

Justification

for the Resolution of the Federal Joint Committee (G-BA) on
an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with
New Active Ingredients according to Section 35a SGB V
Tirzepatide (new therapeutic indication: type 2 diabetes
mellitus, ≥ 10 to < 18 years)

From 20 August 2026

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
- 3rd additional medical benefit in relation to the appropriate comparator therapy,
- 4th number of patients and patient groups for whom there is a therapeutically significant additional benefit,
- 5th treatment costs for the statutory health insurance funds,
- 6th requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient tirzepatide (Mounjaro) was listed for the first time in the Große Deutsche Spezialitäten-Steuer (Lauer-Steuer) on 15 September 2022.

On 22 January 2026, tirzepatide received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 18 February 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with

Chapter 5 Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient tirzepatide with the new therapeutic indication "for the treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 June 2026 on the G-BA website at (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of tirzepatide compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by IQWiG in accordance with the General Methods ¹ was not used in the benefit assessment of tirzepatide.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy

2.1.1 Approved therapeutic indication of tirzepatide (Mounjaro) in accordance with product information

Mounjaro is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications,
- in addition to other medicinal products for the treatment of diabetes mellitus.

Therapeutic indication of the resolution (resolution of 20.08.2026):

Mounjaro is indicated for the treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications,
- in addition to other medicinal products for the treatment of diabetes mellitus.

¹ General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children and adolescents aged 10 to less than 18 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy in addition to diet and exercise

Appropriate comparator therapy:

- An individualised therapy with selection of
 - Metformin + basal insulin²
 - Metformin + liraglutide or dulaglutide
 - Metformin + dapagliflozin or empagliflozin
 - Basal insulin² + metformin + liraglutide or dulaglutide
 - Basal insulin² + metformin + dapagliflozin or empagliflozin
 - Escalation of insulin therapy³: conventional insulin therapy (CT) or intensified conventional insulin therapy (ICT), in each case in combination with metformin and liraglutide or dulaglutide or dapagliflozin or empagliflozin

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the

²Human insulin or insulin analogues (insulin degludec or insulin detemir or insulin glargine)

³ Human insulin or insulin analogues (insulin detemir, insulin glargine, insulin degludec, insulin aspart, insulin glulisine, insulin lispro)

Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

- On 1. In addition to tirzepatide, the active ingredient metformin, the GLP-1 receptor agonists exenatide, dulaglutide and liraglutide, the SGLT-2 inhibitors dapagliflozin and empagliflozin, and insulin (human insulin or insulin analogues [insulin detemir, insulin glargine, insulin degludec, insulin aspart, insulin glulisine, insulin lispro]) are approved for the treatment of type 2 diabetes mellitus in children and adolescents aged 10 years and above.
- On 2. A non-medicinal treatment is not considered the appropriate comparator therapy in this therapeutic indication.
- On 3. The following resolutions of the G-BA on the early benefit assessment of medicinal products with new active ingredients are available for this therapeutic indication in children and adolescents with type 2 diabetes mellitus (Annex XII to the Pharmaceuticals Directive):
- Insulin degludec from 20 August 2015
 - Dapagliflozin from 16 June 2022
 - Dulaglutide from 21 September 2023
 - Empagliflozin from 20 June 2024
- On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

There is an S3 guideline⁴ on the diagnosis, treatment and follow-up of diabetes mellitus in childhood and adolescence. According to the recommendations, metformin is the agent of first choice for the medicinal treatment of type 2 diabetes mellitus. If the HbA1c value is $\geq 8.5\%$ without acidosis, the combination of metformin with basal insulin is recommended as initial therapy. Patients with acidosis or diabetic ketoacidosis should initially receive insulin therapy. However, once the acidosis has normalised, metformin therapy should also be started in these children and adolescents (while maintaining basal insulin therapy).

It is assumed that metformin contraindications, which exist according to the product information of metformin, for example in severe renal failure, metabolic acidoses, diabetic precoma or liver failure, occur less frequently in children and adolescents. Metformin intolerances, for example gastrointestinal intolerances can also occur in children and adolescents with type 2 diabetes mellitus, especially at the start of treatment. Clinical experience shows that metformin intolerance occurs with a comparable frequency in children and adolescents with type 2 diabetes mellitus as in adult patients. According to the product information of metformin for use in children and adolescents, a gradual increase in the dosage has a positive effect on the gastrointestinal tolerability of metformin. Overall, it is therefore assumed that only a smaller percentage of children and adolescents have a metformin contraindication or permanent intolerance compared to the total population.

