Gemeinsamer Bundesausschuss

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) and Annex XIIa – Combinations of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Tirzepatide (type 2 diabetes mellitus)

of 2 May 2024

At its session on 2 May 2024, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Tirzepatide as follows:

Tirzepatide

Resolution of: 2 May 2024
Entry into force on: 2 May 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 September 2022):

Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

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

Therapeutic indication of the resolution (resolution of 2 May 2024):

See therapeutic indication according to marketing authorisation.

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

a1) **Insulin-naïve** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Appropriate comparator therapy:

Patient-individual therapy, taking into account the patient-individual therapeutic goal, depending on comorbidities, diabetes duration, any risks of hypoglycaemia, under selection of:

- metformin + sulphonylureas (glibenclamide or glimepiride),
- metformin + sitagliptin,
- metformin + empagliflozin,
- Metformin + liraglutide

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

An additional benefit is not proven.

a2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Appropriate comparator therapy:

- metformin + empagliflozin, or
- metformin + liraglutide, or
- Metformin + dapagliflozin

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

An additional benefit is not proven.

b1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Appropriate comparator therapy:

- metformin + empagliflozin + sitagliptin, or
- Metformin + empagliflozin + liraglutide

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

An additional benefit is not proven.

b2) **Insulin-naive** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Appropriate comparator therapy:

- metformin + empagliflozin + liraglutide, or
- metformin + dapagliflozin + liraglutide

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

An additional benefit is not proven.

c1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is an indication for an insulin therapy**.

Appropriate comparator therapy:

- Human insulin + metformin

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

An additional benefit is not proven.

c2) **Insulin-naive** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy**

consisting of at least two hypoglycaemic agents, in addition to diet and exercise, and for whom there is an **indication for an insulin therapy**.

Appropriate comparator therapy:

- human insulin + metformin+ empagliflozin, or
- human insulin + metformin + dapagliflozin, or
- human insulin + metformin + liraglutide

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

An additional benefit is not proven.

d1) **Insulin-experienced** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Appropriate comparator therapy:

- Escalation of insulin therapy (conventional therapy (CT) if necessary + metformin or dulaglutide or intensified insulin therapy (ICT))

Extent and probability of the additional benefit of tirzepatide + insulin lispro ± metformin compared with ICT (insulin glargine + insulin lispro ± metformin):

Hint for a minor additional benefit.

d2) **Insulin-experienced** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Appropriate comparator therapy:

- Escalation of insulin therapy: conventional therapy (CT) or intensified insulin therapy (ICT), in each case in combination with metformin and empagliflozin or dapagliflozin or liraglutide

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:[1]

a1) **Insulin-naïve** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

There are no usable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

a2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

There are no usable data for the benefit assessment.

Summary of results for relevant clinical endpoints

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Mortality	∅	No data available.
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[1] Data from the dossier assessment of the IQWiG (A23-112) and from the addendum (A24-32)

b1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

There are no usable data for the benefit assessment.

Summary of results for relevant clinical endpoints

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Health-related quality of life	∅	No data available.
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b2) **Insulin-naive** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

There are no usable data for the benefit assessment.

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c1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is an indication for an insulin therapy**.

There are no usable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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c2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom there is an **indication for insulin therapy**.

There are no assessable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

d1) **Insulin-experienced** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↑	Advantage for the endpoint of health status collected using EQ-5D VAS.
Health-related quality of life	↑	Advantage in quality of life collected using SF-36 in the mental component sum score.
Side effects	↑	Advantage in the overall rate of SAEs; disadvantage in the discontinuation due to AEs; in detail, for specific AEs: Advantage in the prevention of severe hypoglycaemia and non-severe, symptomatic, confirmed hypoglycaemia; disadvantage in gastrointestinal disorders

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
∅: There are no usable data for the benefit assessment.
n.a.: not assessable

SURPASS 6 study:

RCT over 52 weeks; tirzepatide vs insulin lispro, each in combination with insulin glargine and eventually metformin

Mortality

Endpoint	Tirzepatide + insulin glargine ± metformin		Insulin lispro + insulin glargine ± metformin		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Overall mortality	584	3 (0.5)	584	10 (1.7)	0.30 [0.08; 1.08]; 0.053[a]

