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 Ertugliflozin (type 2 diabetes mellitus)

of 19 May 2022

At its session on 19 May 2022, 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 Ertugliflozin as follows:

Ertugliflozin

Resolution of: 19 May 2022
Entry into force on: 19 May 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 October 2021):

Steglatro 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 inappropriate due to intolerance or contraindications;
- in addition to other medicinal products for the treatment of diabetes.

Therapeutic indication of the resolution (resolution of 19 May 2022):

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 ertugliflozin 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 ertugliflozin 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 ertugliflozin 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 ertugliflozin 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 ertugliflozin 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 ertugliflozin 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 ertugliflozin compared to the appropriate comparator therapy:

An additional benefit is not proven.

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) if necessary + metformin or empagliflozin or liraglutide or dapagliflozin or intensified insulin therapy (ICT))

Extent and probability of the additional benefit of ertugliflozin 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 assessable data for the benefit assessment.

[1] Data from the dossier assessment of the IQWiG (A21-158) and from the addendum (G22-12), unless otherwise indicated.

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		

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 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		

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**.

No data available.

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		

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 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.
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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**.

No data available.

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		

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

No data available.

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		

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	∅	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		

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**.

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**.

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**.

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

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

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 Steglatro (active ingredient: ertugliflozin) at the following publicly accessible link (last access: 10 March 2022):

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

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[2]:	
Metformin	€ 33.84 - € 101.53
Glibenclamide or glimepiride	€ 13.33 - € 80.00 € 30.27 - € 152.85
Sitagliptin	€ 506.12
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Ertugliflozin + metformin	€ 479.36 - € -547.05
Ertugliflozin + glibenclamide or Ertugliflozin + glimepiride	€ 458.85 - € 525.52 € 475.79 - € 598.37
Ertugliflozin + sitagliptin	€ 951.64

[2] As an example of the combination of ertugliflozin with a hypoglycaemic agent, metformin, glibenclamide, glimepiride, sitagliptin and liraglutide are presented as possible concomitant active ingredients.

Designation of the therapy	Annual treatment costs/ patient
Ertugliflozin + liraglutide	€ 1,755.09 - 2,409.88
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Glibenclamide or glimepiride	€ 13.33 - € 80.00 € 30.27 - € 152.85
Sitagliptin	€ 506.12
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Metformin + glibenclamide or metformin + glimepiride	€ 47.17 - € 181.53 € 64.11 - € 254.38
Metformin + sitagliptin	€ 539.96 - € 607.65
Metformin + empagliflozin	€ 693.87 - € 761.56
Metformin + liraglutide	€ 1,343.41 - € 2,065.89

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services: not applicable

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[3]:	
Metformin	€ 33.84 - € 101.53
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Ertugliflozin + metformin	€ 479.36 - € -547.05
Ertugliflozin + liraglutide	€ 1,755.09 - 2,409.88
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36

[3] As an example of the combination of ertugliflozin with a hypoglycaemic agent, metformin and liraglutide are presented as possible concomitant active ingredients.

Designation of the therapy	Annual treatment costs/ patient
Dapagliflozin	€ 944.72
	Total:
Metformin + empagliflozin	€ 693.87 - € 761.56
Metformin + liraglutide	€ 1,343.41 - € 2,065.89
Metformin + dapagliflozin	€ 978.56 - € 1,046.25

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services: not applicable

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[4]:	
Metformin	€ 33.84 - € 101.53
Sitagliptin	€ 506.12
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Ertugliflozin + metformin + sitagliptin	€ 985.48 - € 1,053.17
Ertugliflozin + metformin + liraglutide	€ 1,788.93 - € 2,511.41
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Sitagliptin	€ 506.12
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Metformin + empagliflozin + sitagliptin	€ 1,199.99 - € 1,267.68
Metformin + empagliflozin + liraglutide	€ 2,003.44 - € 2,725.92

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services: not applicable

[4] As an example of the combination of ertugliflozin with two hypoglycaemic agents, metformin, sitagliptin and liraglutide are presented as possible concomitant active ingredients.

