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
Risankizumab (new therapeutic indication: psoriatic arthritis, monotherapy or in combination with methotrexate)

of 19 May 2022

At its session on 19 May 2022, 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 Risankizumab in accordance with the resolution of 2 November 2019:

Risankizumab

Resolution of: 19 May 2022
Entry into force on: 19 May 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 November 2021):

Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

Therapeutic indication of the resolution (resolution of 19 May 2022):

See [new] therapeutic indication according to marketing authorisation.

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

a) Adults with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

Appropriate comparator therapy:

- a TNF-alpha antagonist (adalimumab or certolizumab pegol or etanercept or golimumab or infliximab) or an interleukin inhibitor (ixekizumab or secukinumab or ustekinumab), if necessary, in combination with methotrexate

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

An additional benefit is not proven.

b) Adults with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying antirheumatic drug (bDMARD) therapy.

Appropriate comparator therapy:

- switching to another biological disease-modifying antirheumatic drug (adalimumab or certolizumab pegol or etanercept or golimumab or infliximab or ixekizumab or secukinumab or ustekinumab), if necessary, in combination with methotrexate

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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 submitted.

b) Adults with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying antirheumatic drug (bDMARD) therapy.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-156) unless otherwise indicated.

↔: no statistically significant or relevant difference ∅: There are no usable data for the benefit assessment. n.a.: not assessable

No suitable data submitted.

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

a) Adults with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

approx. 20,100 patients

b) Adults with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying antirheumatic drug (bDMARD) therapy.

approx. 9,000 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 Skyrizi (active ingredient: risankizumab) at the following publicly accessible link (last access: 4 March 2022):

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

Treatment with risankizumab should only be initiated and monitored by doctors experienced in treating adults with psoriatic arthritis.

Consider discontinuing treatment in patients who do not show a response after 16 weeks of treatment.

4. Treatment costs

Annual treatment costs:

a) Adults with active psoriatic arthritis who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Risankizumab Additionally required SHI services Total	€ 21,305.30 € 74.45 € 21,379.75
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 11,435.41 € 180.85 € 11,616.26
Certolizumab pegol Additionally required SHI services Total	€ 11,435.41 € 180.85 € 11,616.26
Etanercept Additionally required SHI services Total	€ 11,413.50 € 180.85 € 11,594.35
Golimumab Additionally required SHI services Total	€ 10,416.60 € 180.85 € 10,597.45
Infliximab Additionally required SHI services Total	€ 16,685.14 € 180.85 € 16,865.99
Ixekizumab	€ 17,279.21
Secukinumab	€ 9,304.44 - € 18,608.88
Ustekinumab Additionally required SHI services Total	€ 21,432.83 € 74.45 € 21,507.28

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 2022)

Other SHI services:

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	€ 461.50

b) Adults with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying antirheumatic drug (bDMARD) therapy.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Risankizumab Additionally required SHI services Total	€ 21,305.30 € 74.45 € 21,379.75
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 11,435.41 € 180.85 € 11,616.26
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Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
not applicable					
Appropriate comparator therapy					
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6.5	€ 461.50

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 May 2022.

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

Berlin, 19 May 2022

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

Prof. Hecken