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 Linzagolix (new therapeutic indication: endometriosis)

of 5 June 2025

At their session on 5 June 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 Linzagolix in accordance with the resolution of 6 March 2025:**

Linzagolix

Resolution of: 5 June 2025
Entry into force on: 5 June 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 November 2024):

Yselty is indicated in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.

Therapeutic indication of the resolution (resolution of 5 June 2025):

See new therapeutic indication according to marketing authorisation.

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

Adult patients of reproductive age with endometriosis with a history of previous medical or surgical treatment, for symptomatic treatment

Appropriate comparator therapy:

Individualised therapy with selection of

- Dienogest
- GnRH analogues (goserelin or buserelin or leuprorelin or triptorelin or nafarelin)
- relugolix/ estradiol/ norethisterone acetate
- Surgical measures

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients of reproductive age with endometriosis with a history of previous medical or surgical treatment, for symptomatic treatment

Summary of results for relevant clinical endpoints

There are no assessable data.

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

Adult patients of reproductive age with endometriosis with a history of previous medical or surgical treatment, for symptomatic treatment

Approx. 8,100 to 13,900 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 Yselty (active ingredient: linzagolix) at the following publicly accessible link (last access: 4 April 2025):

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

Treatment with linzagolix should only be initiated and monitored by specialists experienced in treating patients with endometriosis.

When using linzagolix, concomitant hormonal add-back therapy is indicated in the present indication according to the product information.

4. Treatment costs

Annual treatment costs:

Adult patients of reproductive age with endometriosis with a history of previous medical or surgical treatment, for symptomatic treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Linzagolix	€ 1,324.39
Estradiol/ norethisterone acetate	€ 145.91
Appropriate comparator therapy:	
Dienogest	€ 174.11
GnRH analogues	
Goserelin	€ 1,192.04
Buserelin	€ 1,299.97 - € 1,857.10
Leuprorelin	€ 1,072.58 – € 1,094.16
Triptorelin	€ 1,175.58
Nafarelin	€ 1,378.79
Relugolix/ estradiol/ norethisterone acetate	€ 1,140.28
Surgical measures	Different from patient to patient

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

Adult patients of reproductive age with endometriosis with a history of previous medical or surgical treatment, for symptomatic treatment

- 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 5 June 2025.

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

Berlin, 5 June 2025

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

Prof. Hecken