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 Isoflurane (sedation of mechanically ventilated patients during intensive care)

of 21 July 2022

At its session on 21 July 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 isoflurane as follows:

Isoflurane

Resolution of: 21 July 2022
Entry into force on: 21 July 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 24 September 2021):

Sedaconda is used for sedation of mechanically ventilated adult patients during intensive care.

Therapeutic indication of the resolution (resolution of 21 July 2022):

see therapeutic indication according to marketing authorisation

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

Mechanically ventilated adult patients for whom sedation is indicated

Appropriate comparator therapy:

A therapy according to doctor's instructions under consideration of propofol, midazolam and dexmedetomidine

Extent and probability of the additional benefit of isoflurane:

An additional benefit is not proven.

Study results according to endpoints:

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	∅	No data available
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

Mechanically ventilated adult patients for whom sedation is indicated

approx. 146,000 – 219,000 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.
Treatment with Sedaconda should only be initiated and monitored by medical specialists experienced in the treatment of mechanically ventilated patients, the Sedaconda Anaesthetic Conserving Device (ACD) delivery system, and the pharmacodynamic properties of isoflurane.

Sedaconda must only be delivered via Sedaconda ACD, as the efficacy and safety of inhaled isoflurane sedation have only been established with Sedaconda ACD. Sedaconda must only be used in intubated or tracheotomised patients with a secure airway.

4. Treatment costs

Annual treatment costs:

Mechanically ventilated adult patients for whom sedation is indicated

Designation of the therapy	Annual treatment costs/ patient[1]
Medicinal product to be assessed:	
Isoflurane	€ 291.17 - € 1,261.73
Additionally required SHI services	Incalculable
Appropriate comparator therapy:	
Propofol	€ 39.55 - € 504.23
Dexmedetomidine	€ 119.00 - € 773.50
Midazolam	€ 19.06 - € 123.55

LAUER-TAXE® last revised: 1 July 2022

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 21 July 2022.

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

Berlin, 21 July 2022

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

Prof. Hecken

[1] The costs of the medicinal products and the additionally required SHI services are reimbursed via the respectively applicable DRG case flat fees.