Morbidity

Endpoint	Tirzepatide + insulin glargine ± metformin		Insulin lispro + insulin glargine ± metformin		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Diabetic retinopathies[b]	584	6 (1.0)	584	8 (1.4)	0.75 [0.26; 2.15]; 0.683[a]
Health status (improvement at week 52)					
EQ-5D VAS[c]	584	155 (26.5)	584	86 (14.7)	1.80 [1.42; 2.29]; < 0.001[d]

Endpoint	Tirzepatide + insulin glargine ± metformin		Insulin lispro + insulin glargine ± metformin		Intervention vs control
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI] p value
Myocardial infarction	584	n.r. 0 (0)	584	n.r. 4 (0.7)	n.c.; n.d.
Hospitalisation due to angina pectoris	584	n.r. 0 (0)	584	n.r. 1 (0.2)	n.c.; n.d.
Hospitalisation due to heart failure	584	n.r. 0 (0)	584	n.r. 1 (0.2)	n.c.; n.d.
Cerebrovascular morbidity[i]	584	4 (0.7)	584	1 (0.2)	3.89 [0.43; 34.79]; 0.225[j]

Endpoints in the morbidity category presented additionally

	Tirzepatide + insulin glargine ± metformin			Insulin lispro + insulin glargine ± metformin			Intervention vs control
	N[k]	Values at start of study MV (SD)	Change at week 52 MV (SE)	N[k]	Values at start of study MV (SD)	Change at week 52 MV (SE)	MD [95% CI]; p value
HbA1c (%) *(presented additionally)*	584	8.82 (1.0)	-2.20 (0.1)[l]	584	8.84 (1.0)	-1.16 (0.1)[l]	-1.04 [-1.20; -0.89]; < 0.001[l]
Body weight [kg] *(presented additionally)*	584	90.09 (18.5)	-9.11 (0.3)[m]	584	90.48 (18.3)	3.77 (0.3)[m]	-12.88 [-13.67; -12.09]; < 0.001[m]
BMI [kg/m^2][n] *(presented additionally)*	584	33.5 (5.4)	-3.6 (0.1)[o]	584	33.0 (5.2)	1.4 (0.1)[o]	-5.0 [−5.2; -4.8] < 0.001[o]

Health-related quality of life

Endpoint	Tirzepatide + insulin glargine ± metformin		Insulin lispro + insulin glargine ± metformin		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
SF-36v2 (improvement at week 52)					
Physical component summary (PCS) score[e]	584	59 (10.1)	584	43 (7.4)	1.37 [0.94; 2.00]; 0.120[d]
Mental component summary (MCS) score[e]	584	97 (16.6)	584	61 (10.5)	1.59 [1.18; 2.14]; 0.003[d]
Physical functioning[e]	584	112 (19.2)	584	68 (11.6)	1.63 [1.23; 2.14][f]
Physical role functioning[e]	584	148 (25.3)	584	100 (17.1)	1.45 [1.16; 1.82][f]
Physical pain[e]	584	161 (27.6)	584	111 (19.0)	1.42 [1.15; 1.75][f]
General health perception[e]	584	180 (30.8)	584	110 (18.8)	1.63 [1.33; 2.00][f]
Vitality[e]	584	121 (20.7)	584	82 (14.0)	1.44 [1.12; 1.86][f]

Social functioning[e]	584	114 (19.5)	584	78 (13.4)	1.41 [1.08; 1.83][f]
Emotional role functioning[e]	584	150 (25.7)	584	112 (19.2)	1.35 [1.09; 1.68][f]
Psychological well-being[e]	584	136 (23.3)	584	100 (17.1)	1.33 [1.06; 1.67][f]

