Tirbanibulin (actinic keratosis, Olsen grade I)

Resolution of: 17 February 2022
Entry into force on: 17 February 2022
Federal Gazette, BAnz AT 22 03 2022 B3

Valid until: unlimited

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.