilities of the Employers and Employees

Diabetes is a chronic metabolic disease affecting an increasing number of people. It is estimated that approximately 3 million people in Poland have diabetes, of which diagnosed and treated cases account for 60%. The current scale and growing prevalence of diabetes, both type 1 and type 2, have significant consequences not only in medical terms but also in socio-economic contexts. Issues of prevention and effective treatment of diabetes and its complications extend beyond the responsibilities of the medical community and patients themselves.

According to World Bank estimates, diabetes is the second-largest economic burden on society after ischemic heart disease. These expenditures consist not only of the costs of diagnosing and treating diabetes, including the treatment of its complications but also costs resulting from premature cessation of professional activity: incapacity to work and, consequently, pension benefits, as well as unemployment, which particularly severely affects individuals with diabetes.

Given that:

- the rate of unemployment among people with diabetes is more than twice as high as among healthy individuals, and their worse economic situation may hinder proper disease control,
- the workplace is an important link in the process of preventing civilization diseases,

and at the same time being convinced that:

- medications currently used in diabetes therapy, as well as the growing awareness of patients in terms of self-control, lead to an increasingly longer and more effectively maintained good health of patients and the possibility of remaining professionally active,

the fact of suffering from diabetes does not automatically make a person a worse employee.

In reference to numerous initiatives undertaken on the European ground, aimed at prevention, early detection, appropriate treatment, as well as improving the quality of life of people with diabetes, including the European Parliament Resolution of March 13, 2012, on addressing the diabetes epidemic in the EU and the Copenhagen Map, adopted during the European Diabetes Forum in Copenhagen on April 25–26, 2012, on the eve of World Diabetes Day 2012, the signatories of this document, representing the medical community, the community of people with diabetes, and the employer community, advocate the drafting of rights and duties of people with diabetes and their potential employers in such a way as to strengthen the sense of responsibility of patients and their position as employees on the one hand, and on the other to counteract the exclusion of people with diabetes from the labour market.

Rights and responsibilities of the employees with diabetes

1. Every person with diabetes should be aware that effective diabetes control takes place both at home and in the workplace.
2. Employees with diabetes are required to follow the same principles at work as they do at home to manage their condition, including periodic blood glucose monitoring, taking medications as prescribed by their doctor, adhering to mealtimes, following dietary guidelines for diabetes, and maintaining a healthy lifestyle.
3. Employees with diabetes should inform their employer about their condition and, where possible, adjust their working hours and routine to ensure effective disease management
4. Employees with diabetes should be aware of any contraindications to performing specific jobs (e.g., pilot, public transport driver, work at heights, or jobs requiring intense physical exertion) and, if they hold such positions, notify their employer.
5. Employees with diabetes should inform their closest colleagues about their condition so they can assist in the event of hyperglycaemia or hypoglycaemia and ensure continuity of work.

Rights and responsibilities of the employers

1. Employers must recognise that diabetes does not disqualify individuals from professional activity and that any discrimination against employees due to their diabetes is unacceptable. Employers should possess basic knowledge about diabetes to understand the situation of employees with the condition.
2. To fulfil their obligations, including providing safe and hygienic working conditions, employers have the right to know which employees have diabetes.
3. Employers should enable employees with diabetes to follow disease management principles at work and motivate them to act responsibly, ensuring workplace safety for the employee and their colleagues.
4. Employers should, where possible, assign roles to employees with diabetes that facilitate optimal disease management (e.g., avoiding shift work, allowing short breaks for additional meals).
5. Employers should, where possible, offer employees with newly diagnosed diabetes alternative or equivalent positions if their current role poses safety risks or makes disease management difficult.
6. Employers should promote healthy lifestyle principles in the workplace by encouraging physical activity, a balanced diet, and participation in preventive health screenings.

On behalf of the signatories:
Prof. Leszek Czupryniak MD, PhD
President of PTD in 2011–2015

Annex 4.

