Gemeinsamer Bundesausschuss

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

Resolution of: 21 September 2023 valid until: unlimited
Entry into force on: 21 September 2023
Federal Gazette, BAnz AT 21 09 2023 B4

New therapeutic indication (according to the marketing authorisation of 6 March 2023):

Trulicity is indicated for the treatment of patients 10 years and above 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.

Therapeutic indication of the resolution (resolution of 21 September 2023):

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 unsuitable due to intolerance or contraindications.
- 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 for dulaglutide:

- A patient-individual therapy, taking into account the HbA1c value, previous therapies and complications with selection of
  - metformin + human insulin
  - metformin + liraglutide
  - an escalation of insulin therapy (conventional therapy (CT) if necessary + metformin or intensified insulin therapy (ICT)).

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

An additional benefit is not proven.

Study results according to endpoints:[1]

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 ∅: 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. 640 – 710 patients

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-28) unless otherwise indicated.

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 Trulicity (active ingredient: dulaglutide) at the following publicly accessible link (last access: 28 July 2023):

https://www.ema.europa.eu/en/documents/product-information/trulicity-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:	
Dulaglutide	€ 1,126.71
Concomitant active ingredient of the medicinal product to be assessed[2]:	
Metformin	€ 28.61 - € 66.88
Dapagliflozin	€ 883.82
Human insulin (NPH insulin)	€ 261.82 - € 1,332.96
Conventional insulin therapy (CT, mixed insulin) [3]	€ 261.82 - € 1,332.96
	Total:
Dulaglutide + metformin	€ 1,155.32 - € 1,193.58
Dulaglutide + dapagliflozin	€ 2,010.53
Dulaglutide + human insulin (NPH insulin)	€ 1,388.52 - € 2,459.67
Conventional insulin therapy (CT, mixed insulin) + dulaglutide Dulaglutide + human insulin (mixed insulin)	 € 1,388.52 - € 2,459.67
Appropriate comparator therapy:	

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

[3] The combination with mixed insulin is shown as an example of the combination of dulaglutide 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
A patient-individual therapy, taking into account the HbA1c value, previous therapies and complications with selection of the following active ingredients:	
Metformin	€ 28.61 - € 66.88
Human insulin (NPH-insulin)	€ 261.82 - € 1,332.96
Liraglutide	€ 1,453.11 - € 2,179.67
	Total:
Metformin + human insulin (NPH-insulin)	€ 290.43 - € 1,399.84
metformin + liraglutide	1,481.72 - 2,246.55
Conventional insulin therapy (CT, mixed insulin)	€ 261.82 - € 1,332.96
	Total:
<u>Conventional insulin therapy (CT, mixed insulin) if necessary + metformin</u> Mixed insulin + metformin	 € 290.43 - € 1,399.84
<u>Intensified insulin therapy (ICT)</u> Human insulin (NPH insulin) Human insulin (bolus insulin)	 € 104.73 - € 799.78 € 104.73 - € 799.78 Total: € 261.82 - € 1,332.96[4]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2023

[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.

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	€ 116.44 - € 349.31
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 72.82 - € 145.64
Conventional insulin therapy (CT, mixed insulin)	Blood glucose test strips	€ 116.44 - € 349.31
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 72.82 - € 145.64
Appropriate comparator therapy		
Liraglutide	Disposable needles	€ 72.82
Human insulin (NPH-insulin)	Blood glucose test strips	€ 116.44 - € 349.31
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 72.82 - € 145.64
Conventional insulin therapy (CT, mixed insulin)	Blood glucose test strips	€ 116.44 - € 349.31
	Lancets	€ 7.67 - € 23.00
	Disposable needles	€ 72.82 - € 145.64
Intensified conventional insulin therapy (ICT)	Blood glucose test strips	€ 465.74 - € 698.61
	Lancets	€ 30.66 - € 45.99
	Disposable needles	€ 291.27 - € 364.09

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 dulaglutide 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 (Forxiga)

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.