According to the current recommendations, the therapy of type 2 diabetes mellitus in children and adolescents does not represent a static therapeutic concept. Rather, the medication should be reviewed regularly and adjusted patient-individually. The treatment decision is made, in particular, taking into account the HbA1c value, previous therapies and occurring complications (e.g. ketosis or diabetic ketoacidosis).

In addition to metformin and insulin, the GLP-1 receptor agonists liraglutide, dulaglutide and exenatide, as well as the SGLT-2 inhibitors dapagliflozin and empagliflozin, are available as further treatment options for children and adolescents aged 10 years and above with type 2 diabetes mellitus.

According to the S3 guideline, an additional therapy with a GLP-1 receptor agonist or an SGLT-2 inhibitor should be given if children and adolescents do not achieve the patient-individual therapeutic goals with metformin alone. Any insulin therapy already in place (in combination with metformin) should, where possible, be replaced by either a GLP-1-receptor agonist or an SGLT-2 inhibitor, taking into account patient-individual criteria (HbA1c value, previous therapies and complications). In the German healthcare context, the active ingredients liraglutide and dulaglutide – both GLP-1 receptor agonists – and the SGLT-2 inhibitors assume the greatest significance.

Therapy escalation is recommended upon occurrence of metabolic crises (e.g. ketoacidosis), or if adequate glycaemic control is not achieved with a dual combination regimen - either metformin plus a GLP-1 receptor agonist/ SGLT-2 inhibitor, or basal insulin plus metformin. This can be achieved either by adjusting basal-supported oral therapy using a combination therapy of basal insulin and metformin, supplemented by a GLP-1 receptor agonist or an SGLT-2 inhibitor, or by intensifying insulin therapy to

⁴ German Diabetes Society: diagnosis, treatment and follow-up of diabetes mellitus in childhood and adolescence; S3 guideline, extended version, version 4.1 [online]. AWMF registry number: 057-016. [S3 guideline on the diagnosis, treatment and follow-up of diabetes mellitus in childhood and adolescence. Version 4.1](#)

conventional insulin therapy (CT) or intensified conventional insulin therapy (ICT). New recommendations also consider the continuation of the previous combination therapy with metformin and a GLP-1-receptor agonist or an SGLT-2-inhibitor to be indicated even in the case of insulin therapy escalation. Accordingly, the combination of metformin and a GLP-1 receptor agonist or an SGLT-2 inhibitor should be continued as part of the intensification of insulin therapy. In children and adolescents, insulin therapy can take the form of pump therapy.

Overall, especially for children and adolescents, one therapeutic goal is to keep the period of insulin intake as short as possible. The administration of insulin in children and adolescents, who have reached their target blood sugar levels, is usually not a long-term therapy and should be replaced by other therapy options, if possible.

Taking the available evidence into account, an individualised therapy with the selection of the following therapy options constitutes the appropriate comparator therapy for children and adolescents aged 10 to less than 18 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy in addition to diet and exercise: A combination therapy with metformin and basal insulin, or metformin combined with either a GLP-1 receptor agonist (liraglutide or dulaglutide) or an SGLT-2 inhibitor (dapagliflozin or empagliflozin), or the adjustment of basal-supported oral therapy by combining basal insulin with metformin and, in each case, additionally with a GLP-1 receptor agonist or an SGLT-2 inhibitor. Further therapy options include insulin therapy escalation in the form of conventional insulin therapy (CT) or intensified conventional insulin therapy (ICT), in each case in combination with metformin and liraglutide or dulaglutide or dapagliflozin or empagliflozin.

Individualised therapy is based on the assumption that several treatment options, which allow an individualised medical treatment decision, are available. When making the treatment decision, particular consideration should be given to the HbA1c value, previous therapies and occurring complications, taking into account the available evidence.

The continuation of an inadequate therapy for the treatment of type 2 diabetes mellitus, if there are still possibilities of therapy escalation, does not correspond to the appropriate comparator therapy.

It is assumed that possible comorbidities or risk factors of type 2 diabetes mellitus (e.g. hypertension, dyslipidaemia, microvascular complications – nephropathy, neuropathy, retinopathy) are treated patient-individually according to the current state of medical knowledge, in particular by administering anti-hypertensive drugs and/or lipid-lowering agents.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of tirzepatide is assessed as follows:

Children and adolescents aged 10 to less than 18 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy in addition to diet and exercise

An additional benefit is not proven.