Recommendations of the Polish Society of Endocrinology and Diabetes Poland on Screening for Thyroid Disorders in Type 1 and Type 2 Diabetes

Type 1 diabetes

1. During every visit to a diabetologist, a clinical examination for thyroid disorders is mandatory. If thyroid dysfunction is suspected, the level of thyroid-stimulating hormone (TSH) should be measured.
2. It is recommended to measure TSH levels and titres of anti-thyroid peroxidase antibodies (TPOAb) and anti-thyroglobulin antibodies (TgAb) in all newly diagnosed type 1 diabetes patients and in those with long-standing diabetes who have not yet undergone thyroid function testing.
3. TPOAb and TgAb titres should be measured once to diagnose autoimmune thyroid disease. These measurements are not useful for monitoring thyroid diseases.
4. In individuals with elevated TPOAb and/or TgAb levels above the reference range and TSH levels between 2.5 mIU/L and the upper limit of normal, free thyroxine (fT_4) should be measured, and TSH levels should be reassessed annually.
5. In individuals with TPOAb titres within the reference range and TSH levels between 2.5 mIU/L and the upper limit of normal, TSH measurement should be repeated every two years.
6. In individuals with TPOAb titers within the reference values and TSH levels from the lower limit of the reference values to 2.49 mIU/L, the TSH levels measurement should be repeated every 5 years.
7. In individuals with a positive family history of hypothyroidism due to chronic autoimmune thyroiditis, the TSH levels should be measured annually.
8. In patients with diabetes and dyslipidaemia, TSH levels should be measured.
9. In every woman planning a pregnancy, especially those with an adverse obstetric history, TSH levels and TPOAb titres should be measured.
10. In every woman in the 4th–8th week of pregnancy (first obstetric visit), it is recommended to measure the levels of TSH and the titer of TPOAb.
11. In every pregnant woman with a history of Graves' disease, it is recommended to measure the levels of TSH and the titer of antibodies against the TSH receptor (thyrotropin receptor antibody – TRAb) in the 4th–8th week of pregnancy (first obstetric visit). Additionally, it is recommended to repeat the measurement of TRAb titers at the end of the second trimester of pregnancy (before the 22nd week of pregnancy).

Type 2 diabetes

1. During every visit to a diabetologist, a clinical examination for thyroid disorders is mandatory. If abnormalities are found during the physical examination, TSH levels should be measured.
2. For all newly diagnosed type 2 diabetes individuals and those with long-standing diabetes who have not yet undergone thyroid function testing, TSH levels should be measured.
3. In individuals with TSH levels from 2.5 mIU/L to the upper limit of the reference value, TPOAb titers should be determined.
4. If TPOAb titers are found to be above the reference values, the diabetes typology should be verified, primarily by determining the titers of autoantibodies against glutamic acid decarboxylase (anti-glutamic acid decarboxylase autoantibody – anti-GAD).
5. In individuals with elevated TPOAb titres and TSH levels between 2.5 mIU/L and the upper limit of normal, fT_4 levels should be measured, and TSH levels should be reassessed annually.
6. In individuals with TPOAb titres within the reference range and TSH levels between 2.5 mIU/L and the upper limit of normal, TSH measurement should be repeated every two years.
7. In individuals with TPOAb titres within the reference range and TSH levels between the lower reference limit and 2.49 mIU/L, TSH measurement should be repeated every five years.
8. In individuals with diabetes and dyslipidaemia, TSH levels should be measured.
9. Every woman planning pregnancy is recommended to measure the TSH levels.

10. In every pregnant woman in the 4th–8th week of pregnancy (first obstetric visit), it is recommended to measure the TSH levels and TPOAb titers.
11. For pregnant patients with a history of Graves' disease, TSH levels and TRAb titres should be measured between weeks 4 and 8 of gestation (first obstetric visit). A repeat TRAb measurement is recommended at the end of the second trimester (before the 22nd week).

TSH and fT_4 levels should be measured in all individuals with newly diagnosed diabetes induced by modern cancer therapies.

In people with diabetes and chronic kidney disease, TSH, fT_3, fT_4, and TPOAb levels should be evaluated at least annually. If TSH, fT_3, and fT_4 levels are normal but TPOAb is positive, thyroid function tests should be repeated at least every six months.

Thyroid ultrasound is recommended for individuals treated with GLP1 receptor agonists who have additional risk factors for thyroid cancer, including:

- nodular goitre or a palpable thyroid nodule,
- enlarged cervical lymph nodes not associated with infection,
- enlarged thyroid gland without a palpable nodule,
- focal thyroid lesion detected on ultrasound performed for other indications or in another imaging test,
- history of neck exposure to ionizing radiation,
- family history of thyroid cancer,
- RET mutation carrier status,
- ubesity-related conditions.