Side effects

Endpoint	**Tirzepatide + insulin glargine ± metformin**		**Insulin lispro + insulin glargine ± metformin**		**Intervention vs control**
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Overall rates					
AE (presented additionally)	584	423 (72.4)	584	318 (54.5)	–
SAE	584	28 (4.8)	584	59 (10.1)	0.47 [0.31; 0.73]; < 0.001[a]
Discontinuation due to AEs	584	33 (5.7)	584	16 (2.7)	2.06 [1.15; 3.71]; 0.013[a]
Specific adverse events					
Pancreatitis[g]	584	0 (0)	584	0 (0)	–
Non-severe symptomatic, confirmed hypoglycaemia					
PG ≤ 54 mg/dl	584	46 (7.9)	584	250 (42.8)	0.18 [0.14; 0.25]; < 0.001[a]
PG < 70 mg/dl (presented additionally)	*584*	*139 (23.8)*	*584*	*371 (63.5)*	*0.37 [0.32; 0.44]; < 0.001[a]*
Severe hypoglycaemia[h]	584	2 (0.3)	584	22 (3.8)	0.09 [0.02; 0.38]; < 0.001[a]
Gastrointestinal disorders (SOC, AE)	584	260 (44.5)	584	51 (8.7)	5.10 [3.86; 6.73]; < 0.001[a]
Nausea (PT, AE)	584	124 (21.2)	584	7 (1.2)	17.71 [8.34; 37.60]; < 0.001[a]
Vomiting (PT, AE)	584	59 (10.1)	584	4 (0.7)	14.75 [5.39; 40.34]; < 0.001[a]

Diarrhoea (PT, AE)	584	80 (13.7)	584	15 (2.6)	5.33 [3.11; 9.15]; < 0.001[a]

a. IQWiG calculation of effect, CI (asymptotic) and p value (unconditional exact test, CSZ method according to Andrés).
b. Events confirmed by funduscopy that were collected as part of the AE survey on the basis of a PT list compiled by the pharmaceutical company.
c. An increase in EQ-5D VAS score by ≥ 15 points compared to the start of study is considered a clinically relevant improvement (scale range 0 to 100).
d. RR and CI unadjusted, p value using Fisher's exact test. Patients with only one baseline value and no post-baseline value were included in the analysis as non-responders. For patients with values post-baseline but no value at week 52, this value was replaced by LOCF.
e. Adults with an improvement by ≥ 15% of the scale range determined using the empirical minima and maxima from a 2009 norm sample, see information in Table 7.1 of the SF-36 manual; this corresponds to an improvement of the following values:
   - Physical Component Summary (PCS) score: ≥ 9.7 points (scale range from 10.8 to 75.5),
   - Mental Component Summary (MCS) score: ≥ 9.6 points (scale range from 5.6 to 69.7),
   - Physical functioning: ≥ 5.8 points, physical role functioning: ≥ 5.3 points, physical pain: ≥ 5.9 points, general health perception: ≥ 6.6 points, vitality: ≥ 6.5 points, social functioning: ≥ 5.9 points, emotional role functioning: ≥ 6.9 points, psychological well-being: ≥ 7.4 pointse.
f. RR and CI from adjusted model with LOCF. The adjusted model contains the variables of treatment, country/ pooled country, HbA1c value at baseline (≤ 8.5%/ > 8.5%) and treatment with metformin at baseline (yes/ no).
g. Operationalised by adjudicated events based on the events recorded by the SMQ "acute pancreatitis" and the PT "chronic pancreatitis".
h. Hypoglycaemia that met at least one of the following criteria: Emergency room stay or (prolonged) hospitalisation; outside assistance by medical personnel; treatment with glucagon or intravenous glucose; leads to disability or permanent damage to the patient; seizure or loss of consciousness; leads to death or was life-threatening.
i. Including cerebrovascular insult, stroke and transient ischaemic attack.
j. Effect estimator and methodology unclear, discrepancy between results table and methodology section in M 4 D.
k. Number of patients who were taken into account in the evaluation for calculating the effect estimate; the values at start of study can be based on other patient numbers.
l. MMRM with treatment, visit, interaction from treatment and visit, country/ pooled country, treatment with metformin at baseline (yes/ no) as fixed effects and HbA1c value at baseline as covariate.
m. MMRM with treatment, visit, interaction from treatment and visit, country/ pooled country, HbA1c value at baseline (≤ 8.5%/ > 8.5%), treatment with metformin at baseline (yes/ no) as fixed effects and body weight at baseline as covariates.
n. Data for the entire study population. The sub-population of patients without manifest cardiovascular disease relevant to the research question comprises approx. 82% of the total study population.
o. MMRM with baseline value, treatment, visit, interaction from treatment and visit, pooled country, HbA1c value at baseline (≤ 8.5%/ > 8.5%), treatment with metformin at baseline (yes/ no) as fixed effects.

