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 Solriamfetol (Narcolepsy with and without Cataplexy)

of 5 November 2020

On 5 November 2020, the Federal Joint Committee (G-BA) resolved by written statement 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:

I. Annex XII shall be amended in alphabetical order to include the active ingredient solriamfetol as follows:

Solriamfetol

Resolution of: 5 November 2020
Entry into force on: 5 November 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 16 January 2020):

Sunosi is indicated to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy).

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

a) Adult patients with narcolepsy without cataplexy

Appropriate comparator therapy:

Modafinil or pitolisant

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

An additional benefit is not proven.

b) Adult patients with narcolepsy and cataplexy

Appropriate comparator therapy:

Sodium oxybate or pitolisant

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adult patients with narcolepsy without cataplexy

No suitable data were submitted.

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.

[1] Data from the dossier assessment of the IQWiG (A20-47) unless otherwise indicated.

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		

b) Adult patients with narcolepsy and cataplexy

No suitable data were submitted.

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

a) Adult patients with narcolepsy without cataplexy

approx. 3,900–4,700 patients

b) Adult patients with narcolepsy and cataplexy

approx. 12,300–14,800 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 Sunosi® (active ingredient: solriamfetol) at the following publicly accessible link (last access: 26 August 2020):

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

Treatment with solriamfetol should only be initiated and monitored by specialists who are experienced in the treatment of patients with narcolepsy.

4. Treatment costs

Annual treatment costs:

a) Adult patients with narcolepsy without cataplexy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Solriamfetol	€ 6,693.71 – 10,639.62
Appropriate comparator therapy:	
Modafinil	€ 1,643.52 – 3,287.04
Pitolisant	€ 4,757.78 – 9,369.71

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2020

b) Adult patients with narcolepsy and cataplexy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Solriamfetol	€ 6,693.71 – 10,639.62
Appropriate comparator therapy:	
Sodium oxybate	€ 7,010.92 – 14,021.84
Pitolisant	€ 4,757.78 – 9,369.71

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2020

Costs for additionally required SHI services: not applicable

II. 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 5 November 2020.

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

Berlin, 5 November 2020

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

Prof. Hecken