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 Secukinumab (New Therapeutic Indication: Axial Spondyloarthritis)

of 18 February 2021

At its session on 18 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), as amended on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

In Annex XII, the following information shall be added after No. 16 to the information on the benefit assessment of secukinumab in accordance with the resolution of 18 February 2021:

Secukinumab

Resolution of: 18 February 2021
Entry into force on: 18 February 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 28 April 2020):

Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

Therapeutic indication of the resolution (resolution of 18 February 2021):

See new therapeutic indication according to marketing authorisation

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

Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs)

Appropriate comparator therapy:

A TNF-α inhibitor (etanercept or adalimumab or golimumab or certolizumab pegol)

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

Additional benefit is not proven

Study results according to endpoints:[1]

Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs)

[1] Data from the dossier assessment of the IQWiG (A20-79) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	There are no usable data for the benefit assessment.
Morbidity	∅	There are no usable data for the benefit assessment.
Health-related quality of life	∅	There are no usable data for the benefit assessment.
Side effects	∅	There are no usable data for the benefit assessment.

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

No suitable data were submitted.

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

Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs)

approx. 19,500 patients

19. 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 accessed: 6 January 2021):
https://www.ema.europa.eu/documents/product-information/cosentyx-epar-product-information_en.pdf

In patients who have not responded to therapy in up to 16 weeks of treatment, the discontinuation of treatment should be considered. Some patients with an initially partial response improve over time if treatment is continued beyond 16 weeks.

20. Treatment costs

Annual treatment costs:

Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs)

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Secukinumab	€ 10,343.44
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 11,510.06 € 180.64 € 11,690.70
Certolizumab pegol Additionally required SHI services Total	€ 19,808.29 € 180.64 € 19,988.93
Etanercept Additionally required SHI services Total	€ 16,885.18 € 180.64 € 17,065.82
Golimumab Additionally required SHI services Total	€ 20,974.88 € 180.64 € 21,155.52

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2021

Costs for additionally required SHI services: not applicable

I. 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 18 February 2021.

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

Berlin, 18 February 2021

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

Prof. Hecken