Justification:

In their dossier, the pharmaceutical company did not present any suitable study for the assessment of the additional benefit of tirzepatide in comparison with the appropriate comparator therapy.

They identified the label-enabling SURPASS-PEDS study in the present therapeutic indication and presented it in the dossier. This is a randomised, double-blind, placebo-controlled phase III study. Previous therapy with metformin and/or basal insulin was continued in both arms of this study, and was only permitted to be escalated in the event of hyperglycaemia. However, the pharmaceutical entrepreneur did not explain to what extent treatment with metformin and/or basal insulin constituted an individualised therapy. In this context, continuing with inadequate antidiabetic treatment does not constitute the implementation of the specified appropriate comparator therapy. In accordance with the pharmaceutical company's approach in the dossier, this study is not considered for the present benefit assessment due to the lack of comparison with the appropriate comparator therapy. An additional benefit is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient tirzepatide. The therapeutic indication assessed here is as follows: "For the treatment of adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise."

The G-BA determined an individualised therapy with the selection of the following therapy options as the appropriate comparator therapy: Metformin + basal insulin, metformin + liraglutide or dulaglutide, metformin + dapagliflozin or empagliflozin, basal insulin + metformin + liraglutide or dulaglutide, basal insulin + metformin + dapagliflozin or empagliflozin and insulin therapy escalation.

In their dossier, the pharmaceutical company did not present any suitable study for the assessment of the additional benefit of tirzepatide in comparison with the appropriate comparator therapy.

An additional benefit of tirzepatide in children and adolescents aged 10 to less than 18 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy in addition to diet and exercise, is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The information is based on the data of the pharmaceutical company from the dossier and the patient numbers from the resolution on the benefit assessment of the active ingredient empagliflozin⁵. The G-BA take into account the patient numbers stated in the pharmaceutical company's dossier, which are, however, subject to uncertainty as in the previous procedure.

2.3 Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Mounjaro (active ingredient: tirzepatide) at the following publicly accessible link (last access: 15 June 2026):

https://www.ema.europa.eu/en/documents/product-information/mounjaro-epar-product-information_en.pdf

The use of GLP-1 receptor agonists (among others, tirzepatide) has been associated with a risk of developing acute pancreatitis. Patients should be informed about the characteristic symptoms of acute pancreatitis and therapy should be changed if necessary.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 June 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

Treatment duration and consumption

With regard to consumption, the average annual consumption was determined by indicating the number of tablets or (international) units. The daily dosages recommended in the product information were used as a basis for calculation and, if necessary, appropriate ranges were formed. The costs of a possibly necessary titration phase have not been shown, since the anti-diabetic therapy is a continuous long-term therapy and the titration is patient-specific.

The information on treatment duration and dosage was taken from the corresponding product information.

A variety of different insulin dosing regimens are available for insulin therapy. In addition, according to the insulin dosage regimen used, the amount of insulin and the frequency of application must be individually adjusted according to the patient's physical activity and lifestyle. To ensure comparability of costs, simplified assumptions have been made for the presentation of treatment duration and dosage. In the "Treatment duration" table, the treatment mode for human insulin (NPH insulin or mixed insulin) is shown as "1 - 2 x daily", although the frequency of application may differ for individual patients.

The insulin dosages (I.U. or U.) per patient are calculated based on the dosage requirement in the age group (children and adolescents aged 10 years and above). The calculation of

⁵ Resolution of the G-BA on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V for empagliflozin dated 20 June 2024.

consumption is based on a dosage requirement of 0.25 to 1.5 I.U./ kg BW/ day for children and adolescents going through puberty^{6,7}.

The basal insulin daily requirement is usually 40 - 60% of the insulin daily requirement, the remaining requirement is covered accordingly by meal-dependent bolus insulin. Three main meals are assumed when calculating bolus insulin consumption. This information was used to calculate the dose of insulin per patient.

Insulin detemir is no longer commercially available, which is why it cannot be included in the cost calculation.

Taking into account the prescription restriction of insulin analogues set out in Annex III, Nos. 33 and 33a of the Pharmaceuticals Directive (AM-RL), the annual treatment costs for the insulin analogues insulin glargine, insulin aspart, insulin glulisine and insulin lispro are stated as "non-quantifiable". As a rule, these active ingredients cannot be prescribed at SHI's expense as long as they entail additional costs compared with human insulin.

