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 Lisdexamfetamine dimesylate (new therapeutic indication: ADHD, adult patients)

of 17 October 2019

At its session on 17 October 2019, the Federal Joint Committee (G-BA) resolved 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of lisdexamfetamine dimesylate in accordance with the resolution of 14 November 2013:

Lisdexamfetamine dimesylate

Resolution of: 17 October 2019
Entry into force on: 17 October 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 February 2019):

Elvanse® Adult is indicated as part of an overall therapeutic strategy to treat attention deficit hyperactivity disorder (ADHD) in adults.

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

a) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have already received medicinal therapy:

Appropriate comparator therapy:

A patient-individual therapy involving the selection of atomoxetine and methylphenidate in which the possible continuation or resumption with a medicinal product already used must also be examined and described as part of an overall therapeutic strategy.

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

An additional benefit is not proven.

b) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have not yet been treated with medication:

Appropriate comparator therapy:

Atomoxetine or methylphenidate as part of an overall therapeutic strategy.

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have already received medicinal therapy:

[1] Data from the dossier evaluation of the IQWiG (A19-40) unless otherwise indicated.

No suitable data were submitted.

b) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have not yet been treated with medication:

No suitable data were submitted.

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

Patient population a) and b)

Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity with or without previous medicinal treatment:

Approx. 73,000 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

Treatment with lisdexamfetamine dimesylate may only be initiated and monitored by a specialist for behavioural disorders in adults (specialist for neurology and/or psychiatry or for psychiatry and psychotherapy, specialist for psychosomatic medicine and psychotherapy, medical psychotherapists according to the demand planning guideline). In therapeutically justified cases, in the case of continued treatment in a transitional phase up to the maximum age of 21, prescriptions can also be made by specialists for behavioural disorders in children and adolescents. In exceptional cases, general practitioners may also make follow-up prescriptions if it is ensured that the supervision is carried out by a specialist for behavioural disorders.

The use of stimulants in the course of the treatment, in particular long-term therapy over 12 months, must be documented as well as the assessment of non-treatment periods, which should take place at least once a year.

The potential for abuse, misuse or misappropriation of lisdexamfetamine dimesylate should be considered prior to the prescription.

Officially approved training materials are available for both pre-treatment investigations and ongoing monitoring.

4. Treatment costs

Annual treatment costs:

a) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have already received medicinal therapy:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Lisdexamfetamine	€ 1,313.51 – € 1,441.99
Appropriate comparator therapy:	
Atomoxetine	€ 974.94
Methylphenidate	€ 285.03 – € 1,067.10

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2019

b) Adults with attention deficit hyperactivity disorder (ADHD) since childhood with at least moderate severity (at least moderate functional impairment in two or more situations and affecting several aspects of life) who have not yet been treated with medication:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Lisdexamfetamine	€ 1,313.51 – € 1,441.99
Appropriate comparator therapy:	
Atomoxetine	€ 974.94
Methylphenidate	€ 285.03 – € 1,067.10

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2019

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 17 October 2019.

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

Berlin, 17 October 2019

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

Prof Hecken