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
Dapagliflozin (new therapeutic indication: type 2 diabetes mellitus, ≥ 10 years)

of 16 June 2022

At its session on 16 June 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. **In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Dapagliflozin in accordance with the resolution of 17.02.2022:**

Dapagliflozin

Resolution of: 16 June 2022
Entry into force on: 16 June 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 November 2021):

Forxiga is indicated in adults and children aged 10 years and above for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance.
- in addition to other medicinal products for the treatment of type 2 diabetes.

Therapeutic indication of the resolution (resolution of 16 June 2022):

For the treatment of children and adolescents aged 10 to 17 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance.
- in addition to other medicinal products for the treatment of type 2 diabetes.

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

a) Insulin-naïve children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy consisting of at least one hypoglycaemic agent in addition to diet and exercise

Appropriate comparator therapy for dapagliflozin:

- Human insulin + metformin

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

An additional benefit is not proven.

b) Insulin-experienced children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous insulin regime in addition to diet and exercise

Appropriate comparator therapy for dapagliflozin:

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

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Insulin-naïve children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy consisting of at least one hypoglycaemic agent in addition to diet and exercise

There are no assessable data.

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.
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		

b) Insulin-experienced children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous insulin regime in addition to diet and exercise

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-167) 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	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

a) Insulin-naïve children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy consisting of at least one hypoglycaemic agent in addition to diet and exercise

b) Insulin-experienced children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous insulin regime in addition to diet and exercise

approx. 650 - 710 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 Forxiga (active ingredient: dapagliflozin) at the following publicly accessible link (last access: 7 March 2022):
https://www.ema.europa.eu/en/documents/product-information/forxiga-epar-product-information_en.pdf

4. Treatment costs

Annual treatment costs:

a) Insulin-naïve children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous medicinal therapy consisting of at least one hypoglycaemic agent in addition to diet and exercise

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Dapagliflozin	€ 944.72
Concomitant active ingredient of the medicinal product to be assessed[2]:	
Metformin	€ 16.92 - € 67.69
Liraglutide	€ 1,309.57 - € 1,964.36
	Total:
Dapagliflozin + metformin	€ 961.64 - € 1,012.40
Dapagliflozin + liraglutide	€ 2,254.29 - € 2,909.07
Appropriate comparator therapy:	
Metformin	€ 16.92 - € 67.69
Human insulin (NPH-insulin)	€ 262.43 - € 1,336.06
Basal supported oral therapy (BOT)	Total:
Human insulin (NPH-insulin) + metformin	€ 279.35 - € 1,403.75

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 May 2022)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Concomitant active ingredient of the medicinal product to be assessed		
Liraglutide	Disposable needles	€ 72.82
Appropriate comparator therapy		
Human insulin (NPH-insulin)	Blood glucose test strips	€ 116.44 - € 349.31
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 72.82 - € 145.64

b) Insulin-experienced children and adolescents aged 10 to 17 years with type 2 diabetes mellitus, who have not achieved sufficient glycaemic control with their previous insulin regime in addition to diet and exercise

[2] For the combination of dapagliflozin with a hypoglycaemic agent, metformin and liraglutide are presented as possible concomitant active ingredients.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Dapagliflozin	€ 944.72
Concomitant active ingredient of the medicinal product to be assessed[3]:	
Conventional insulin therapy (CT, mixed insulin)	€ 262.43 - € 1,336.06
	Total:
Conventional insulin therapy (CT, mixed insulin) + dapagliflozin Dapagliflozin + human insulin (mixed insulin)	€ 1,207.14 -€ 2,280.78
Appropriate comparator therapy:	
Metformin	€ 16.92 - € 67.69
Conventional insulin therapy (CT, mixed insulin)	€ 262.43 - € 1,336.06
	Total:
Conventional insulin therapy (CT, mixed insulin) if necessary + metformin Mixed insulin + metformin	€ 279.35 - € 1,403.75
Intensified insulin therapy Human insulin (NPH insulin) Human insulin (bolus insulin)	€ 104.97 - € 801.63 € 104.97 - € 801.63 Total: € 262.43 - € 1,336.06

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 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	€ 465.74 - € 698.61
	Lancets	€ 30.66 - € 45.99
	Disposable needles	€ 291.27 - € 364.09

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

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 June 2022.

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

Berlin, 16 June 2022

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

Prof. Hecken