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 (uterine fibroid)

of 6 March 2025

At its session on 6 March 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. Annex XII shall be amended in alphabetical order to include the active ingredient Linzagolix as follows:

Linzagolix

Resolution of: 6 March 2025
Entry into force on: 6 March 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 14 June 2022):

Yselty is indicated in adult women for treatment of moderate to severe symptoms of uterine fibroids of reproductive age.

Therapeutic indication of the resolution (resolution of 6 March 2025):

Therapeutic indication according to marketing authorisation.

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

Adult women of reproductive age with moderate to severe symptoms of uterine fibroids

Appropriate comparator therapy:

- Individualised therapy with selection of:
  - a symptom-oriented treatment:
    - relugolix/ estradiol/ norethisterone acetate
    - progestogens under consideration of the respective authorisation status (for patients for whom symptomatic treatment of prolonged and/or heavy menstruation (menorrhagia, hypermenorrhoea) is sufficient.)
  - invasive treatment options

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 women of reproductive age with moderate to severe symptoms of uterine fibroids

There are no assessable data.

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	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 women of reproductive age with moderate to severe symptoms of uterine fibroids

approx. 20,160 – 100,840 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: 10 January 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 doctors experienced in treating patients with uterine fibroids.

4. Treatment costs

Annual treatment costs:

Adult women of reproductive age with moderate to severe symptoms of uterine fibroids

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Linzagolix	€ 1,324.39
Estradiol/ norethisterone acetate	€ 145.91
Total:	€ 1,324.39 – € 1,470.30
Appropriate comparator therapy:	
Symptom-oriented treatment	
Relugolix/ estradiol/ norethisterone acetate	€ 1,140.28
Chlormadinone	€ 47.81 – € 95.03
Levonorgestrel Additionally required SHI services: Total:	€ 115.05 € 7.68 € 122.73
Invasive treatment options	
Hysterectomy	€ 4,301.33 – € 5,740.00
Myomectomy	€ 3,686.63 – € 5,217.72
Percutaneous transluminal angioplasty	€ 5,479.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 February 2025)

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 women of reproductive age with moderate to severe symptoms of uterine fibroids

- 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 6 March 2025.

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

Berlin, 6 March 2025

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

Prof. Hecken