Abbreviations:
AD = absolute difference; BMI: body mass index; HbA1c: glycated haemoglobin; HR: hazard ratio; n.d.: no data; CI: confidence interval; LOCF: Last Observation Carried Forward; MCS: mental component summary score; MD: mean difference; MedDRA: Medical Dictionary for Regulatory Activities; MMRM: mixed model with repeated measures; MV: mean value; n: number of patients with (at least 1) event; N: number of patients evaluated; n.c.: not calculable; n.r. = not reached; PCS: physical component summary score; PG: plasma glucose; PT: preferred term; RCT: randomised controlled study; RR: relative risk; SD: standard deviation; SE: standard error; SF-36v2: Short Form-36 Health Survey Version 2; SGLT2: sodium/ glucose cotransporter 2; SOC: system organ class; SMQ: standardised MedDRA query; SAE: serious adverse event; AE: adverse event; VAS: visual analogue scale; vs: versus

d2) **Insulin-experienced** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

There are no assessable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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2. Number of patients or demarcation of patient groups eligible for treatment

a1) **Insulin-naïve** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Approx. 334,000 to 437,000 patients

a2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Approx. 205,000 to 308,000 patients

b1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Approx. 42,000 to 54,000 patients

b2) **Insulin-naive** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Approx. 25,000 to 38,000 patients

c1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is an indication for an insulin therapy**.

Approx. 186,000 to 243,000 patients

c2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom there is an **indication for insulin therapy**.

Approx. 114,000 to 172,000 patients

d1) **Insulin-experienced** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Approx. 344,000 to 451,000 patients

d2) **Insulin-experienced** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Approx. 211,000 to 318,000 patients

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: 21 March 2024):

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:

a1) **Insulin-naïve** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[2]:	
Metformin	€ 33.44 - € 100.31
Glibenclamide or glimepiride	€ 13.14 - € 78.84 € 29.89 - € 152.49
Sitagliptin	€ 97.81
Empagliflozin	€ 659.30 - € 837.64
	Total:
Tirzepatide + metformin	€ 3,208.15 - € 4,333.44
Tirzepatide + glibenclamide or Tirzepatide + glimepiride	€ 3,187.85 - € 4,311.97 € 3,204.60 - € 4,385.61
Tirzepatide + sitagliptin	€ 3,272.52 - € 4,330.93
Tirzepatide + empagliflozin	€ 3,834.01 - € 5,070.76
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31

[2] Metformin, glibenclamide, glimepiride, sitagliptin, and empagliflozin are presented as possible concomitant active ingredients, exemplifying the combination of tirzepatide with a hypoglycemic agent.

Designation of the therapy	Annual treatment costs/ patient
Glibenclamide or glimepiride	€ 13.14 - € 78.84 € 29.89 - € 152.49
Sitagliptin	€ 97.81
Empagliflozin	€ 659.30 - € 837.64
Liraglutide	€ 1,515.63 - € 2,273.44
	Total:
Metformin + glibenclamide or metformin + glimepiride	€ 46.58 - € 179.15 € 63.33 - € 252.80
Metformin + sitagliptin	€ 131.24 - € 198.12
Metformin + empagliflozin	€ 692.74 - € 937.95
Metformin + liraglutide	€ 1,549.06 - € 2,373.75

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Liraglutide	Disposable needles	€ 47.45

a2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of one hypoglycaemic agent**, in addition to diet and exercise

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[3]:	
Metformin	€ 33.44 - € 100.31
Empagliflozin	€ 659.30 - € 837.64
Dapagliflozin	€ 883.82
	Total:
Tirzepatide + metformin	€ 3,208.15 - € 4,333.44
Tirzepatide + empagliflozin	€ 3,834.01 - € 5,070.76
Tirzepatide + dapagliflozin	€ 4,058.53 - € 5,116.95
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31

[3] Metformin, empagliflozin, and dapagliflozin are presented as possible concomitant active ingredients, exemplifying the combination of tirzepatide with a hypoglycemic agent.