Compiled by: Marek Ruchała, Leszek Czupryniak, Alicja Hubalewska-Dydejczyk, Andrzej Lewiński, Małgorzata Karbownik-Lewińska, Małgorzata Szelachowska, Monika Karczewska-Kupczewska, Ewa Wender-Ożegowska, Dorota Zozulińska-Ziółkiewicz, Maria Górska, Roman Junik, Katarzyna Siewko, Beata Kos-Kudła, Irina Kowalska, Nadia Sawicka-Gutaj, Paweł Gutaj, Andrzej Milewicz, Jerzy Sowiński;

Recommendations of the Polish Society of Endocrinology and the Diabetes Poland on the diagnosis and therapeutic management of thyroid dysfunction in type 1 and type 2 diabetes.

Annex 5.

Standards of Care on Personal Insulin Pump Treatment and Automated Insulin Delivery Systems

I. Requirements for centres initiating and/or managing diabetes treatment using personal insulin pumps (PIP) and automated insulin delivery (AID) systems

Facility requirements: the service should be provided in a diabetes outpatient clinic or a diabetology department equipped with computers with software or access to cloud-based applications enabling data reading and analysis from insulin pumps, continuous glucose monitoring (CGM) systems, and AID systems.

Staff qualifications: the medical team should comprise doctors who are specialists in endocrinology and paediatric diabetology, with a particular emphasis on those who have specialized in diabetology and are adept in the administration of PIP therapies. It is highly recommended that these doctors hold a certification from the Polish Diabetes Association's Pump School. The nursing staff and educators are to be thoroughly trained in PIP therapy. Regular appointments should be scheduled for the meticulous reading and analysis of data from the Personal Insulin Pump, glucometers, CGM systems, and AID systems.

II. The initiation of therapy includes patient qualification for therapy with PIP, patient training in continuous subcutaneous insulin infusion, connecting the insulin pump to the patient, and a verification visit to assess the patient's skills and the achieved metabolic control of diabetes.

Patients opting for therapy with IP should be aware of the functionalities and technical parameters of individual pump models. This includes: the type of pump (tubed or tubeless – patch type), the type of bolus calculator, options for integration with a continuous glucose monitoring system (sensor type), integration with the application dedicated to the pump, including the "hybrid closed loop" (HCL) function, and the selection of the infusion set type.

III. Indications and contraindications for therapy with a personal insulin pump funded by the National Health Fund.

A. Criteria for funding of PIP for individuals with diabetes who require ongoing treatment with functional intensive insulin therapy using basal insulin.

Any person with diabetes who prefers and accepts this method of treatment and does not have contraindications that would prevent its safe use is eligible.

The currently preferred therapy includes AID systems with a hybrid closed loop (HCL).

B. Contraindications for funding of PIP by the National Health Fund for treating diabetes.

1. Certain mental illnesses that, in the treating physician's opinion, make safe use of PIP impossible.
2. Intellectual disabilities preventing understanding of intensive insulin therapy principles and pump operation, as well as substance abuse (alcohol or psychoactive drugs). This also applies to parents of children under 16. For children aged 13–16, HCL use should be individually assessed based on the child's capabilities under close supervision from the diabetes care team and family assistant.
3. Certain eating disorders preventing the safe use of a personal insulin pump- according to physician's opinion.
4. Addiction to alcohol and psychoactive substances, including among parents of children under 16 years of age.
5. Unjustified absence from medical appointments (only one visit per year or none)
6. Non-compliance or misunderstanding of intensive insulin therapy principles, including lack of glycaemic self-monitoring or inaccurate estimation of insulin doses.
7. More than one episode of diabetic ketoacidosis within a year.
8. Severe, rapidly progressing proliferative retinopathy before or during laser therapy.
9. Lack of acceptance of the disease despite full diabetological and psychological care (confirmed by a psychologist experienced in diabetes care).
10. Non-adherence to personal hygiene standards.
11. Regular exposure to strong magnetic field.

In individuals with diabetes who are chronically metabolically unbalanced (HbA_{1c} ≥ 9.0%, average from the last year, or TIR < 30% from at least 90 days combined on two consecutive visits), the decision to initiate PIP therapy is made by the therapeutic team, assessing each case individually.

For these patients, the preferred, and often the only therapeutic option allowing for the optimal glycaemic control in a short period is the hybrid closedloop (HCL) system. However, it should be emphasized that, in the case of limited availability of hybrid systems, the decision about who should receive these devices first should depend on the overall clinical picture and the individually assessed needs and capabilities of the patient.