For the calculation of the consumption of medicinal products to be dosed according to weight, the G-BA generally uses non-indication-specific average weights as a basis. For body weight, a range between 39.4 kg for 10-year-olds and 67.9 kg for 17-year-olds is therefore assumed according to the official representative statistics "2025 Microcensus"⁸.

Consequently, weight differences between boys and girls as well as the fact that the bodyweight of patients with type 2 diabetes mellitus may be higher than the average values typical of the age are not taken into account for the cost calculation.

⁶ According to the WHO definition, adolescents aged 10 to 19 are in puberty. World Health Organisation. Maternal, Newborn, Child and Adolescent Health and Ageing Data portal [online] URL: <https://platform.who.int/data/maternal-newborn-child-adolescent-ageing/adolescent-data>

⁷ Shah AS, Barrientos-Pérez M, Chang N, Fu JF, Hannon TS, Kelsey M, Peña AS, Pinhas-Hamiel O, Urakami T, Wicklow B, Wong J, Mahmud FH. ISPAD Clinical Practice Consensus Guidelines 2024: Type 2 Diabetes in Children and Adolescents. *Horm Res Paediatr.* 2024;97(6):555-583. doi: 10.1159/000543033. Epub 2024 Dec 14. PMID: 39675348; PMCID: PMC11854986; DOI: [10.1159/000543033](https://doi.org/10.1159/000543033)

⁸ Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

Children and adolescents aged 10 to less than 18 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy in addition to diet and exercise

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year	
Medicinal product to be assessed					
Tirzepatide	Continuously, 1 x every 7 days	52.1	1	52.1	
Concomitant active ingredient of the medicinal product to be assessed					
Metformin	Continuously, 1 – 3 x daily	365.0	1	365.0	
Dapagliflozin	Continuously, 1 x daily	365.0	1	365.0	
Empagliflozin	Continuously, 1 x daily	365.0	1	365.0	
Basal insulin					
Human insulin (NPH insulin)	Continuously, 1 – 2 x daily	365.0	1	365.0	
Insulin degludec	Continuously, 1 x daily				
Insulin glargine	Continuously, 1 x daily				
Conventional insulin therapy (CT, mixed insulin) or intensified conventional insulin therapy (ICT)					
Conventional insulin therapy (CT, mixed insulin) ⁹	Continuously, 1 – 2 x daily	365.0	1	365.0	
<u>Intensified conventional insulin therapy (ICT)</u> ¹⁰					
	Human insulin (NPH insulin)	Continuously, 1 – 2 x daily	365.0	1	365.0
		Continuously, 3 x daily	365.0	1	365.0

⁹ The combination with mixed insulin and metformin is shown as an example of the combination of tirzepatide with an insulin in the context of escalation of insulin therapy, in this case with conventional insulin therapy.

¹⁰ The combination with and without metformin is shown as an example of the combination of tirzepatide with an insulin in the context of escalation of insulin therapy, in this case with an intensified conventional insulin therapy.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Human insulin (bolus insulin)				
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec or insulin glargine or human insulin (NPH insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin)	Continuously, 1 x daily Continuously, 1 - 2 x daily Continuously, 3 x daily	365.0	1	365.0
Appropriate comparator therapy				
Metformin	Continuously, 1 – 3 x daily	365.0	1	365.0
Dapagliflozin	Continuously, 1 x daily	365.0	1	365.0
Empagliflozin	Continuously, 1 x daily	365.0	1	365.0
Dulaglutide	Continuously, 1 x every 7 days	52.1	1	52.1
Liraglutide	Continuously, 1 x daily	365.0	1	365.0
Basal insulin				
Human insulin (NPH insulin)	Continuously, 1 – 2 x daily	365.0	1	365.0
Insulin degludec	Continuously, 1 x daily			
Insulin glargine	Continuously, 1 x daily			
Conventional insulin therapy (CT, mixed insulin) or intensified conventional insulin therapy (ICT)				
Conventional insulin therapy (CT, mixed insulin)	Continuously, 1 – 2 x daily	365.0	1	365.0