Designation of the therapy	Annual treatment costs/ patient
Empagliflozin	€ 659.30 - € 837.64
Liraglutide	€ 1,515.63 - € 2,273.44
Dapagliflozin	€ 883.82
	Total:
Metformin + empagliflozin	€ 692.74 - € 937.95
Metformin + liraglutide	€ 1,549.06 - € 2,373.75
Metformin + dapagliflozin	€ 917.26 - € 984.14

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Liraglutide	Disposable needles	€ 47.45

b1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents** in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[4]:	
Metformin	€ 33.44 - € 100.31
Sitagliptin	€ 97.81
Empagliflozin	€ 659.30 - € 837.64
	Total:
Tirzepatide + metformin + sitagliptin	€ 3,305.96 - € 4,431.24
Tirzepatide + metformin + empagliflozin	€ 3,867.45 - € 5,171.08
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Sitagliptin	€ 97.81
Empagliflozin	€ 659.30 - € 837.64
Liraglutide	€ 1,515.63 - € 2,273.44
	Total:

[4] Metformin, sitagliptin, and empagliflozin are presented as possible concomitant active ingredients, exemplifying the combination of tirzepatide with two hypoglycemic agents.

Designation of the therapy	Annual treatment costs/ patient
Metformin + empagliflozin + sitagliptin	€ 790.54 - € 1,035.76
Metformin + empagliflozin + liraglutide	€ 2,208.36 - € 3,211.39

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Liraglutide	Disposable needles	€ 47.45

b2) **Insulin-naive** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is no indication for an insulin therapy**.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[5]:	
Metformin	€ 33.44 - € 100.31
Empagliflozin	€ 659.30 - € 837.64
Dapagliflozin	€ 883.82
	Total:
Tirzepatide + metformin + empagliflozin	€ 3,867.45 - € 5,171.08
Tirzepatide + metformin + dapagliflozin	€ 4,091.97 - € 5,217.26
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Empagliflozin	€ 659.30 - € 837.64
Dapagliflozin	€ 883.82
Liraglutide	€ 1,515.63 - € 2,273.44
	Total:
Metformin + empagliflozin + liraglutide	€ 2,208.36 - € 3,211.39
Metformin + dapagliflozin + liraglutide	€ 2,432.89 - € 3,257.57

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

[5] Metformin and empagliflozin or metformin and dapagliflozin are presented as examples of possible concomitant active ingredients in the combination of tirzepatide with two hypoglycemic agents.

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Liraglutide	Disposable needles	€ 47.45

c1) **Insulin-naive** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom **there is an indication for an insulin therapy**.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[6]:	
Metformin	€ 33.44 - € 100.31
Human insulin (NPH insulin)	€ 386.46 - € 772.92
Basal supported oral therapy (BOT)	Total:
Tirzepatide + human insulin (NPH insulin)	€ 3,561.17 - € 5,006.04
Tirzepatide + metformin + human insulin (NPH insulin)	€ 3,594.61 - € 5,106.36
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Human insulin (NPH insulin)	€ 386.46 - € 772.92
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH insulin) + metformin	€ 419.90 - € 873.23

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services: not applicable

c2) **Insulin-naïve** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their current medicinal therapy consisting of at least two hypoglycaemic agents**, in addition to diet and exercise, and for whom there is an **indication for insulin therapy**.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13

[6] As an example for the use in type 2 diabetics with a first-time indication for insulin therapy, the combination of tirzepatide with human insulin (NPH insulin) with and without metformin in the context of basal supported oral therapy (BOT) is shown.

Designation of the therapy	Annual treatment costs/ patient
Concomitant active ingredient of the medicinal product to be assessed[7]:	
Metformin	€ 33.44 - € 100.31
Human insulin (NPH insulin)	€ 386.46 - € 772.92
Basal supported oral therapy (BOT)	Total:
Tirzepatide + metformin + human insulin (NPH insulin)	€ 3,594.61 - € 5,106.36
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Empagliflozin	€ 659.30 - € 837.64
Liraglutide	€ 1,515.63 - € 2,273.44
Dapagliflozin	€ 883.82
Human insulin (NPH insulin)	€ 386.46 - € 772.92
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH insulin) + metformin + empagliflozin	€ 1,079.20 - € 1,710.87
Human insulin (NPH insulin) + metformin + liraglutide	€ 1,935.52 - € 3,146.67
Human insulin (NPH insulin) + metformin + dapagliflozin	€ 1,303.72 - € 1,757.05

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Liraglutide	Disposable needles	€ 47.45

d1) **Insulin-experienced** adults with type 2 diabetes mellitus **without manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[8]:	
Metformin	€ 33.44 - € 100.31
Conventional insulin therapy (CT, mixed insulin)	€ 386.46 - € 772.92

[7] The combination of tirzepatide with human insulin (NPH insulin) and with metformin in the context of basal supported oral therapy (BOT) is shown as an example for the use in type 2 diabetics with a first-time indication for insulin therapy.

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

Designation of the therapy	Annual treatment costs/ patient
Tirzepatide + conventional insulin therapy (CT, mixed insulin) Tirzepatide + human insulin (mixed insulin)	Total: € 3,561.17 - € 5,006.04
Tirzepatide + metformin + conventional insulin therapy (CT, mixed insulin) Tirzepatide + metformin + human insulin (mixed insulin)	Total: € 3,594.61 - € 5,106.36
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Dulaglutide	€ 1,174.20
Conventional insulin therapy (CT, mixed insulin)	€ 386.46 - € 772.92
	Total:
Conventional insulin therapy (CT, mixed insulin) if necessary + metformin or dulaglutide Mixed insulin + metformin Mixed insulin + dulaglutide	€ 419.90 - € 873.23 € 1,560.66 - € 1,947.12
Intensified insulin therapy Human insulin (NPH insulin) Human insulin (bolus insulin)	Total: € 154.58 - € 463.75 € 154.58 - € 463.75 Total: € 386.46 - € 772.92

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Concomitant active ingredient of the medicinal product to be assessed		
Conventional insulin therapy (CT, mixed insulin)	Blood glucose test strips Lancets Disposable needles	€ 116.44 - € 349.31 € 7.67 - € 23.00 € 47.45 - € 94.90
Appropriate comparator therapy:		
Intensified conventional insulin therapy	Blood glucose test strips Lancets Disposable needles	€ 465.74 - € 698.61 € 30.66 - € 45.99 € 189.80 - € 237.25

d2) **Insulin-experienced** adults with type 2 diabetes mellitus **with manifest cardiovascular disease**, who have not achieved adequate glycaemic control **with their previous insulin regime**, in addition to diet and exercise

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirzepatide	€ 3,174.71 - € 4,233.13
Concomitant active ingredient of the medicinal product to be assessed[9]:	
Metformin	€ 33.44 - € 100.31
Conventional insulin therapy (CT, mixed insulin)	€ 386.46 - € 772.92
Tirzepatide + metformin + conventional insulin therapy (CT, mixed insulin) Tirzepatide + metformin + human insulin (mixed insulin)	Total: € 3,594.61 - € 5,106.36
Appropriate comparator therapy:	
Metformin	€ 33.44 - € 100.31
Empagliflozin	€ 659.30 - € 837.64
Liraglutide	€ 1,515.63 - € 2,273.44
Dapagliflozin	€ 883.82
Conventional insulin therapy (CT, mixed insulin)	€ 386.46 - € 772.92
Conventional insulin therapy (CT, mixed insulin) + metformin + empagliflozin or dapagliflozin or + liraglutide Mixed insulin + metformin + empagliflozin Mixed insulin + metformin + dapagliflozin Mixed insulin + metformin + liraglutide	Total: € 1,079.20 - € 1,710.87 € 1,303.72 - € 1,757.05 € 1,935.52 - € 3,146.67
Intensified insulin therapy Human insulin (NPH insulin) Human insulin (bolus insulin) Intensified insulin therapy + metformin + empagliflozin or dapagliflozin or + liraglutide NPH insulin + bolus insulin + metformin + empagliflozin NPH insulin + bolus insulin + metformin + dapagliflozin NPH insulin + bolus insulin + metformin + liraglutide	 € 154.58 - € 463.75 € 154.58 - € 463.75 Total: € 386.46 - € 772.92 Total: € 1,079.20 - € 1,710.87 € 1,303.72 - € 1,757.05 € 1,935.52 - € 3,146.67