C. Contraindications to the continuation of treatment with a personal insulin pump and coverage of equipment by the National Health Fund in individuals with diabetes

1. More than one episode of diabetic ketoacidosis within a year (even during HCL therapy).
2. More frequent severe hypoglycaemia episodes than with multiple daily injections.
3. Non-compliance with intensive insulin therapy or insufficient patient knowledge.
4. Severe skin reactions at infusion set sites despite attempts to change the type of set.
5. Irregular replacement of infusion sets (not following manufacturer recommendations).
6. Unjustified absence from medical appointments (only one visit within a year or no visit).

In individuals with diabetes who are chronically poorly metabolically controlled (HbA_{1c} ≥ 9.0%, average from the last year or TIR < 30% for at least 90 days combined over two consecutive visits), the decision to continue IP therapy is made by the therapeutic team, assessing each case individually:

- in cases where classic PIP has been used so far, the use of HCL may be indicated,
- continuation of HCL therapy should be considered, ideally following psychological consultation.

IV. Qualification for initiation or continuation of NFZ-funded PIP therapy

Patients applying to a centre that provides the service covered by government funding should submit:

- a referral with preliminary qualification from a physician working in a diabetic clinic/department,
- a glucometer report from the last 4 weeks – at least 7 measurements per day are required (data glucometer can be read at the clinic), or a CGM report from last 4 weeks,
- in some individuals with unsatisfactory metabolic control before qualifying for PIP, it is advisable to check additional information regarding the amount of carbohydrates consumed, insulin doses; sources of this information can be a self-control notebook or an appropriate application (electronic record).

In the case of children with newly diagnosed diabetes, the qualification is carried out by a diabetologist or a paediatric endocrinologist and diabetologist employed in the paediatric diabetology department.

The diabetologist/endocrinologist-paediatric diabetologist making decisions regarding the NHF coverage of PIP should consider the special clinical and life situations of everyone with diabetes.

V. Training individuals in the use of personal insulin pump (PIP)

Education of the individual and/or their family to enable independent use of the pump and equipment (confirmed by a medical certificate or information card) (education scope in Chapter 9, point III.6).

Special attention should be paid to procedures in **case of IP failure.**

Organizational requirements for initiating PIP therapy: the minimum training duration is 9 hours, spread over at least 3 sessions. For a pump with CGM, training must be extended by an additional 2 hours. Additional training on the automatic mode when using HCL. Training should take place in groups of no more than 6–8 people. For children and adolescents, the participation of parents or legal guardians is mandatory. The individual should have the opportunity for practical exercises with infusion sets on models. It is also recommended to insert an infusion set into the individual's subcutaneous tissue prior to starting continuous subcutaneous insulin infusion therapy**.**

Training should be conducted until the individual/guardian attains proficiency in the practical aspects of using IP/IP with the CGM system. Responsibility for conducting the training correctly lies with the centre initiating the therapy or the centre referring the individual for therapy using IP. The individual's knowledge should be verified by the educational team. It is recommended to prepare a test based on the centre's own educational materials.

It is advisable to teach the individual how to use computer software for reading data from IP, CGM, AID systems, and glucometers, which enables clinically effective teleconsultation.

In the case of continuing CSII therapy when changing the type of IP: re-education in FIIT, technical training on pump operation (and potentially CGM), and additional training on the automatic mode when using HCL.

VI. Equipping an individual with PIP should consider the individual's preferences and perceptual abilities, which are important factors in the education and customization of treatment.

Recommendations regarding insulin pump requirements for centres administering therapy can be found in the table included in Annex 5. It is beneficial for centres to offer a variety of insulin pump models, allowing individuals to select the device that best suits their specific need.

VII. Connecting the insulin pump.

The initial setup of the insulin pump is performed by the centre initiating the therapy. The setup should include activating the bolus calculator function. For pumps integrated with a CGM system, it is recommended to configure the system parameters, including alarms, considering the current metabolic control of diabetes, additional pump functions, and the individual's skills.

A trained individual, under the supervision of an educator, installs:

- when connecting the PIP – the infusion set,
- when connecting the PIP with an integrated CGM system – the infusion set and the sensor.

For Annex 5.

