

Resolution

of the Federal Joint Committee 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

At their session on 20 August 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

- I. In Annex XII, the following information shall be added after number 5 to the information on the benefit assessment of tirzepatide in accordance with the resolution of 2 May 2024 (type 2 diabetes mellitus), as last amended on 10 September 2024:**

Tirzepatide

Resolution of: 20 August 2026

Entry into force on: 20 August 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 January 2026):

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

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 insulin¹
 - Metformin + liraglutide or dulaglutide
 - Metformin + dapagliflozin or empagliflozin
 - Basal insulin¹ + metformin + liraglutide or dulaglutide
 - Basal insulin¹ + metformin + dapagliflozin or empagliflozin
 - Escalation of insulin therapy²: 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

¹ Human insulin or insulin analogues (insulin degludec, insulin detemir or insulin glargine)

² Human insulin or insulin analogues (insulin detemir, insulin glargine, insulin degludec, insulin aspart, insulin glulisine, insulin lispro)

Extent and probability of the additional benefit of tirzepatide compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:³

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

There are no suitable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.c.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: no data available n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

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

Approx. 300 – 390 patients

³ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-14), unless otherwise indicated.

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.

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,308.22 – € 4,614.89
Concomitant active ingredient of the medicinal product to be assessed	
Metformin	€ 29.08 - € 67.81
Empagliflozin	€ 649.92 - € 808.37
Dapagliflozin	€ 874.03
Tirzepatide + metformin + dapagliflozin or empagliflozin	Total: € 3,337.30 - € 4,682.70 Total: € 4,211.33 - € 5,556.73 Total: € 3,987.22 - € 5,491.07
Basal insulin, in each case in combination with metformin	
Human insulin (NPH insulin) + tirzepatide + metformin	€ 105.71 – € 1,093.08 Total: € 3,413.93 - € 5,707.97 Total: € 3,443.01 – € 5,775.77
Insulin degludec + tirzepatide + metformin	€ 92.99 – € 961.50 ⁴ Total: € 3,401.21 - € 5,576.39 Total: € 3,430.29 - € 5,644.20

⁴ 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	Annual treatment costs/ patient
Insulin glargine + tirzepatide + metformin	Non-quantifiable ⁵
Conventional insulin therapy (CT, mixed insulin) ⁶ or intensified conventional insulin therapy (ICT) ⁷ , in each case in combination with metformin	
<u>Conventional insulin therapy (CT)</u> Mixed insulin (regular insulin + NPH insulin) + tirzepatide + metformin	€ 105.71 – € 1,093.08 Total: € 3,413.93 - € 5,707.97 Total: € 3,443.01 – € 5,775.78
<u>Conventional insulin therapy (CT)</u> Protamine-mixed analogue insulin + tirzepatide + metformin	Non-quantifiable ⁵
<u>Intensified conventional insulin therapy (ICT)</u> Human insulin (NPH insulin) + human insulin (bolus insulin) + tirzepatide + metformin	€ 42.28 – € 655.85 € 42.28 – € 655.85 Total: € 105.71 – € 1,093.08 ⁸ Total: € 3,413.93 - € 5,707.97 Total: € 3,443.01 – € 5,775.78
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec (basal insulin) + human insulin (bolus insulin) + tirzepatide + metformin	€ 37.17 – € 576.92 ⁴ € 42.28 – € 655.85 Total: € 100,60 – € 1,014.15 ⁸ Total: € 3,408.82 - € 5,629.04 Total: € 3,437.90 - € 5,696.85
<u>Intensified conventional insulin therapy (ICT)</u> Insulin glargine or human insulin (NPH insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin) + tirzepatide + metformin	Non-quantifiable ⁵
Appropriate comparator therapy:	

⁵ 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 insulin analogues 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.

⁶ 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.

⁷ 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.

⁸ The lower range (dosage requirement of 0.25 I.U./ kg BW/ day) results for the 10-year-olds with 40 – 60% NPH insulin and 40 - 60% bolus insulin. The upper range (dosage requirement of 1.5 I.U./ kg BW/ day) results for the 17-year-olds with 40 – 60% NPH insulin and 40 - 60% bolus insulin.

Designation of the therapy	Annual treatment costs/ patient
Metformin	€ 29.08 - € 67.81
Empagliflozin	€ 649.92 - € 808.37
Dapagliflozin	€ 874.03
Dulaglutide	€ 1,175.20
Liraglutide	€ 1,579.62 – € 2,369.43
Metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Total: € 1,608.70 – € 2,437.24 Total: € 1,204.28 – € 1,243.01 Total: € 903.11 – € 941.84 Total: € 679.00 – € 876.18
Basal insulin, in each case in combination with metformin and liraglutide or dulaglutide or dapagliflozin or empagliflozin	
Human insulin (NPH insulin) + metformin	€ 105.71 – € 1,093.08 Total: € 134.79 – € 1,160.89
in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Total: € 1,714.41 – € 3,530.32 Total: € 1,309.99 – € 2,336.09 Total: € 1,008.82 – € 2,034.92 Total: € 784.71 – € 1,969.26
Insulin degludec (basal insulin) + metformin	€ 92.99 – € 1,201.88 ⁴ Total: € 145.32 – € 1,269.69
in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Total: € 1,701.69 – € 3,398.74 ⁴ Total: € 1,297.27 – € 2,204.51 ⁴ Total: € 1,019.35 – € 2,143.72 Total: € 795.24 – € 2,078.06
Insulin glargine + metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Non-quantifiable ⁵
Conventional insulin therapy (CT, mixed insulin) or intensified conventional insulin therapy (ICT), in each case in combination with metformin and liraglutide or dulaglutide or dapagliflozin or empagliflozin	
<u>Conventional insulin therapy (CT)</u> Mixed insulin (NPH insulin + regular insulin) + metformin	€ 105.71 – € 1,093.08 Total: € 134.79 – € 1,160.89
in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Total: € 1,714.41 – € 3,530.32 Total: € 1,309.99 – € 2,336.09 Total: € 1,008.82 – € 2,034.92 Total: € 784.71 – € 1,969.26

