Empagliflozin (new therapeutic indication: type 2 diabetes mellitus, ≥ 10 to ≤ 17 years)

Resolution of: 20 June 2024 Valid until: unlimited
Entry into force on: 20 June 2024
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New therapeutic indication (according to the marketing authorisation of 7 December 2023):

Jardiance 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 diabetes.

Therapeutic indication of the resolution (resolution of 20 June 2024):

Jardiance is indicated in children and adolescents aged 10 to 17 years 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 diabetes.

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

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:

A patient-individual therapy, taking into account the HbA1c value, previous therapies and complications with selection of

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

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

An additional benefit is not proven.

Study results according to endpoints:

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

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

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

Children and adolescents aged 10 to 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

Approx. 300 - 385 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 Jardiance (active ingredient: empagliflozin) at the following publicly accessible link (last access: 26 April 2024):

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

4. Treatment costs

Annual treatment costs:

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:	
Empagliflozin	€ 659.30 - € 837.64
Concomitant active ingredient of the medicinal product to be assessed[1]:	
Metformin	€ 28.61 - € 66.88
Liraglutide	€ 1,515.63 - € 2,273.44
Dulaglutide	€ 1,174.20
Human insulin (NPH insulin)	€ 261.82 - € 1,336.94
Conventional insulin therapy (CT, mixed insulin)[2]	€ 261.82 - € 1,336.94

[1] For the combination of empagliflozin with a hypoglycaemic agent, metformin, liraglutide, dulaglutide and human insulin are presented as possible concomitant active ingredients.

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

Designation of the therapy	Annual treatment costs/ patient
Intensified insulin therapy (ICT)[3] Human insulin (NPH insulin) Human insulin (bolus insulin)	 € 104.73 - € 802.16 € 104.73 - € 802.16 Total: € 261.82- € 1,336.94[4]
	TOTAL:
empagliflozin + metformin	€ 687.91 - € 904.52
Empagliflozin + liraglutide	€ 2,174.93 - € 3,111.08
Empagliflozin + dulaglutide	€ 1,833.50 - € 2,011.84
Empagliflozin + human insulin (NPH insulin)	€ 921.12 - € 2,174.58
Empagliflozin + conventional insulin therapy (CT, mixed insulin)[2]	€ 921.12 - € 2,174.58
Empagliflozin + metformin + conventional insulin therapy (CT, mixed insulin)[2]	€ 949.73 - € 2,241.46
Empagliflozin+ Intensified conventional insulin therapy (ICT)[3]	€ 921.12 - € 2,174.58
Empagliflozin + metformin + intensified conventional insulin therapy (ICT)[3]	€ 949.73 - € 2,241.46
Appropriate comparator therapy:	
A patient-individual therapy taking into account the HbA1c value, previous therapies and complications by selecting the following active ingredients:	
Metformin	€ 28.61 - € 66.88
Dapagliflozin	€ 883.82
Liraglutide	€ 1,515.63 - € 2,273.44
Dulaglutide	€ 1,174.20
Human insulin (NPH insulin)	€ 261.82 - € 1,336.94
Conventional insulin therapy (CT, mixed insulin)	€ 261.82- € 1,336.94
Intensified insulin therapy (ICT) Human insulin (NPH insulin) Human insulin (bolus insulin)	 € 104.73 - € 802.16 € 104.73 - € 802.16 Total:

[3] The combination with and without metformin is shown as an example of the combination of empagliflozin with an insulin in the context of escalation of insulin therapy, in this case with an intensified conventional insulin therapy.

[4] The lower range (dosage requirement of 0.7 I.U. / kg BW/ day) results for the 10-year-olds with 40 - 60% NPH insulin and 40 - 60% bolus insulin. The upper range (dosage requirement of 2 I.U. / kg BW/ day) results for the 17-year-olds with 40 - 60% NPH insulin and 40 - 60% bolus insulin.

Designation of the therapy	Annual treatment costs/ patient
	€ 261.82- € 1,336.94[4]
	TOTAL:
metformin + dapagliflozin	€ 912.43 - € 950.70
Metformin + liraglutide	€ 1,544.24 - € 2,340.32
Metformin + dulaglutide	€ 1,202.81 - € 1,241.08
Metformin + human insulin (NPH insulin)	€ 290.43 - € 1,403.82
Conventional insulin therapy (CT, mixed insulin) + metformin+ dapagliflozin	€ 1,174.25 - € 2,287.64
Conventional insulin therapy (CT, mixed insulin) + metformin + liraglutide	€ 1,806.06 - € 3,677.26
Conventional insulin therapy (CT, mixed insulin) + metformin+ dulaglutide	€ 1,464.63 - € 2,578.02
Intensified insulin therapy (ICT) + metformin + dapagliflozin	€ 1,174.25 - € 2,287.64
Intensified insulin therapy (ICT) + metformin + liraglutide	€ 1,806.06 - € 3,677.26
Intensified insulin therapy (ICT) + metformin + dulaglutide	€ 1,464.63 - € 2,578.02

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Concomitant active ingredient of the medicinal product to be assessed		
Human insulin (NPH-insulin)	Blood glucose test strips	€ 131.04 - € 393.11
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 47.45 - € 94.90
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 conventional 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
Appropriate comparator therapy		
Human insulin (NPH-insulin)	Blood glucose test strips	€ 131.04 - € 393.11
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 47.45 - € 94.90
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 conventional 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:

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

The following medicinal products with new active ingredients that can be used in a combination therapy with empagliflozin 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:

- 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.