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Intensified conventional <u>insulin therapy (ICT)</u> Human insulin (NPH insulin) + human insulin (bolus insulin)	Continuously, 1 – 2 x daily Continuously, 3 x daily	365.0	1	365.0
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec or insulin glargine or human insulin (NPH insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin)	Continuously, 1 x daily Continuously, 1 - 2 x daily Continuously, 3 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Tirzepatide	5 mg - 10 mg	5 mg - 10 mg	1 x 5 mg – 1 x 10 mg	52.1	52.1 x 5 mg – 52.1 x 10 mg
Concomitant active ingredient of the medicinal product to be assessed					
Metformin	500 mg – 1,000 mg	500 mg – 2,000 mg	1 x 500 mg – 2 x 1,000 mg	365.0	365 x 500 mg – 730 x 1,000 mg
Dapagliflozin	10 mg	10 mg	1 x 10 mg	365.0	365 x 10 mg
Empagliflozin	10 mg – 25 mg	10 mg – 25 mg	1 x 10 mg – 1 x 25 mg	365.0	365 x 10 mg – 365 x 25 mg
Basal insulin					
Human insulin (NPH insulin)	0.25 I.U./ kg BW – 1.5 I.U./ kg BW	9.85 I.U. – 101.85 I.U.	1 x 9.85 I.U. – 1 x 101.85 I.U.	365.0	3,595.3 I.U. – 37,175.3 I.U.
Insulin degludec (basal insulin)	0.25 U./ kg BW – 1.5 U./ kg BW or ¹¹ 0.2 U./ kg BW – 1.2 U./ kg BW	9.85 U. – 101.85 U. or ¹¹ 7.88 U. – 81.48 U.	1 x 9.85 U. – 1 x 101.85 U. or ¹¹ 1 x 7.88 U. – 1 x 81.48 U.		3,595.3 U. – 37,175.3 U. or ¹¹ 2,876.20 U. – 29,740.20 U.
Insulin glargine (basal insulin)	0.25 U./ kg BW – 1.5 U./ kg BW	9.85 U. – 101.85 U.	1 x 9.85 U. – 1 x 101.85 U.		3,595.3 U. – 37,175.3 U.
conventional insulin therapy (CT, mixed insulin)					
Conventional insulin therapy (CT, mixed insulin)	0.25 I.U./ kg BW – 1.5 I.U./ kg BW	9.85 I.U. – 101.85 I.U.	1 x 9.85 I.U. – 1 x 101.85 I.U.	365.0	3,595.3 I.U. – 37,175.3 I.U.

¹¹ According to the PI, it is recommended that the dose of insulin degludec in combination therapy with a GLP-1 receptor agonist be reduced by 20% in order to minimise the risk of hypoglycaemia.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Intensified conventional insulin therapy (ICT)					
Human insulin (NPH insulin) + human insulin (bolus insulin)	0.1 I.U./ kg BW – 0.9 I.U./ kg BW + 0.1 I.U./ kg BW – 0.9 I.U./ kg BW	3.94 I.U. – 61.11 I.U. + 3.94 I.U. – 61.11 I.U.	1 x 3.94 I.U. – 1 x 61.11 I.U. + 1 x 3.94 I.U. – 1 x 61.11 I.U.	365.0	1,438.1 I.U. – 22,305.15 I.U. + 1,438.1 I.U. – 22,305.15 I.U.
Insulin degludec + human insulin (bolus insulin)	0.1 U./ kg BW – 0.9 U./ kg BW or ¹¹ 0.08 U./ kg BW – 0.72 U./ kg BW + 0.1 I.U./ kg BW – 0.9 I.U./ kg BW	3.94 I.U. – 61.11 I.U. or ¹¹ 3.15 U. – 48.89 U. + 3.94 I.U. – 61.11 I.U.	1 x 3.94 U. – 1 x 61.11 U. or ¹¹ 1 x 3.15 U. – 1 x 48.89 U. + 1 x 3.94 I.U. – 1 x 61.11 I.U.	365	1,438.1 U. – 22,305.15 U. or ¹¹ 1,149.75 U. – 17,844.85 U. + 1,438.1 I.U. – 22,305.15 I.U.
Human insulin (NPH insulin) ¹² or insulin glargine + human insulin (bolus insulin) ¹² insulin aspart or insulin glulisine or insulin lispro	0.1 U./ kg BW – 0.9 U./ kg BW + 0.1 U./ kg BW – 0.9 U./ kg BW	3.94 I.U. – 61.11 I.U. + 3.94 I.U. – 61.11 I.U.	1 x 3.94 U. – 1 x 61.11 U. + 1 x 3.94 U. – 1 x 61.11 U.	365.0	1,438.1 U. – 22,305.15 U. + 1,438.1 U. – 22,305.15 U.
Appropriate comparator therapy					