Designation of the therapy	Annual treatment costs/ patient
<u>Conventional insulin therapy (CT)</u> Mixed insulin (NPH insulin + insulin lispro or insulin aspart) + metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Non-quantifiable ⁵
<u>Intensified conventional insulin therapy (ICT)</u> Human insulin (NPH insulin) + human insulin (bolus insulin) + metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	€ 42.28 – € 655.85 € 42.28 – € 655.85 Total: € 105.71 - € 1,093.08 ⁸ Total: € 1,714.41 – € 3,530.32 Total: € 1,309.99 – € 2,336.09 Total: € 1,008.82 – € 2,034.92 Total: € 784.71 – € 1,969.26
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec + human insulin (bolus insulin) + metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	€ 37.17 – € 721.13 ⁴ € 42.28 – € 655.85 Total: € 100.60 - € 1,158.36 ⁸ Total: € 1,709.30 – € 3,451.39 € ⁴ Total: € 1,304.88 – € 2,257.16 ⁴ Total: € 1,013.03 – € 2,100.20 Total: € 788.92 – € 2,034.54
<u>Intensified conventional insulin therapy (ICT)</u> Insulin glargine or human insulin (NPH insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin) + metformin in combination with liraglutide or dulaglutide or dapagliflozin or empagliflozin	Non-quantifiable ⁵

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2026)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Annual treatment costs/ patient
Medicinal product to be assessed:		
Tirzepatide	Disposable needles	€ 10.94
Concomitant active ingredient of the medicinal product to be assessed		
Human insulin (NPH insulin) or	Blood glucose test strips	€ 131.04 – € 393.11

Designation of the therapy	Designation	Annual treatment costs/ patient
conventional insulin therapy (CT, mixed insulin)	Lancets	€ 7.67 – € 23.00
	Disposable needles	€ 76.61 – € 153.23
Intensified conventional insulin therapy (ICT)	Blood glucose test strips	€ 524.14 – € 786.21
	Lancets	€ 30.66 – € 45.99
	Disposable needles	€ 306.45 – € 383.07
Insulin degludec (basal insulin)	Blood glucose test strips	€ 131.04 – € 393.11
	Lancets	€ 7.67 – € 23.00
	Disposable needles	€ 76.61
Insulin glargine (basal insulin)	Non-quantifiable	
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec (basal insulin) + human insulin (bolus insulin)	Blood glucose test strips	€ 524.14 – € 786.21
	Lancets	€ 30.66 – € 45.99
	Disposable needles	€ 306.45
<u>Intensified conventional insulin therapy (ICT)</u> Insulin glargine or human insulin (basal insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin)	Non-quantifiable	
Appropriate comparator therapy:		
Human insulin (NPH insulin) or conventional insulin therapy (CT, mixed insulin)	Blood glucose test strips	€ 131.04 – € 393.11
	Lancets	€ 7.67 – € 23.00
	Disposable needles	€ 76.61 – € 153.23
Intensified conventional insulin therapy (ICT)	Blood glucose test strips	€ 524.14 – € 786.21
	Lancets	€ 30.66 – € 45.99
	Disposable needles	€ 306.45 – € 383.07
Insulin degludec (basal insulin)	Blood glucose test strips	€ 131.04 – € 393.11
	Lancets	€ 7.67 – € 23.00
	Disposable needles	€ 76.61
Insulin glargine (basal insulin)	Non-quantifiable	

Designation of the therapy	Designation	Annual treatment costs/ patient
<u>Intensified conventional insulin therapy (ICT)</u> Insulin degludec (basal insulin) + human insulin (bolus insulin)	Blood glucose test strips	€ 524.14 – € 786.21
	Lancets	€ 30.66 – € 45.99
	Disposable needles	€ 306.45
<u>Intensified conventional insulin therapy (ICT)</u> Insulin glargine or human insulin (basal insulin) + insulin aspart or insulin glulisine or insulin lispro or human insulin (bolus insulin)	Non-quantifiable	
Liraglutide	Disposable needles	€ 76.61

II. The resolution will enter into force on the day of its publication on the G-BA website on 20 August 2026.

The justification for this resolution will be published on the G-BA website at www.g-ba.de.

Berlin, 20 August 2026

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

Dr Optendrenk