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 Ixekizumab (New Therapeutic Indication: Plaque Psoriasis in Children and Adolescents)

of 21 January 2021

At its session on 21 January 2021, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 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. 4 to the information on the benefit assessment of ixekizumab in accordance with the resolution of 16 August 2018:

Benefit assessment procedure comprises several resolutions.
Please note the current version of the Pharmaceuticals Directive/Annex XII.

Courtesy translation – only the German version is legally binding.

Ixekizumab

Resolution of: 21 January 2021
Entry into force on: 21 January 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 June 2020):

Taltz is indicated for the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy.

Therapeutic indication of the resolution (resolution of 21 January 2021):

See new therapeutic indication according to marketing authorisation

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

Children from the age of 6 years and with a body weight of at least 25 kg and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Appropriate comparator therapy:

Adalimumab or etanercept or ustekinumab

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

An additional benefit is not proven.

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

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

Children from the age of 6 years and with a body weight of at least 25 kg and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy.

approx. 270–2035 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 Taltz (active ingredient: ixekizumab) at the following publicly accessible link (last access: 8 December 2020):

https://www.ema.europa.eu/en/documents/product-information/taltz-epar-product-information_de.pdf

In patients who have not responded to treatment after 16 to 20 weeks, discontinuation of treatment should be considered. In some patients with an initial partial response, the response may improve if treatment is continued beyond 20 weeks.

4. Treatment costs

Annual treatment costs:

Children from the age of 6 years and with a body weight of at least 25 kg and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Ixekizumab	€ 18,087.16
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 6,280.18 – 11,510.06 € 180.64 € 6,460.82 – 11,690.70
Etanercept Additionally required SHI services Total	€ 3,943.31 – 7,778.20 € 180.64 € 4,123.95 – 7,958.84
Ustekinumab Additionally required SHI services Total	€ 21,326.37 € 74.24 € 20,400.61

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

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Benefit assessment according to the Pharmaceuticals Directive/Annex XII.

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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 21 January 2021.

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

Berlin, 21 January 2021

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

Prof. Hecken

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