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 Guselkumab (New Therapeutic Indication: Psoriatic Arthritis)

of 20 May 2021

At its session on 20 May 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 last amended on DD. 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 guselkumab in accordance with the resolution of 17 May 2018 last modified on 24 July 2018:

Courtesy translation – only the German version is legally binding.

Guselkumab

Resolution of: 20 May 2021
Entry into force on: 20 May 2021
BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 20 November 2020):

Tremfya, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying anti-rheumatic drug (DMARD) therapy.

Therapeutic indication of the resolution (resolution from the 20/05/2021):

See new therapeutic indication according to marketing authorisation.

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

a) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior disease-modifying anti-rheumatic 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 guselkumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying anti-rheumatic drug (bDMARDs).

Appropriate comparator therapy:

- switching to another biological disease-modifying anti-rheumatic 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 guselkumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

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Study results according to endpoints:

a) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior disease-modifying anti-rheumatic 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 suitable data.
Morbidity	n.a.	There are no suitable data.
Health-related quality of life	n.a.	There are no suitable data.
Side effects	n.a.	There are no suitable 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) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior biological disease-modifying anti-rheumatic drug (bDMARDs).

Summary of results for relevant clinical endpoints

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

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

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

approx. 20,100 patients

b) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior therapy with biologic disease-modifying anti-rheumatic drugs (bDMARDs).

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 Tremfya (active ingredient: guselkumab) at the following publicly accessible link (last access: 24 February 2021):
https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_de.pdf

Treatment with guselkumab should only be initiated and monitored by specialists who are experienced in the treatment of patients with psoriatic arthritis.

In patients who have not responded to therapy after 24 weeks of treatment duration, discontinuation of treatment should be considered.

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4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Guselkumab	€ 19,791.95
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 11,434.37 € 180.64 € 11,615.01
Certolizumab pegol Additionally required SHI services Total	€ 11,434.37 € 180.64 € 11,615.01
Etanercept Additionally required SHI services Total	€ 11,412.46 € 180.64 € 11,593.10
Golimumab Additionally required SHI services Total	€ 9,584.00 € 180.64 € 9,764.64
Infliximab Additionally required SHI services Total	€ 16,683.89 € 180.64 € 16,864.53
Ixekizumab	€ 18,087.16
Secukinumab	€ 10,343.44 – € 20,686.88
Ustekinumab Additionally required SHI services Total	€ 21,326.37 € 74.24 € 21,400.61

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 April 2021)

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

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b) Adult patients with active psoriatic arthritis who have had an inadequate response or have been intolerant to a prior therapy with biologic disease-modifying anti-rheumatic drugs (bDMARDs).

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Guselkumab	€ 19,791.95
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services Total	€ 11,434.37 € 180.64 € 11,615.01
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II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 May 2021.

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

Berlin, 20 May 2021

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

Prof. Hecken

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