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Costs for additionally required SHI services:

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

Designation of the therapy	Designation	Costs/ year
Concomitant active ingredient of the medicinal product to be assessed		
Conventional insulin therapy (CT, mixed insulin)	Blood glucose test strips Lancets Disposable needles	€ 116.44 - € 349.31 € 7.67 - € 23.00 € 47.45 - € 94.90
Appropriate comparator therapy:		
Intensified conventional insulin therapy	Blood glucose test strips Lancets Disposable needles	€ 465.74 - € 698.61 € 30.66 - € 45.99 € 189.80 - € 237.25
Liraglutide	Disposable needles	€ 47.45

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a1) Insulin-naïve adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of one hypoglycaemic agent, in addition to diet and exercise

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

a2) Insulin-naïve adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of one hypoglycaemic agent, in addition to diet and exercise

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

b1) Insulin-naive adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of two hypoglycaemic agents, in addition to diet and exercise, and for whom there is no indication for an insulin therapy.

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

b2) Insulin-naive adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of two hypoglycaemic agents, in addition to diet and exercise, and for whom there is no indication for an insulin therapy.

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

c1) Insulin-naive adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of at least two hypoglycaemic agents, in addition to diet and exercise, and for whom there is an indication for an insulin therapy.

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

c2) Insulin-naïve adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of at least two hypoglycaemic agents, in addition to diet and exercise, and for

whom there is an indication for insulin therapy.

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

d1) Insulin-experienced adults with type 2 diabetes mellitus without manifest cardiovascular disease and who have not achieved adequate glycaemic control with their previous insulin regime, in addition to diet and exercise

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

d2) Insulin-experienced adults with type 2 diabetes mellitus with manifest cardiovascular disease and who have not achieved adequate glycaemic control with their previous insulin regime, in addition to diet and exercise

The following medicinal products with new active ingredients that can be used in a combination therapy with tirzepatide in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. **In Annex XIIa of the Pharmaceuticals Directive, the following information shall be added in alphabetical order:**

"Active ingredient of the assessed medicinal product

Tirzepatide

Resolution according to Section 35a paragraph 3 SGB V from

02.05.2024

Therapeutic indication of the resolution

Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

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

Patient group a1

Insulin-naïve adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of one hypoglycaemic agent, in addition to diet and exercise

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group a2

Insulin-naïve adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of one hypoglycaemic agent, in addition to diet and exercise

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group b1

Insulin-naive adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of two hypoglycaemic agents, in addition to diet and exercise, and for whom there is no indication for an insulin therapy.

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group b2

Insulin-naive adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of two hypoglycaemic agents, in addition to diet and exercise, and for whom there is no indication for an insulin therapy.

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group c1

Insulin-naive adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of at least two hypoglycaemic agents, in addition to diet and exercise, and for whom there is an indication for an insulin therapy.

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group c2

Insulin-naïve adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their current medicinal therapy consisting of at least two hypoglycaemic agents, in addition to diet and exercise, and for whom there is an indication for insulin therapy.

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), dapagliflozin/ saxagliptin (Qtern), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group d1

Insulin-experienced adults with type 2 diabetes mellitus without manifest cardiovascular disease, who have not achieved adequate glycaemic control with their previous insulin regime, in addition to diet and exercise

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

Patient group d2

Insulin-experienced adults with type 2 diabetes mellitus with manifest cardiovascular disease, who have not achieved adequate glycaemic control with their previous insulin regime, in addition to diet and exercise

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), dulaglutide (Trulicity)

Period of validity of the designation (since... or from... to)

Since 2 May 2024

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 2 May 2024.

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

Berlin, 2 May 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken