Secukinumab (new therapeutic indication: hidradenitis suppurativa (acne inversa))

Resolution of: 7 December 2023 valid until: unlimited
Entry into force on: 7 December 2023
Federal Gazette, BAnz AT 16 01 2024 B2

New therapeutic indication (according to the marketing authorisation of 26 May 2023):

Cosentyx is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.

Therapeutic indication of the resolution (resolution of 7 December 2023):

See new therapeutic indication according to marketing authorisation.

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

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

Appropriate comparator therapy:

Adalimumab

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:[1]

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

No data available.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-51) unless otherwise indicated.

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 moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

approx. 4,800 – 6,400 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: 23 October 2023):

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 hidradenitis suppurativa.

4. Treatment costs

Annual treatment costs:

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Secukinumab	€ 17,858.12 - € 38,841.41
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 22,825.27 - € 22,869.08 € 181.18 € 23,006.45 - € 23,050.26

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

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 moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

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