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
Secukinumab (new therapeutic indication: enthesitis-related arthritis, ≥ 6 years)

of 5 January 2023

At its session on 5 January 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Secukinumab in accordance with the resolution of 18 February 2021:

Secukinumab

Resolution of: 5 January 2023
Entry into force on: 5 January 2023
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 20 June 2022):

Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.

Therapeutic indication of the resolution (resolution of 5 January 2023):

See new therapeutic indication according to marketing authorisation

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

Patients 6 years and older with active enthesitis-related arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy

Appropriate comparator therapy:

- Therapy according to doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:

Patients 6 years and older with active enthesitis-related arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy

There are no appropriate data for the benefit assessment.

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
∅: There are no usable data for the benefit assessment.
n.c.: not calculable

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

Patients 6 years and older with active enthesitis-related arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy

approx. 240 – 290 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 Cosentyx (active ingredient: secukinumab) at the following publicly accessible link (last access: 10 November 2022):

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

Treatment with secukinumab should only be initiated and monitored by doctors experienced in treating adults with enthesitis-related arthritis.

4. Treatment costs

Annual treatment costs:

Patients 6 years and older with active enthesitis-related arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Secukinumab monotherapy	
Secukinumab	€ 4,855.20 - € 9,304.44
Secukinumab in combination with methotrexate	
Secukinumab Methotrexate Total	€ 4,855.20 - € 9,304.44 € 52.40 - € 337.47 € 4,920.19 [1] - € 9,641.91
Appropriate comparator therapy:	
Therapy according to doctor's instructions	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 December 2022)

Costs for additionally required SHI services: not applicable

5. 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 Secukinumab

Medicinal products with the following new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with secukinumab for the treatment of enthesitis-related arthritis on the basis of the marketing authorisation granted under Medicinal Products Act:

Patients 6 years and older with active enthesitis-related arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy

No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

[1] Arithmetically, the lower limit of the total range is € 64.99, taking into account the lower limit of methotrexate (oral) for children.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 5 January 2023.

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

Berlin, 5 January 2023

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

Prof. Hecken