¹² Human insulins are shown here in combination with insulin analogues

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Metformin	500 mg – 1,000 mg	500 mg – 2,000 mg	1 x 500 mg – 2 x 1,000 mg	365.0	365 x 500 mg – 730 x 1,000 mg
Dapagliflozin	10 mg	10 mg	1 x 10 mg	365.0	365 x 10 mg
Empagliflozin	10 mg – 25 mg	10 mg – 25 mg	1 x 10 mg – 1 x 25 mg	365.0	365 x 10 mg – 365 x 25 mg
Liraglutide ¹³	1.2 mg – 1.8 mg	1.2 mg – 1.8 mg	1 x 1.2 mg – 1 x 1.8 mg	365.0	365 x 1.2 mg – 365 x 1.8 mg
Dulaglutide	0.75 mg – 1.5 mg	0.75 mg – 1.5 mg	1 x 0.75 mg – 1 x 1.5 mg	52.1	52.1 x 0.75 mg – 52.1 x 1.5 mg
Basal insulin					
Human insulin (NPH insulin)	0.25 I.U./ kg BW – 1.5 I.U./ kg BW	9.85 I.U. – 101.85 I.U.	1 x 9.85 I.U. – 1 x 101.85 I.U.	365.0	3,595.3 I.U. – 37,175.3 I.U.
Insulin degludec (basal insulin)	0.25 U./ kg BW – 1.5 U./ kg BW or ¹¹ 0.2 U./ kg BW – 1.2 U./ kg BW	9.85 U. – 101.85 U. or ¹¹ 7.88 U. – 81.48 U.	1 x 9.85 U. – 1 x 101.85 U. or ¹¹ 1 x 7.88 U. – 1 x 81.48 U.		3,595.3 U. – 37,175.3 U. or ¹¹ 2,876.20 U. – 29,740.20 U.
Insulin glargine (basal insulin)	0.25 U./ kg BW – 1.5 U./ kg BW	9.85 U. – 101.85 U.	1 x 9.85 U. – 1 x 101.85 U.		3,595.3 U. – 37,175.3 U.
conventional insulin therapy (CT, mixed insulin)					
Conventional insulin therapy (CT, mixed insulin)	0.25 I.U./ kg BW – 1.5 I.U./ kg BW	9.85 I.U. – 101.85 I.U.	1 x 9.85 I.U. – 1 x 101.85 I.U.	365.0	3,595.3 I.U. – 37,175.3 I.U.
Intensified conventional insulin therapy (ICT)					
Human insulin (NPH insulin)	0.1 I.U./ kg BW –	3.94 I.U. –	1 x 3.94 I.U. –	365.0	1,438.1 I.U. –

¹³ According to the product information, each pre-filled pen contains 18 mg liraglutide in 3 ml solution, corresponding to 10 – 15 single doses. Packs of 2, 5 and 10 pre-filled pens are available.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
+ human insulin (bolus insulin)	0.9 I.U./ kg BW + 0.1 I.U./ kg BW – 0.9 I.U./ kg BW	61.11 I.U. + 3.94 I.U. – 61.11 I.U.	1 x 61.11 I.U. + 1 x 3.94 I.U. – 1 x 61.11 I.U.		22,305.15 I.U. + 1,438.1 I.U. – 22,305.15 I.U.
Insulin degludec + human insulin (bolus insulin)	0.1 U./ kg BW – 0.9 U./ kg BW or ¹¹ 0.08 U./ kg BW – 0.72 U./ kg BW + 0.1 I.U./ kg BW – 0.9 I.U./ kg BW	3.94 I.U. – 61.11 I.U. or ¹¹ 3.15 U. – 48.89 U. + 3.94 I.U. – 61.11 I.U.	1 x 3.94 U. – 1 x 61.11 U. or ¹¹ 1 x 3.15 U. – 1 x 48.89 U. + 1 x 3.94 I.U. – 1 x 61.11 I.U.	365	1,438.1 U. – 22,305.15 U. or ¹¹ 1,149.75 U. – 17,844.85 U. + 1,438.1 I.U. – 22,305.15 I.U.
Human insulin (NPH insulin) or insulin glargine + human insulin (bolus insulin) insulin aspart or insulin glulisine or insulin lispro	0.1 U./ kg BW – 0.9 U./ kg BW + 0.1 U./ kg BW – 0.9 U./ kg BW	3.94 I.U. – 61.11 I.U. + 3.94 I.U. – 61.11 I.U.	1 x 3.94 U. – 1 x 61.11 U. + 1 x 3.94 U. – 1 x 61.11 U.	365.0	1,438.1 U. – 22,305.15 U. + 1,438.1 U. – 22,305.15 U.

