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
Insulin icodec (type 2 diabetes mellitus)

of 20 February 2025

At its session on 20 February 2025, 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 Insulin icodec as follows:

Insulin icodec

Resolution of: 20 February 2025
Entry into force on: 20 February 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 May 2024):

Treatment of diabetes mellitus in adults.

Therapeutic indication of the resolution (resolution of 20 February 2025):

Treatment of type 2 diabetes mellitus in adults.

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

a1) **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 insulin icodec compared to the appropriate comparator therapy:

An additional benefit is not proven.

a2) **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 insulin icodec compared to the appropriate comparator therapy:

An additional benefit is not proven.

b1) **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 insulin icodec compared to the appropriate comparator therapy:

An additional benefit is not proven.

b2) **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 insulin icodec compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

a1) **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 assessable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.c.	There are no assessable data.
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		

a2) **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**

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 ∅: No data available. n.a.: not assessable		

b1) **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

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.c.	There are no assessable data.
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		

b2) **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

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 ∅: No data available. n.a.: not assessable		

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

a1) **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

a2) **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**

Approx. 114,000 to 172,000 patients

b1) **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

b2) **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 Awiqli (active ingredient: insulin icodec) at the following publicly accessible link (last access: 6 January 2025):

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

4. Treatment costs

Annual treatment costs:

a1) **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/ subject
Medicinal product to be assessed:	
Insulin icodec	€ 827.24 - € 1,654.49
Concomitant active ingredient of the medicinal product to be assessed[1]:	
Metformin	€ 33.90 - € 101.71
Basal supported oral therapy (BOT) Insulin icodec + metformin	Total: € 861.14 - € 1,756.20
Appropriate comparator therapy:	
Metformin	€ 33.90 - € 101.71
Human insulin (NPH insulin)	€ 387.55 - € 775.09
Basal supported oral therapy (BOT) Human insulin (NPH insulin) + metformin	Total: € 421.45 - € 876.80

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Medicinal product to be assessed:		
Insulin icodec	Blood glucose test strips Lancets	€ 18.70 - € 56.11 € 1.09 - € 3.28
Appropriate comparator therapy:		
Basal supported oral therapy (BOT) Human insulin (NPH insulin)	Blood glucose test strips Lancets Disposable needles	€ 131.04 - € 393.11 € 7.67 - € 23.00 € 47.45 - € 94.90

[1] The combination of insulin icodec with metformin in the context of basal supported oral therapy (BOT) is shown as an example for the use in subjects with type 2 diabetes mellitus without manifest cardiovascular disease with a first-time indication for insulin therapy.

a2) **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**

Designation of the therapy	Annual treatment costs/ subject
Medicinal product to be assessed:	
Insulin icodec	€ 827.24 - € 1,654.49
Concomitant active ingredient of the medicinal product to be assessed[2]:	
Metformin	€ 33.90 - € 101.71
Empagliflozin	€ 654.55 - € 817.64
Dapagliflozin	€ 878.53
Liraglutide	€ 1,604.30 - € 2,406.45
Basal supported oral therapy (BOT)	Total:
Insulin icodec + metformin + empagliflozin	€ 1,515.69 - € 5,573.84
Insulin icodec + metformin + dapagliflozin	€ 1,739.67 - € 2,634.73
Insulin icodec + metformin + liraglutide	€ 2,465.44 - € 4,162.65
Appropriate comparator therapy:	
Metformin	€ 33.90 - € 101.71
Empagliflozin	€ 654.55 - € 817.64
Dapagliflozin	€ 1,604.30 - € 2,406.45
Liraglutide	€ 878.53
Human insulin (NPH insulin)	€ 387.55 - € 775.09
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH insulin) + metformin + empagliflozin	€ 1,076.00 - € 1,694.44
Human insulin (NPH insulin) + metformin + dapagliflozin	€ 1,299.98 - € 1,755.33
Human insulin (NPH insulin) + metformin + liraglutide	€ 2,025.75 - € 3,283.25

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

[2] The combination of insulin icodec with metformin and in each case additionally with empagliflozin, dapagliflozin or liraglutide as part of basal supported oral therapy (BOT) is shown as an example for use in subjects with type 2 diabetes mellitus with manifest cardiovascular disease with a first-time indication for insulin therapy.