Specification of Personal Insulin Pumps – Standards of Care of the Diabetes Poland. Recommended Necessary Requirements

Parameter		Description
Pump suspension of insulin delivery		Alarm indicating that the pump has been suspended
Pump lock		Electronic button lock
Bolus programming	Normal	Accuracy not less than 0.1 units/bolus
	Square Wave bolus (S)	Accuracy not less than 0.1 units/bolus Maximum bolus duration - not less than 7 hours
	Dual Wave bolus (D)	Accuracy not less than 0.1 units/bolus
Temporary change of basal delivery	Settings	Possible percentage or unit increase or decrease in insulin delivery, every 30 min with automatic return to basal delivery at programmed time
	Information about the active basal delivery (basal insulin)	Accessible from the home screen position or recalled with the touch of a button
	Time	Up to 24 hours
Basal delivery programming	Entering hourly rates (number of units per hour)	Accuracy not less than 0.1, and in children < 6 years of age not less than 0.05 IU/hr. At least 2 additional basal profiles for advance preparation with the option to recall from memory and apply
„Pump memory"	History of boluses, alarms, basal dose, daily dose, temporary basal change, infusion set filling; the program to read data from the pump should have the ability to simultaneously read data from the glucometer for which strips are refunded on the date of the tender as well as to integrate both sets of information or data from the CGM system with which it is integrated	For a minimum of 30 days, data should be collected via a computer program using a reader. The company provides free access to the software (either a local version or an online cloud version) and the necessary devices for reading data through the computer for the diabetic clinic managing the therapy (links) and the pump user. Program requirements are outlined in Appendix 1. Directly from the pump: current doses in the database, at least the last 20 boluses (doses and type), and total daily doses from the last 30 days.
Bolus calculator that is an integral part of the insulin delivery system (feature available on the insulin pump or a device that communicates wirelessly with the insulin pump or in an app on a smartphone)		**With the possibility:** • to program settings in several time intervals • user input of carbohydrate grams or carbohydrate exchanges • active insulin calculation with user-set insulin duration, which only reduces the correction dose of the insulin bolus. • manual entry of glucose levels into the bolus calculator or communication with a glucometer, for which strips are refunded as of the date of the tender, or communication with the CGM system
Automatic infusion set filling		Yes - unlimited number of infusions set fillings per day directly using only the function in the pump
Infusion sets		**Insertion sets** Insertions: metal (rigid) and plastic (flexible) – all types of insertions within the reimbursement amount Length of the drain – at least 2 lengths Length of cannula – at least 2 lengths **Drainless sets for patch pumps.** Cannula length – at least 2 lengths
Service		Providing telephone contact 24 hours a day with an authorized hotline (knowing exactly how the pump works, all possible alarms, errors), subject to customer review. Website with the information contained in Attachment 2. Replacement of the pump within 24 hours (working days) Shipping of the pump at the expense of the company

Parameter	Description
Batteries – powering the pump	AA, AAA batteries (commonly available in retail outlets, gas stations, home appliance and consumer electronics stores, etc.). In the case of rechargeable batteries, the possibility of powering them with a charger connected to electricity. Audible and displayed on the pump screen information on battery consumption/battery discharge greater than 70%
Additional accessories needed to use a personal insulin pump	Additional accessories for the personal insulin pump, which must be systematically replaced according to the instruction manual, are provided by the manufacturer free of charge for the life of the pump (does not apply to infusion sets, insulin reservoirs, batteries, insulin pump case).
Guarantee	At least 4 years, in case of malfunction replacement with a new pump In the case of replacement of the equipment with a new one, the total warranty period is not shorter than the one proposed in the offer; the warranty calculated from the date of implementation of the NFZ (NHF) procedure, not from the date of purchase from the manufacturer
Menu	Entirely Polish language or icons or symbols
User's manual	Entirely Polish language, all messages displayed by the pump must be described in the instructions

Insulin pump systems functionally integrated with a continuous glucose monitoring system (CGM) and automated insulin delivery (AID) systems must meet the following requirements:

- the CGM system is part of the insulin pump or directly connects to the application managing the PIP or AID,
- sensors and, if necessary, the transmitter for the CGM system are reimbursed on the day of the tender announcement,
- the integrated system must have a function for automatically suspending insulin in anticipation of hypoglycaemia based on values indicated by the CGM system,
- the automated insulin delivery (AID) system-hybrid closed loop (HCL) must include following functions:
  - » automatic basal delivery,
  - » automatic delivery of correction doses,
  - » additional features or settings for hypoglycaemia prevention in situations of increased risk,
  - » automatic transition to manual mode in case of CGM system and/or AID application failure.,
- in the case of application-based systems, the patient, along with the PIP, receives free access to the application for a minimum period of 4 years, and before choosing an integrated system or AID, must be informed about the necessity of having a smartphone model that allows for the use of the application,
- data from integrated systems and AID systems must be automatically transmitted to computer software that must be provided to both the individual with diabetes and the therapy centre, enabling the therapeutic team to have real-time access to the individual's data.

