Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Trifarotene (Acne Vulgaris)

of 4 February 2021

At its session on 4 February 2021 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), amended by the announcement on DD 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 trifarotene as follows:

Trifarotene

Resolution of: 4 February 2021
Entry into force on: 4 February 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 April 2020)

Trifarotene is indicated for the topical treatment of acne vulgaris on the face and/or trunk in patients 12 years of age and older if many comedones, papules, and pustules are present.

Therapeutic indication of the resolution (resolution of 4 February 2021)

See therapeutic indication according to marketing authorisation

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

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

Appropriate comparator therapy:

- A topical combination therapy of adapalene + benzoyl peroxide

or

- A topical combination therapy of clindamycin + benzoyl peroxide

Extent and probability of the additional benefit of trifarotene compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

There are no relevant data compared with the appropriate comparator therapy.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	No relevant data are available.
Morbidity	n.a.	No relevant data are available.
Health-related quality of life	n.a.	No relevant data are available.
Side effects	n.a.	No relevant data are 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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

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

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

approx. 887,500 to 1,950,700 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

4. Treatment costs

Annual treatment costs:

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Trifarotene	different for each individual patient
Appropriate comparator therapy:	
Topical combination therapy of adapalene + benzoyl peroxide	different for each individual patient

Designation of the therapy	Annual treatment costs/patient
Topical combination therapy of clindamycin + benzoyl peroxide	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 January 2021

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 4 February 2021.

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

Berlin, 4 February 2021

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken