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: Tirbanibulin (actinic keratosis, Olsen grade I)

of 17 February 2022

At its session on 17 February 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. Annex XII shall be amended in alphabetical order to include the active ingredient Tirbanibulin as follows:

Tirbanibulin

Resolution of: 17 February 2022
Entry into force on: 17 February 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 16 July 2021):

Klisyri is indicated for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

Therapeutic indication of the resolution (resolution of 17 February 2022):

see therapeutic indication according to marketing authorisation.

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

Adults with non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp

Appropriate comparator therapy:

- Diclofenac hyaluronic acid gel (3%) or 5-fluorouracil (5 FU) or (surgical) cryotherapy for the treatment of solitary lesions

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

An additional benefit is not proven.

Study results according to endpoints:

Adults with non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp

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		

There are no relevant data for the benefit assessment.

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

Adults with non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp

Approx. 700,000 to 1,380,000 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 Klisyri (active ingredient: tirbanibulin) at the following publicly accessible link (last access: 29 November 2021):

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

4. Treatment costs

Annual treatment costs:

Adults with non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tirbanibulin (ointment)	€ 112.22
Appropriate comparator therapy:	
Diclofenac hyaluronic acid (gel, 3%)	€ 89.26
5-fluorouracil (cream)	€ 75.42
(Surgical) cryotherapy for the treatment of solitary lesions[1]	No specification possible

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2022)

Costs for additionally required SHI services: not applicable

1 Cryotherapy is covered by the basic flat rate for insured persons.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 February 2022.

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

Berlin, 17 February 2022

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

Prof. Hecken