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: Misoprostol (labour induction)

of 17 February 2022

At its session on 17 February 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 Misoprostol as follows:

Misoprostol

Resolution of: 17 February 2022
Entry into force on: 17 February 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 14 September 2020):

Angusta is used to induce labour.

Therapeutic indication of the resolution (resolution of 17 February 2022):

see therapeutic indication according to marketing authorisation.

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

Pregnant women with indication for induction of labour in case of unfavourable cervix (Bishop score < 7)

Appropriate comparator therapy:

- Dinoprostone

Extent and probability of the additional benefit of Misoprostol compared to Dinoprostone:

An additional benefit is not proven.

Study results according to endpoints:[1]

Pregnant women with indication for induction of labour in case of unfavourable cervix (Bishop score < 7)

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 ∅: 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

Pregnant women with indication for induction of labour in case of unfavourable cervix (Bishop score < 7)

Approx. 76,500 – 90,000

3. Requirements for a quality-assured application

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

Treatment with misoprostol should only be initiated and monitored by specialists experienced in the treatment of pregnant women with an indication for induction of labour in the case of unfavourable cervix (Bishop score < 7). It should only be administered by trained medical professionals in a hospital where there are facilities for continuous monitoring of the foetus and uterus

[1] Data from the dossier assessment of the IQWiG (A21-114) and from the addendum (G22-04), unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Pregnant women with indication for induction of labour in case of unfavourable cervix (Bishop score < 7)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Misoprostol	€ 14.62 - € 116.98
Appropriate comparator therapy:	
Dinoprostone - vaginal gel	€ 41.07 - € 123.21

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 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 17 February 2022.

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

Berlin, 17 February 2022

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

Prof. Hecken