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: Axial Spondyloarthritis)

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 2020:

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 2 June 2020):

Axial spondyloarthritis

Ankylosing spondylitis (radiographic axial spondyloarthritis)

Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy.

Non-radiographic axial spondyloarthritis

Taltz is indicated for the treatment of 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).

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

a1) Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Appropriate comparator therapy:

A TNF-α inhibitor (etanercept or adalimumab or infliximab or golimumab or certolizumab pegol) or an IL17 inhibitor (secukinumab)

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

Additional benefit is not proven

a2) Adult patients with active ankylosing spondylitis who have responded inadequately to, or who are intolerant to therapy with biological antirheumatic drugs (bDMARDs)

Appropriate comparator therapy:

Switching to another biological disease-modifying antirheumatic: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab or infliximab) or IL17 inhibitor (secukinumab)

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

Additional benefit is not proven

b) 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 ixekizumab compared with the appropriate comparator therapy:

Additional benefit is not proven

Study results according to endpoints:[1]

a1) Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Summary of results for relevant clinical endpoints

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

a2) Adult patients with active ankylosing spondylitis who have responded inadequately to, or who are intolerant to therapy with biological antirheumatic drugs (bDMARDs)

[1] Data from the dossier assessment of the IQWiG (A20-66) unless otherwise indicated.

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No suitable data were submitted.

b) 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)

Summary of results for relevant clinical endpoints

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No suitable data were submitted.

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

a1) Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

approx. 10,700 patients

a2) Adult patients with active ankylosing spondylitis who have responded inadequately to, or who are intolerant to therapy with biological antirheumatic drugs (bDMARDs)

approx. 6,100 patients

b) 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

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: 17 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:

a1) Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Ixekizumab	€ 18,087.16
Appropriate comparator therapy:	

Designation of the therapy	Annual treatment costs/patient
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
Infliximab Additionally required SHI services Total	€ 16,683.89 – 22,330.74 € 180.64 € 16,864.53 – 22,511.38
Secukinumab	€ 10,343.44 – 20,686.88

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

a2) Adult patients with active ankylosing spondylitis who have responded inadequately to, or who are intolerant to therapy with biological antirheumatic drugs (bDMARDs)

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b) 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)

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

Other services covered by SHI funds:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6.5–8.7	€ 461.50 – 617.70

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