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)
Tixagevimab/ cilgavimab (first dossier requirement: COVID-19, pre-exposure prophylaxis, ≥ 12 years)

of 2 November 2023

At its session on 2 November 2023, 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. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Tixagevimab/ cilgavimab in accordance with the resolution of 20 April 2023:**

**Tixagevimab/ cilgavimab**

Resolution of: 2 November 2023
Entry into force on: 2 November 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

**Therapeutic indication (according to the marketing authorisation of 25 March 2022):**

EVUSHELD is indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg.

**Therapeutic indication of the resolution (resolution of 2 November 2023):**

EVUSHELD is indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg, who are entitled to a supply of this medicinal product in accordance with Section 2 paragraph 1 of the COVID-19 Prevention Ordinance.

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

Adults and adolescents aged 12 years and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19

**Appropriate comparator therapy:**

- Monitoring wait-and-see approach

**Extent and probability of the additional benefit of tixagevimab/ cilgavimab compared to the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:**[1]

Adults and adolescents aged 12 years and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19

There are no assessable data.

[1] Data from the dossier assessment of the IQWiG (A23-42) and from the addendum (A23-96), unless otherwise indicated.

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | not assessable |
| Morbidity | n.a. | not assessable |
| Health-related quality of life | ∅ | No data available. |
| Side effects | n.a. | not assessable |

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

Adults and adolescents 12 years of age and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19 with a virus variant against which tixagevimab/ cilgavimab has significantly reduced or insufficient neutralisation activity

0 patients[2]

Adults and adolescents 12 years of age and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19 with a viral variant against which tixagevimab/ cilgavimab has sufficient neutralisation activity

0 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 Evusheld (active ingredient: tixagevimab/ cilgavimab) at the following publicly accessible link (last access: 28 July 2023):

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

[2] The efficacy of tixagevimab/ cilgavimab is significantly reduced to non-existent under the currently circulating sublines of the Omikron viral variant. (ECDC, Country overview report: week 39 2023: https://covid19-country-overviews.ecdc.europa.eu/variants_of_concern.html)

For tixagevimab/ cilgavimab, a significantly reduced (BA.1, BA.4, BA.5) or no (BQ.1/BQ.1.1, BA.4.6, BF.7. XBB) efficacy against the omicron viral variants circulating in Germany at the time of drafting the resolution was demonstrated by in vitro neutralisation tests.

## 4. Treatment costs

**Annual treatment costs:**

Adults and adolescents aged 12 years and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Tixagevimab/ cilgavimab | € 2,256.00 |
| Appropriate comparator therapy: | |
| Monitoring wait-and-see approach | Incalculable |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2023)

Costs for additionally required SHI services: not applicable

## 5. 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 tixagevimab/ cilgavimab

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:

Adults and adolescents aged 12 years and older weighing at least 40 kg for pre-exposure prophylaxis of COVID-19

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.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 2 November 2023.**

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

Berlin, 2 November 2023

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

Prof. Hecken