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
Anifrolumab (systemic lupus erythematosus)

of 6 October 2022

At its session on 6 October 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. Annex XII shall be amended in alphabetical order to include the active ingredient anifrolumab as follows:

Anifrolumab

Resolution of: 6 October 2022
Entry into force on: 6 October 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 14 February 2022):

Saphnelo is indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

Therapeutic indication of the resolution (resolution of 6 October 2022):

See therapeutic indication according to marketing authorisation.

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

Adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy

Appropriate comparator therapy:

Belimumab

Extent and probability of the additional benefit of anifrolumab as add-on therapy compared to belimumab:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy

[1] Data from the dossier assessment of the IQWiG (A-22-35) and from the addendum (A22-85), unless otherwise indicated.

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		

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

Adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy

approx. 4,600 – 18,500 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 Saphnelo (active ingredient: anifrolumab) at the following publicly accessible link (last access: 30 June 2022):

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

Treatment with anifrolumab should only be initiated and monitored by doctors experienced in SLE therapy.

4. Treatment costs

Annual treatment costs:

Adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Anifrolumab	€ 20,962.24
Additionally required SHI services	€ 74.45
Total	21,036.69
Appropriate comparator therapy:	
Belimumab	€ 14,032.85

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Anifrolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	13.0	€ 923
Belimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	13.0	€ 923

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 October 2022.

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

Berlin, 6 October 2022

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

Prof. Hecken