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[5]:	
Metformin	€ 33.84 - € 101.53
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Ertugliflozin + metformin + liraglutide	€ 1,788.93 - € 2,511.41
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36
Dapagliflozin	€ 944.72
	Total:
Metformin + empagliflozin + liraglutide	€ 2,003.44 - € 2,725.92
metformin + dapagliflozin + liraglutide	€ 2,288.13 - € 3,010.61

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services: not applicable

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[6]:	
Metformin	€ 33.84 - € 101.53
Human insulin (NPH insulin)	€ 383.87 - € 767.73
Basal supported oral therapy (BOT)	Total:

[5] As an example of the combination of ertugliflozin with two hypoglycaemic agents, metformin and liraglutide are presented as possible concomitant active ingredients.
[6] As an example, for the use in type 2 diabetics with a first-time indication for insulin therapy, the combination of ertugliflozin 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
Ertugliflozin + human insulin (NPH insulin)	€ 829.39 - € 1,213.26
Ertugliflozin + human insulin (NPH insulin) + metformin	€ 863.23 - € 1,314.79
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Human insulin (NPH insulin)	€ 383.87 - € 767.73
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH insulin) + metformin	€ 417.71 - € 869.26

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[7]:	
Metformin	€ 33.84 - € 101.53
Human insulin (NPH insulin)	€ 383.87 - € 767.73
Basal supported oral therapy (BOT)	Total:
Ertugliflozin + metformin + human insulin (NPH insulin)	€ 863.23 - € 1,314.78
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36
Dapagliflozin	€ 944.72
Human insulin (NPH insulin)	€ 383.87 - € 767.73
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH insulin) + metformin + empagliflozin	€ 1,077.74 - € 1,529.29
Human insulin (NPH insulin) + metformin + liraglutide	€ 1,727.28 - € 2,833.62
Human insulin (NPH insulin) + metformin + dapagliflozin	€ 1,362.43 - € 1,813.98

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

[7] The combination of ertugliflozin 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.*]*

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy		
Liraglutide	Disposable needles	€ 72.82

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[8]:	
Conventional insulin therapy (CT, mixed insulin)	€ 383.87 - € 767.73
	Total:
Conventional insulin therapy (CT, mixed insulin) + ertugliflozin Ertugliflozin + human insulin (mixed insulin)	 € 829.39 - € 1,213.25
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Dulaglutide	€ 1,175.07
Conventional insulin therapy (CT, mixed insulin)	€ 383.87 - € 767.73
	Total:
Conventional insulin therapy (CT, mixed insulin) if necessary + metformin or dulaglutide Mixed insulin + metformin Mixed insulin + dulaglutide	 € 417.71 - € 869.26 € 1,558.94 - € 1,942.80
Intensified insulin therapy Human insulin (NPH insulin) Human insulin (bolus insulin)	 € 153.55 - € 460.64 € 153.55 - € 460.64 Total: € 383.87 - € 767.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services:

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

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy		
Intensified conventional insulin therapy	Blood glucose test strips Lancets Disposable needles	€ 465.74 - € 698.61 € 30.66 - € 45.99 € 291.27 - € 364.09

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:	
Ertugliflozin	€ 445.52
Concomitant active ingredient of the medicinal product to be assessed[9]:	
Conventional insulin therapy (CT, mixed insulin)	€ 383.87 - € 767.73
	Total:
Conventional insulin therapy (CT, mixed insulin) + ertugliflozin Ertugliflozin + human insulin (mixed insulin)	 € 829,39 - € 1,213.25
Appropriate comparator therapy:	
Metformin	€ 33.84 - € 101.53
Empagliflozin	€ 660.03
Liraglutide	€ 1,309.57 - € 1,964.36
Dapagliflozin	€ 944.72
Conventional insulin therapy (CT, mixed insulin)	€ 383.87 - € 767.73
	Total:
Conventional insulin therapy (CT, mixed insulin) if necessary + metformin or empagliflozin or liraglutide or dapagliflozin Mixed insulin + metformin Mixed insulin + empagliflozin Mixed insulin + liraglutide Mixed insulin + dapagliflozin	 € 417.71 - € 869.26 € 1,043.90 - € 1,427.76 € 1,693.44 - € 2,732.09 € 1,328.59 - € 1,712.45
Intensified insulin therapy Human insulin (NPH insulin) Human insulin (bolus insulin)	 € 153.55 - € 460.64 € 153.55 - € 460.64

[9] The combination with mixed insulin is shown as an example of the combination of ertugliflozin 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
	Total: € 383.87 - € 767.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2022)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy		
Intensified conventional insulin therapy	Blood glucose test strips Lancets Disposable needles	€ 465.74 - € 698.61 € 30.66 - € 45.99 € 291.27 - € 364.09
Liraglutide	Disposable needles	€ 72.82

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 May 2022.

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

Berlin, 19 May 2022

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

Prof. Hecken