Specification of personal insulin pumps – Standards of care of Diabetes Poland 2025. Recommended additional requirements

Parameter	Description
Reminder to replace the infusion set	Alarm indicating that the infusion set needs to be replaced
History of infusion set fillings	Ability to check directly in the pump's memory the history of infusion set fills
IPX 8 standard	IPX 8
Additional: a device for users to read the pump memory at home with the ability to send data to the doctor	Access to the software (either a locally running version or an online version in the cloud) and the device needed for the computer to read the data
Additional basal delivery profiles	More than 3
Bolus calculator	With user-selectable mg/dl or mmol/l (glycemic determination) settings Ability to manually enter blood glucose levels into the bolus calculator
Continuous glucose levels monitoring system	System integrated with insulin pump or additional CGM device to support therapy with personal insulin pump
Computer software to read data from the pump	Devices with the ability to simultaneously read data from a glucometer, for which test strips are reimbursed on the day the tender is announced, or from a CGM system, as well as integrate both sets of information

For selected groups of individuals, it is permissible to modify the specifications of personal insulin pumps considering the patient's educational opportunities and personalization/individualization of therapeutic.

Attachment 1.

Requirements for the computer software for reading the memory of the pump:

- current basal deliveries (all possible from a single pump data retrieval, displayed in graphs or tables with exact dosages and times, precise to the pump's basal rate delivery),
- conversion values used within the bolus calculator, with set time intervals,
- bolus history (all boluses administered with a distinction between types and timing, including extended boluses),
- history of cannula fillings,
- daily charts must include:
  - basal rates for the day,
  - administered boluses,
  - temporary basal modification,
  - indication of the moments when the pump was stopped and restarted,
  - glucose readings transmitted from the associated CGM and/or glucometer,
- alarm history,
- for AID systems (HCL), data related to system settings necessary for activating automatic mode,
- the program for reading data from the pump must also have the capability to read data from a glucometer whose strips are reimbursed as of the tender announcement date and integrate both sets of information or with the CGM system integrated with the pump,
- free provision of software and the necessary device for retrieving pump memory data at home, with the capability of transferring this information to the therapeutic team.

Attachment 2.

Information required on the website:

- a helpline number offering 24-hour technical support for PIP users,
- contact details of local representatives, including their working hours,
- details regarding pump accessories (types of infusion sets, reservoirs, batteries, prices, etc.)

RECOMMENDED ADDITIONAL OPTIONS

1. Compatibility with at least one glucometer; wireless connectivity; option to enable or disable data transfer from the glucometer to the pump; capability to log glucose readings with the bolus calculator function active or inactive.
2. Insulin pumps, in the case of which there is a dedicated glucometer that is part of the system, should be distributed with it.
3. User-configurable reminders for boluses or glucose checks.
4. The cost of infusion sets should not exceed the monthly government funding limit for individuals < 26 years old and should be within 30% of this limit for individuals > 26 years old.

ADDITIONAL NOTE

The contracting entity may define extra parameters tailored to the needs of specific patient groups. Furthermore, the offer must include accessories essential for initiating therapy and conducting education: insertion devices, various infusion sets, insulin cartridges, batteries for powering the pump, protective cases. In evaluating pumps during the tender process, the cost of the pump should account for 60% of the assessment, while additional features should constitute 40%.

Annex 6.

Recommendations of the Diabetes Poland and the Polish Society of Sports Medicine Concerning Obtaining Consent for Participation in Sports by Individuals with Type 1 Diabetes

Individuals with type 1 diabetes, upon receiving a positive opinion from a diabetologist, can be qualified by a sports medicine specialist to practice any sport discipline.

One of the conditions for qualification to practice sports is treatment with intensive functional insulin therapy and understanding its principles. Treatment can be administered using pen-type injectors or a personal insulin pump. The preferred method for athletes with diabetes is treatment using an insulin pump, which allows for more precise adjustment of the insulin dose to the current demand during physical exertion. It is the duty of the athlete with diabetes to systematically monitor glycaemia using a glucometer, at least 6 times a day, with additional measurements during training and sporting competitions. The use of continuous glucose monitoring systems (CGM) is advisable, which additionally support treatment and increase the safety of the athlete.

Type 1 diabetes should not be a contraindication to participation in physical education classes at any educational level or in school sports (school sports associations, student sports clubs, school competitions, etc.).

Optimal glycemic levels at the start and during sports activity are within the range: for aerobic effort 126–180 mg/dl (7–10 mmol/l), for anaerobic effort 90–180 mg/dl (5–10 mmol/l).

It should be emphasized that the condition for maintaining high fitness and physical performance in individuals with type 1 diabetes who practice sports intensively over a longer period of time is > 70% of the time within the target range of 70–180 mg/dl and < 4% below 70 mg/dl, and on the day of sporting competitions < 1%.

I. Contraindications to sports participation by children and adults with type 1 diabetes requiring a sports medicine specialist's assessment:

1. HbA_{1c} – average from the last 12 months > 8.5% or a current result ≥ 9%.
2. More than one episode of ketoacidosis in the last 12 months.
3. More than one episode of severe hypoglycaemia in the last 12 months.
4. Self-monitoring of glycaemia: number of measurements < 6 per day using a glucometer in athletes not using CGM.
5. Visits to the diabetes clinic: for children < 4/year, for adults < 2/year.
6. Hypoglycaemia unawareness during wakefulness – relative contraindication, may be waived depending on the sport discipline and the use of CGM.
7. Chronic diabetes complications depending on the stage of progression and the sport discipline:

- proliferative retinopathy until the completion of laser therapy – absolute contraindication for all sports activities,
- clinically evident autonomic neuropathy – contraindication for high-intensity physical efforts,
- any microangiopathic complication or type 1 diabetes lasting more than 15 years in individuals > 35 years of age; high and very high-intensity physical activity – qualification after conducting cardiological diagnostics including resting EKG, echocardiographic examination, exercise test, 24-hour EKG recording using the Holter method,
- macrovascular complications – qualification after conducting cardiological diagnostics including resting EKG, echocardiographic examination, exercise test, 24-hour EKG recording using the Holter method,
- sgnificant proteinuria 0.2–0.5 g/day (UACR 30–100 mg/g) – relative contraindication to competitive sports, temporary exclusion, necessary re-examination under non-exercise conditions 48 hours before and during the test, and observation – proteinuria control (UACR) every 3–6 months, systematic blood pressure monitoring, and kidney function,
- proteinuria > 0.5 g/day (UACR > 100 mg/g) – absolute (temporary or permanent) disqualification from sports participation, necessary nephrological consultation,
- eGFR 45–60 ml/min/1.73 m^2 (G3a) – creatinine and eGFR monitoring at least every 3 months,
- eGFR 30–45 ml/min/1.73 m^2 (G3b) – relative contraindication to competitive sports, tempo-

rary exclusion, creatinine and eGFR monitoring every 4–6 weeks,
- eGFR < 30 ml/min/1.73 m^2 (G4) – absolute prohibition of sports participation.

*eGFR calculation according to the Schwartz formula up to 15 years of age, according to the CKD-EPI formula from 16 years of age.

II. Examinations to be performed during the qualification of an athlete with type 1 diabetes.

Preliminary qualification: current examinations consistent with the standards of the Polish Diabetes Association. HbA_{1c} values from the last 3 months, glucometer and/or CGM report, and insulin pump report (if used).

III. High-risk sports disciplines: motor, water, aviation, climbing

Practicing sports disciplines in which hypoglycaemia constitutes a particularly high threat to the safety of the patient and the environment is not recommended for individuals with type 1 diabetes.

Their practice is permitted under the following conditions:

- the athlete is very well educated and achieves treatment goals,
- glycaemia measurement up to 15 minutes before the start of activity and its value ≥ 120 mg/dl (6.7 mmol/l), glycaemia control using a glucometer every 30–60 minutes or less frequently in case of CGM use.

For high-risk sports disciplines, the use of CGM is advisable.

IV. Contraindications to participation in training and sports competitions

1. Severe hypoglycaemia in the last 24 hours.
2. Hyperglycaemia above 250 mg/dl (13.9 mmol/l) with accompanying ketonemia/ketonuria resulting from insulin deficiency, not carbohydrate deficiency.
3. Ketonemia ≥ 1.5 mmol/l constitutes an absolute contraindication to start and continue physical exertion.
4. Hyperglycaemia > 300 mg/dl (16.7 mmol/l) persisting for more than 2 hours.
5. Any acute event requiring medical assistance, such as visual disturbance, chest pain, fainting, acute infection, etc.

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Annex 7.

Organizational Requirements in Diabetic Care

Specialized Diabetic Units

1. Medical staff – two specialists in diabetology employed full-time, or alternatively, one diabetology specialist and one specialist in internal medicine with a minimum of one year of experience working in a diabetes ward or clinic, or a doctor in their second year of diabetology specialisation training.
2. Nursing staff:

- a nurse with specialization in diabetic nursing or internal medicine nursing, or who has completed a specialised course "Diabetes Educator" or a qualification course in diabetes nursing, or with at least two years of professional experience in a diabetic ward/clinic,
- one nurse per 10 diabetic beds, whose duties are limited to education and care for individuals with diabetes.

3. Dietitian working at least ½ FTE (full-time equivalents).
4. Psychologist working at least ¼ FTE.
5. Access to specialist consultations.
6. Equipment:

- at least two stations for treating individuals in acute metabolic states equipped with an ECG monitor, blood pressure monitor, infusion pump, pulse oximeter, and access to oxygen therapy,
- an educational room,
- intravenous infusion pumps,
- equipment for diagnosing and treating diabetic foot syndrome,
- access to cardiological diagnostics (stress test, ECG, echocardiography, Holter ECG, Holter RR) and vascular diagnostics (Doppler artery examination).
- necessary rooms serving as a wound care office.

Specialized Diabetic Clinics

1. The team providing care for a person with diabetes within the framework of outpatient specialist care (AOS) includes:

- a specialist in diabetology or internal medicine with at least two years of professional experience in a diabetes ward or clinic, or a doctor in their second year of diabetology specialisation
- for specialist clinics for children and adolescents – a specialist in diabetology, diabetology and paediatric endocrinology, or a paediatrician with at least two years of professional experience in a paediatric diabetes clinic/ward, or a doctor in their second year of specialisation in diabetology or paediatric diabetology and endocrinology
- a nurse specialised in diabetes nursing or having completed the "Diabetes Educator" course, or a nurse specialised in internal medicine nursing or having completed a qualification course in diabetes nursing, or with at least two years of experience in a diabetes ward or specialised diabetes clinic.
- dietitian working at least ¼ FTE.
- access to psychological care in justified individual clinical cases.

Children and Adolescents, Pregnant Women (refer to thematic chapters).

2. Equipment of specialized clinics:

- doctor's offices,
- a procedure room with a designated area for sample collection and analysis,
- a nursing and educational room with a dietary section,
- capability to read and analyse data from glucometers, insulin pumps, and continuous glucose monitoring devices using IT systems,
- set for diabetic foot syndrome examination (thermotip, tuning fork – 128 Hz, monofilament 10 g, neurological hammer),
- access to imaging studies.

Access to specialist consultations should also be ensured for regular monitoring of complications.

Organization of care for individuals with diabetic foot syndrome

Reference diabetic foot clinics.

1. Personnel requirements:

- physicians: at least two FTE – Equivalent of at least one FTE – a specialist in diabetology with documented experience of at least one year in treating individuals with diabetic foot syndrome,
- purses: Equivalent of one FTE; documented at least one year of experience in treating and caring for individuals with diabetic foot syndrome or chronic wounds.

2. Access to hospitalisation in a ward (or clinic) under contract with the National Health Fund (NFZ).

3. Access to multidisciplinary care, including consultations with a surgeon, vascular surgeon or angiologist, and orthopaedist.
4. Ensuring intravenous antibiotic therapy capability.
5. Access to basic imaging diagnostics, i.e., X-ray, ultrasound (including Doppler ultrasound), as well as CT and/or MRI.
6. Access to laboratory and microbiological tests performed in a medical diagnostic laboratory registered in the register of the National Council of Laboratory Diagnosticians (KRDL).

Primary Clinics

These clinics should provide diagnostics, treatment, and prevention of ulcers, infections, and Charcot neuroarthropathy associated with diabetic foot syndrome. Basic clinics collaborate with reference clinics where more severe clinical cases are consulted and potentially transferred for treatment.

Teleconsultations as an Element of Diabetes Care. Each diabetes clinic should be equipped with the necessary tools to conduct effective teleconsultations. Clinics must have a computer with appropriate software, and staff should be trained. Individuals with diabetes should be encouraged to use new technologies and applications that facilitate remote medical consultations. It is important to note that the effectiveness of teleconsultations increases with the amount of source data available about the individual's treatment (e.g., data from glucometer memory, CGM systems, personal insulin pumps) provided to the doctor conducting the teleconsultation.

For individuals with diabetes, remote medical consultations can be an integral part of regular diabetes care and can also be utilized in situations of epidemiological risk.