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Medicinal product to be assessed:		
Insulin icodec	Blood glucose test strips Lancets	€ 18.70 - € 56.11 € 1.09 - € 3.28
Liraglutide	Disposable needles	€ 47.45
Appropriate comparator therapy:		
Basal supported oral therapy (BOT) Human insulin (NPH insulin)	Blood glucose test strips Lancets Disposable needles	€ 131.04 - € 393.11 € 7.67 - € 23.00 € 47.45 - € 94.90
Liraglutide	Disposable needles	€ 47.45

b1) **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/ subject
Medicinal product to be assessed:	
Insulin icodec	€ 827.24 - € 1,654.49
Concomitant active ingredient of the medicinal product to be assessed[3]:	
Metformin	€ 33.90 - € 101.71
Intensified insulin therapy (ICT) + insulin icodec Insulin icodec Human insulin (bolus insulin) Insulin icodec + bolus insulin Insulin icodec + bolus insulin + metformin	 € 330.90 - € 992.69 € 155.02 - € 465.06 Total: € 563.43 - € 1,302.73 € 597.33 - € 1,404.44
Appropriate comparator therapy:	
Metformin	€ 33.90 - € 101.71
Dulaglutide	€ 1,175.20
Conventional insulin therapy (CT) (mixed insulin)	€ 387.55 - € 775.09
CT (mixed insulin) if necessary + metformin or + dulaglutide Mixed insulin + metformin Mixed insulin + dulaglutide	Total: € 421.45 - € 876.80 € 1,562.75 - € 1,950.29

[3] The combination of insulin icodec with bolus insulin and metformin is shown as an example for use in insulin-experienced subjects with type 2 diabetes mellitus without manifest cardiovascular disease.

Designation of the therapy	Annual treatment costs/ subject
Appropriate comparator therapy:	
Intensified insulin therapy	
Human insulin (NPH insulin)	€ 155.02 - € 465.06
Human insulin (bolus insulin)	€ 155.02 - € 465.06
NPH insulin + bolus insulin	Total: € 387.55 - € 775.09

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Medicinal product to be assessed:		
Insulin icodec	Blood glucose test strips	€ 18.70 - € 56.11
	Lancets	€ 1.09 - € 3.28
Concomitant active ingredient of the medicinal product to be assessed:		
Intensified insulin therapy (ICT)	Blood glucose test strips	€ 393.11
	Lancets	€ 142.35
	Disposable needles	€ 23.00
Appropriate comparator therapy:		
Conventional insulin therapy (CT) (mixed insulin)	Blood glucose test strips	€ 131.04 - € 393.11
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 47.45 - € 94.90
Intensified insulin therapy (ICT)	Blood glucose test strips	€ 524.14 - € 786.21
	Lancets	€ 30.66 - € 45.99
	Disposable needles	€ 189.80 - € 237.25

b2) **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/ subject
Medicinal product to be assessed:	
Insulin icodec	€ 827.24 - € 1,654.49
Concomitant active ingredient of the medicinal product to be assessed[4]:	
Metformin	€ 33.90 - € 101.71
Empagliflozin	€ 654.55 - € 817.64
Dapagliflozin	€ 878.53
Liraglutide	€ 1,604.30 - € 2,406.45
Intensified insulin therapy (ICT) + insulin icodec	
Insulin icodec	€ 330.90 - € 992.69
Human insulin (bolus insulin)	€ 155.02 - € 465.06
	Total:
Insulin icodec + bolus insulin	€ 563.43 - € 1,302.73
Insulin icodec + bolus insulin + metformin + empagliflozin	€ 1,251.88 - € 2,222.08
Insulin icodec + bolus insulin + metformin+ dapagliflozin	€ 1,475.86 - € 2,282.97
Insulin icodec + bolus insulin + metformin + liraglutide	€ 2,201.63 - € 3,810.89
Appropriate comparator therapy:	
Metformin	€ 33.90 - € 101.71
Empagliflozin	€ 654.55 - € 817.64
Dapagliflozin	€ 878.53
Liraglutide	€ 1,604.30 - € 2,406.45
Conventional insulin therapy (CT) (mixed insulin)	€ 387.55 - € 775.09
CT (mixed insulin) + metformin + empagliflozin or + dapagliflozin or liraglutide	Total:
Mixed insulin + metformin + empagliflozin	€ 1,076.00 - € 1,694.44
Mixed insulin + metformin + dapagliflozin	€ 1,299.98 - € 1,755.33
Mixed insulin + metformin + liraglutide	€ 2,025.75 - € 3,283.25

[4] The combination of insulin icodec with bolus insulin and with metformin and in each case additionally with empagliflozin, dapagliflozin or liraglutide is shown as an example for use in insulin-experienced subjects with type 2 diabetes mellitus with manifest cardiovascular disease.

Designation of the therapy	Annual treatment costs/ subject
Appropriate comparator therapy:	
Intensified insulin therapy	
Human insulin (NPH insulin)	€ 155.02 - € 465.06
Human insulin (bolus insulin)	€ 155.02 - € 465.06
	Total:
NPH insulin + bolus insulin	€ 387.55 - € 775.09
ICT + metformin + empagliflozin or + dapagliflozin or liraglutide	Total:
NPH insulin + bolus insulin + metformin + empagliflozin	€ 1,076.00 - € 1,694.44
NPH insulin + bolus insulin + metformin + dapagliflozin	€ 1,299.98 - € 1,755.33
NPH insulin + bolus insulin + metformin + liraglutide	€ 2,025.75 - € 3,283.25

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Medicinal product to be assessed:		
Insulin icodec	Blood glucose test strips	€ 18.70 - € 56.11
	Lancets	€ 1.09 - € 3.28
Concomitant active ingredient of the medicinal product to be assessed:		
Intensified insulin therapy (ICT)	Blood glucose test strips	€ 393.11
	Lancets	€ 142.35
	Disposable needles	€ 23.00
Liraglutide	Disposable needles	€ 47.45
Appropriate comparator therapy:		
Conventional insulin therapy (CT) (mixed insulin)	Blood glucose test strips	€ 131.04 - € 393.11
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 47.45 - € 94.90
Intensified insulin therapy (ICT)	Blood glucose test strips	€ 524.14 - € 786.21
	Lancets	€ 30.66 - € 45.99
	Disposable needles	€ 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-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 insulin icodec 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:

Dapagliflozin/ saxagliptin (Qtern), empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

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 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 insulin icodec 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:

Dapagliflozin/ saxagliptin (Qtern), empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

b1) 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

The following medicinal products with new active ingredients that can be used in a combination therapy with insulin icodec 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), tirzepatide (Mounjaro)

b2) 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

The following medicinal products with new active ingredients that can be used in a combination therapy with insulin icodec 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), tirzepatide (Mounjaro)

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

Insulin icodec

Resolution according to Section 35a paragraph 3 SGB V from

20.02.2025

Therapeutic indication of the resolution

Treatment of type 2 diabetes mellitus in adults

Patient group a1

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[2])

Dapagliflozin/ saxagliptin (Qtern), empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

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

From 20 February 2025

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 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[2])

Dapagliflozin/ saxagliptin (Qtern), empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), empagliflozin/ linagliptin (Glyxambi), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), ertugliflozin/ sitagliptin (Steglujan), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

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

From 20 February 2025

Patient group b1

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[2])

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

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

From 20 February 2025

Patient group b2

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[2])

Empagliflozin (Jardiance), empagliflozin/ metformin (Synjardy), ertugliflozin (Steglatro), ertugliflozin/ metformin (Segluromet), semaglutide (Ozempic), semaglutide (Rybelsus), tirzepatide (Mounjaro)

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 20 February 2025.

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

Berlin, 20 February 2025

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

Prof. Hecken