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction

of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

In the case of conventional insulin therapy, the costs for mixed insulin (i.e. a human insulin preparation in a specific mixing ratio of 30% regular insulin to 70% basal insulin) were used as a basis.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Tirzepatide 5 mg	3 SFI	€ 807.84	€ 1.77	€ 44.10	€ 761.97
Tirzepatide 10 mg	3 SFI	€ 1,126.44	€ 1.77	€ 61.74	€ 1,062.93
+ metformin 500 mg, if applicable ¹⁴	180 FCT	€ 16.52	€ 1.77	€ 0.41	€ 14.34
+ metformin 1,000 mg, if applicable ¹⁴	180 FCT	€ 19.11	€ 1.77	€ 0.62	€ 16.72
+ dapagliflozin 10 mg, if applicable	98 FCT	€ 236.44	€ 1.77	€ 0.00	€ 234.67
+ empagliflozin 10 mg, if applicable	100 FCT	€ 235.66	€ 1.77	€ 12.42	€ 221.47
+ empagliflozin 25 mg, if applicable	100 FCT	€ 189.71	€ 1.77	€ 9.88	€ 178.06
+ human insulin ¹⁴ (NPH insulin), if applicable	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21
+ mixed insulin ¹⁴ , if applicable	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21
+ human insulin ¹⁴ (bolus insulin), if applicable	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21
Long-acting insulin analogues					
+ insulin degludec 100 U./ml, if applicable	3,000 U.	€ 103.88	€ 1.77	€ 5.12	€ 96.99
+ insulin glargine 100 U./ml, if applicable	Non-quantifiable				
Short-acting insulin analogues					
+ insulin aspart 100 U./ml, if applicable	Non-quantifiable				
+ insulin glulisine 100 U./ml, if applicable	Non-quantifiable				
+ insulin lispro 100 U./ml, if applicable	Non-quantifiable				
Appropriate comparator therapy					
Metformin 500 mg ¹⁴	180 FCT	€ 16.52	€ 1.77	€ 0.41	€ 14.34
Metformin 1,000 mg ¹⁴	180 FCT	€ 19.11	€ 1.77	€ 0.62	€ 16.72
Dapagliflozin 10 mg	98 FCT	€ 236.44	€ 1.77	€ 0.00	€ 234.67
Empagliflozin 10 mg	100 FCT	€ 235.66	€ 1.77	€ 12.42	€ 221.47
Empagliflozin 25 mg	100 FCT	€ 189.71	€ 1.77	€ 9.88	€ 178.06
Dulaglutide 0.75 mg	12 SFI	€ 287.75	€ 1.77	€ 15.30	€ 270.68
Dulaglutide 1.5 mg	12 SFI	€ 287.75	€ 1.77	€ 15.30	€ 270.68
Liraglutide 18 mg	100 150 SD	€ 688.42	€ 1.77	€ 37.49	€ 649.16
Human insulin ¹⁴ (NPH insulin)	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21
Mixed insulin ¹⁴	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21
Human insulin ¹⁴ (bolus insulin)	3,000 I.U.	€ 89.98	€ 1.77	€ 0.00	€ 88.21

¹⁴ Fixed reimbursement rate

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Long-acting insulin analogues					
Insulin degludec 100 U./ml	3,000 U.	€ 103.88	€ 1.77	€ 5.12	€ 96.99
Insulin glargine 100 U./ml	Non-quantifiable				
Short-acting insulin analogues					
Insulin aspart 100 U./ml	Non-quantifiable				
Insulin glulisine 100 U./ml	Non-quantifiable				
Insulin lispro 100 U./ml	Non-quantifiable				
Abbreviations: U. = units; SD = single doses; FCT = film-coated tablets; I.U. = international units; SFI = solution for injection, i.e. pre-filled pen					

LAUER-TAXE® last revised: 15 June 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised in the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

