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 Remdesivir (New therapeutic indication: COVID-19, not requiring supplemental oxygen, < 18 years, ≥ 40 kg)

of 6 April 2023

At its session on 6 April 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. 4 to the information on the benefit assessment of Remdesivir according to the resolution of 6 April 2023 on the therapeutic indication "for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients (aged at least 4 weeks to 11 years weighing at least 3 kg) with pneumonia requiring supplementary oxygen (low or high-flow oxygen therapy or other non-invasive ventilation at the start of therapy)":**

Remdesivir

Resolution of: 6 April 2023
Entry into force on: 6 April 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 16 September 2022):

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

Therapeutic indication of the resolution (resolution of 6 April 2023):

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

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

Children and adolescents weighing at least 40 kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

Appropriate comparator therapy:

- Therapy according to doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:1

Children and adolescents weighing at least 40 kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

There are no assessable data.

1 Data from IQWiG's dossier assessment (A22-112)

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

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

Children and adolescents weighing at least 40 kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

approx. 2,600 – 14,200 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 Veklury (active ingredient: remdesivir) at the following publicly accessible link (last access: 20 February 2023):

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

Remdesivir should only be used in clinical settings where patients can be closely monitored.

4. Treatment costs

Annual treatment costs:

Children and adolescents weighing at least 40 kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Remdesivir	€ 1,642.20
Therapy according to doctor's instructions	Different from patient to patient
Appropriate comparator therapy:	
Therapy according to doctor's instructions	Different from patient to patient

Cost of the clinic pack plus value added tax of 19% (LAUER-TAXE® last revised: 15 March 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 Remdesivir

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients which are used in a combination therapy with remdesivir for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients (weighing at least 40 kg) who do not require supplementary oxygen and have an increased risk of progressing to severe COVID-19 on the basis of the marketing authorisation under Medicinal Products Act:

Children and adolescents weighing at least 40 kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

- No active ingredient that can be used in a combination therapy that 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 6 April 2023.

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

Berlin, 6 April 2023

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

Prof. Hecken