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)
Nintedanib (new therapeutic indication: systemic sclerosis associated interstitial lung disease, 6 to < 18 years)

of 7 August 2025

At their session on 7 August 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 Nintedanib in accordance with the resolution of 7 August 2025:

Nintedanib

Resolution of: 7 August 2025
Entry into force on: 7 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 12 February 2025):

Ofev is indicated in adults, adolescents and children aged 6 years and older for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

Therapeutic indication of the resolution (resolution of 7 August 2025):

Ofev is indicated in children and adolescents from 6 to 17 years old for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

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

Children and adolescents from 6 to 17 years old with systemic sclerosis associated interstitial lung disease (SSc-ILD)

Appropriate comparator therapy:

- Best supportive care

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Children and adolescents from 6 to 17 years old with systemic sclerosis associated interstitial lung disease (SSc-ILD)

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-29) unless otherwise indicated.

Summary of results for relevant clinical endpoints

No suitable data available.

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

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

Children and adolescents from 6 to 17 years old with systemic sclerosis associated interstitial lung disease (SSc-ILD)

Approx. 0 – 8 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 Ofev (active ingredient: nintedanib) at the following publicly accessible link (last access: 3 June 2025):

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

Treatment should be initiated and monitored only after involvement of a multidisciplinary team (physicians, radiologists, pathologists) experienced in the diagnosis and treatment of fibrosing interstitial lung diseases (ILDs).

4. Treatment costs

Annual treatment costs:

Children and adolescents from 6 to 17 years old with systemic sclerosis associated interstitial lung disease (SSc-ILD)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nintedanib	€ 23,393.95 - € 34,999.49
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

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

Children and adolescents from 6 to 17 years old with systemic sclerosis associated interstitial lung disease (SSc-ILD)

- 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.

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 7 August 2025.**

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

Berlin, 7 August 2025

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

Prof. Hecken