Designation of the therapy	Designation	Costs/ pack ¹⁵	Number	Consumption/ year
Medicinal product to be assessed				
Tirzepatide	Disposable needles	€ 20.99	1 x every 7 days	52.1
Concomitant active ingredient of the medicinal product to be assessed				
Human insulin (NPH insulin) or conventional insulin therapy (mixed insulin, CT)	Blood glucose test strips	€ 17.95	1 – 3 x daily	365.0 – 1,095.0
	Lancets	€ 4.20	1 – 3 x daily	365.0 – 1,095.0
	Disposable needles	€ 20.99	1 – 2 x daily	365.0 – 730.0

¹⁵ Number of test strips/ pack = 50 pcs.; number of lancets/ pack = 200 pcs.; number of disposable needles/ pack = 100 pcs.; presentation of the lowest-priced pack according to LAUER-TAXE®, last revised: 15 September 2025.

Designation of the therapy	Designation	Costs/ pack ¹⁵	Number	Consumption/ year
Intensified conventional insulin therapy (ICT)	Blood glucose test strips	€ 17.95	4 – 6 x daily	1,460 – 2,190
	Lancets	€ 4.20	4 – 6 x daily	1,460 – 2,190
	Disposable needles	€ 20.99	4 – 5 x daily	1,460 – 1,825
Insulin degludec (basal insulin)	Blood glucose test strips	€ 17.95	1 – 3 x daily	365.0 – 1,095.0
	Lancets	€ 4.20	1 – 3 x daily	365.0 – 1,095.0
	Disposable needles	€ 20.99	1 x daily	365.0
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec + human insulin (bolus insulin)	Blood glucose test strips	€ 17.95	4 – 6 x daily	1,460 – 2,190
	Lancets	€ 4.20	4 – 6 x daily	1,460 – 2,190
	Disposable needles	€ 20.99	4 x daily	1,460
Insulin glargine + insulin aspart or insulin glulisine or insulin lispro	Non-quantifiable			
Appropriate comparator therapy				
Human insulin (NPH insulin) or conventional insulin therapy (mixed insulin, CT)	Blood glucose test strips	€ 17.95	1 – 3 x daily	365.0 – 1,095.0
	Lancets	€ 4.20	1 – 3 x daily	365.0 – 1,095.0
	Disposable needles	€ 20.99	1 – 2 x daily	365.0 – 730.0
Intensified conventional insulin therapy (ICT)	Blood glucose test strips	€ 17.95	4 – 6 x daily	1,460 – 2,190
	Lancets	€ 4.20	4 – 6 x daily	1,460 – 2,190
	Disposable needles	€ 20.99	4 – 5 x daily	1,460 – 1,825
Liraglutide	Disposable needles	€ 20.99	1 x daily	365.0
Insulin degludec	Blood glucose test strips	€ 17.95	1 – 3 x daily	365.0 – 1,095.0
	Lancets	€ 4.20	1 – 3 x daily	365.0 – 1,095.0
	Disposable needles	€ 20.99	1 x daily	365.0

Designation of the therapy	Designation	Costs/ pack ¹⁵	Number	Consumption/ year
<u>Intensified conventional insulin therapy (ICT)</u>	Blood glucose test strips	€ 17.95	4 – 6 x daily	1,460 – 2,190
Insulin degludec + human insulin (bolus insulin)	Lancets	€ 4.20	4 – 6 x daily	1,460 – 2,190
	Disposable needles	€ 20.99	4 x daily	1,460
Insulin glargine + insulin aspart or insulin glulisine or insulin lispro	Non-quantifiable			

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 10 February 2026, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 18 February 2026, the pharmaceutical company submitted a dossier for the benefit assessment of tirzepatide to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 24 February 2026 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient tirzepatide.

The dossier assessment by the IQWiG was submitted to the G-BA on 26 May 2026, and the written statement procedure was initiated with publication on the G-BA website on 1 June 2026. The deadline for submitting written statements was 22 June 2026.

The oral hearing was held on 6 July 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 11 August 2026, and deliberation of the draft resolution was concluded.

At their session on 20 August 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	10 February 2026	Determination of the appropriate comparator therapy
Working group Section 35a	1 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	6 July 2026	Conduct of the oral hearing
Working group Section 35a	15 July 2026 5 August 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	11 August 2026	Concluding discussion of the draft resolution
Plenum	20 August 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 20 August 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk