Gemeinsamer Bundesausschuss

Empagliflozin (new therapeutic indication: chronic kidney disease)

Resolution of: 1 February 2024 valid until: unlimited
Entry into force on: 1 February 2024
Federal Gazette, BAnz AT 23 02 2024 B3

New therapeutic indication (according to the marketing authorisation of 24 July 2023):

Jardiance is indicated in adults for the treatment of chronic kidney disease.

Therapeutic indication of the resolution (resolution of 1 February 2024):

See new therapeutic indication according to marketing authorisation.

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

Adults with chronic kidney disease

Appropriate comparator therapy:

An optimised standard therapy for the treatment of chronic kidney disease, taking into account the underlying disease and common comorbidities (such as diabetes mellitus, hypertension, dyslipoproteinaemia, anaemia, heart failure).

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:[1]

Adults with chronic kidney disease

No suitable data versus the appropriate comparator therapy were presented.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-78) 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.

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

Adults with chronic kidney disease

approx. 2,259,300 – 2,478,100 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: 19 September 2023):

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

4. Treatment costs

Annual treatment costs:

Adults with chronic kidney disease

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Empagliflozin	€ 837.64
+ optimised standard therapy	Different from patient to patient
Appropriate comparator therapy:	
Optimised standard therapy	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 January 2024)

Costs for additionally required SHI services: not applicable

Other SHI benefits: not applicable

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:

Adults with chronic kidney disease

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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.