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 Daridorexant (reassessment following amendment of Annex III to the Pharmaceuticals Directive: insomnia)

of 15 August 2024

At its session on 15 August 2024, 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 is amended as follows:

1. The information on daridorexant in the version of the resolution of 12 May 2023 (BAnz AT 19.06.2023 B4) last modified on 21 December 2023 (BAnz AT 31.01.2024 B3) is repealed.
2. Annex XII shall be amended in alphabetical order to include the active ingredient daridorexant as follows:

Daridorexant

Resolution of: 15 August 2024
Entry into force on: 15 August 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 29 April 2022):

Quviviq is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.

Therapeutic indication of the resolution (resolution of 15 August 2024):

See therapeutic indication according to marketing authorisation.

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

Adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning

Appropriate comparator therapy:

Best supportive care

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning

There are no assessable data.

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 ∅: No data available. n.a.: not assessable		

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

Adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning

Approx. 8,300 – 218,500 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 Quviviq (active ingredient: daridorexant) at the following publicly accessible link (last access: 1 July 2024):

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

4. Treatment costs

Annual treatment costs:

Adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Daridorexant	€ 1,108.75
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	

Designation of the therapy	Annual treatment costs/ patient
Best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2024)

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 15 August 2024.

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

Berlin, 15 August 2024

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

Prof. Hecken