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
Nirsevimab (new therapeutic indication: secondary prevention of RSV infections, children during their 2nd RSV season, ≤ 24 months of life)

of 20 February 2025

At its session on 20 February 2025, 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 Nirsevimab in accordance with the resolution of 15 August 2024.

Courtesy translation – only the German version is legally binding.

Nirsevimab

Resolution of: 20 February 2025
Entry into force on: 20 February 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 01 August 2024):

Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season .

Beyfortus should be used in accordance with official recommendations.

Therapeutic indication of the resolution (resolution of 20 February 2025):

Prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in children up to 24 months of age with indication for secondary prevention during their second RSV season.

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

a) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is indicated

Appropriate comparator therapy:

Palivizumab

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

An additional benefit is not proven.

b) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is not indicated

Appropriate comparator therapy:

Monitoring wait-and-see approach

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

An additional benefit is not proven.

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Study results according to endpoints:[1]

a) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is indicated

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.c.	There are no assessable data.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.c.	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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-82) unless otherwise indicated.

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b) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is not indicated

No suitable data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

a) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is indicated

Approx. 9,000 patients

b) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is not indicated

Approx. 535 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 Beyfortus (active ingredient: nirsevimab) at the following publicly accessible link (last access: 6 February 2025):

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

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4. Treatment costs

Annual treatment costs:

a) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nirsevimab	€ 855.12
Appropriate comparator therapy:	
Palivizumab	€ 11,676 - € 13,337.50

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

Costs for additionally required SHI services: not applicable

b) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is not indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nirsevimab	€ 855.12
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

Costs for additionally required SHI services: not applicable

5. Designation of 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 the assessed medicinal product

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:

a) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is indicated

- 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.

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b) Children during their 2nd RSV season up to 24 months of age with indication for secondary prevention of lower respiratory tract infections caused by RSV for whom palivizumab is not indicated

- No medicinal product with new active ingredients 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 20 February 2025.

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

Berlin, 20 February 2025

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

Prof. Hecken

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