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) Voclosporin (lupus nephritis)

of 17 August 2023

At its session on 17 August 2023, 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 Voclosporin as follows:

Voclosporin

Resolution of: 17 August 2023

Entry into force on:

Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 September 2022):

Lupkynis is indicated in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN).

Therapeutic indication of the resolution (resolution of 17 August 2023):

See therapeutic indication according to marketing authorisation.

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

Adults with active class III, IV or V (including mixed classes III/V and IV/V) lupus nephritis, in combination with mycophenolate mofetil

Appropriate comparator therapy:

- A patient-individual therapy taking into account any previous therapy and the disease activity, selecting the following active ingredients:

glucocorticoids, azathioprine, cyclophosphamide, hydroxychloroquine, chloroquine, mycophenolate mofetil/ mycophenolenic acid[1]

Extent and probability of the additional benefit of voclosporin in combination with mycophenolate mofetil compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adults with active class III, IV or V (including mixed classes III/V and IV/V) lupus nephritis, in combination with mycophenolate mofetil

There are no appropriate data for the benefit assessment.

[1] See resolution on an amendment of the Pharmaceuticals Directive (AM-RL) of Annex VI - Off-Label-Use of mycophenolate mofetil/ mycophenolenic acid for lupus nephritis.

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

Adults with active class III, IV or V (including mixed classes III/V and IV/V) lupus nephritis, in combination with mycophenolate mofetil

approx. 1,090 – 13,050 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 Lupkynis (active ingredient: voclosporin) at the following publicly accessible link (last access: 27 April 2023):

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

Treatment with voclosporin should only be initiated and monitored by doctors experienced in treating lupus nephritis.

4. Treatment costs

Annual treatment costs:

Adults with active class III, IV or V (including mixed classes III/V and IV/V) lupus nephritis, in combination with mycophenolate mofetil

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Voclosporin	€ 17,995.60
Mycophenolate mofetil	€ 1,099.03 - € 2,198.06
Total:	€ 19,094.62 - € 20,193.65
Appropriate comparator therapy:	
Patient-individual therapy taking into account any previous therapy and the disease activity, selecting the following active ingredients:	
Azathioprine	€ 163.30 - € 477.64
Cyclophosphamide	€ 348.58 - € 522.86
Hydroxychloroquine	€ 90.74 - € 181.48
Chloroquine[2]	€ 104.80
Mycophenolate mofetil	€ 1,099.03 - € 2,198.06
Glucocorticoids	
Prednisolone	Different from patient to patient
Prednisone	Different from patient to patient

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

Costs for additionally required SHI services: not applicable

[2] Only available as import without group association

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 active class III, IV or V (including mixed classes III/V and IV/V) lupus nephritis, in combination with mycophenolate mofetil

- No medicinal product with new active ingredients that can be used in a combination therapy that 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 August 2023.

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

Berlin, 17 August 2023

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

Prof. Hecken