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To the Minister of Health, Welfare and Sport
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2026006225

**National Health Care
Institute**

Research, Development and
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Medicinal Products Team

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Our reference

2026006225

Date 23 March 2026
Re: GVS advice for linzagolix (Yselty®) for the treatment of symptoms of
uterine fibroids

Dear Ms Hermans,

The National Health Care Institute advises you on the inclusion of linzagolix (Yselty®) in the Medicine Reimbursement System (GVS) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This advice was prompted by your request in the letter of 12 August 2025 (CIBG-25-08558).

Condition

Uterine fibroids are benign hormone-sensitive tumours of muscle tissue. They affect almost half of all women under the age of 50; ~70% has no symptoms, but ~30% has (severe) symptoms. Heavy menstrual bleeding (HMB, also known as menorrhagia) is the most characteristic symptom. This can be so severe that a woman's quality of life is severely affected, and treatment is necessary. It is estimated that the maximum number of women affected is 7700. Linzagolix is an oral medicine (tablet to swallow).

Registered indication

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

Linzagolix is also registered for endometriosis. This indication does not form part of this reimbursement request and has not been taken into account here.

Linzagolix is available as a 100 mg or 200 mg film-coated tablet.

Claim by the marketing authorisation holder (MAH)

Linzagolix has an equal value to relugolix in the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

As a short-term treatment for the reduction of uterine myoma volume, linzagolix has an equal value compared to GnRH agonists.

The marketing authorisation holder is requesting inclusion on List 1B of the Health Insurance Regulation.

Advice

The National Health Care Institute advises you to include linzagolix (Yselyt®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age in List 1B of the GVS. The price of linzagolix with add-back therapy should not exceed the price of the fixed combination of relugolix with add-back therapy (Ryeqo®). We have explained below how we reached this advice.

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Substantive assessment

Assessment of interchangeability

Based on the criteria for interchangeability, the National Health Care Institute concluded that linzagolix is *not* interchangeable with other medicinal products included in the GVS. Relugolix, already included in the GVS, is a fixed-dose combination preparation with add-back therapy, whereas linzagolix is used in combination with add-back therapy. As a result, linzagolix cannot be placed on List 1A. The National Health Care Institute has therefore assessed whether linzagolix can be included in List 1B.

Therapeutic value

For the assessment of linzagolix as long-term treatment of moderate to severe symptoms of uterine fibroids, the National Health Care Institute has compared it to relugolix in a fixed combination with oestradiol (E2) and norethisterone acetate (NETA); Ryeqo®. For the assessment of linzagolix as short-term perioperative treatment in moderate to severe symptoms of uterine fibroids, this treatment was compared to the GnRH agonists. The National Health Care Institute concludes that linzagolix for these indications has an equivalent value to the current available treatment, which also includes a place for linzagolix 100 mg for women who cannot tolerate add-back therapy. Linzagolix thus complies with the established medical science and medical practice for the treatment of uterine fibroids in women of reproductive age.

Budget impact analysis

The National Health Care Institute expects that the total group of patients eligible for treatment of moderate to severe symptoms of uterine fibroids will not exceed approximately 7700 women.¹ The National Health Care Institute expects linzagolix to account for a maximum of 30 - 40% of the total market. This corresponds to 3080 patients at most in the 3rd year after inclusion in the package. Of this group, ~60% will use this medicinal product for a short time, since only GnRH agonists are an alternative here. It is expected that ~40% will use this long-term, since GnRH agonists and relugolix combined with add-back therapy are an alternative here. Some of these patients will use linzagolix in combination with add-back therapy, and others without. See Table 1 for the treatment costs involved.

¹ This is based on a data analysis of users of GNRH analogues in the period 2021-2023. This calculation may be an overestimation because endometriosis patients are also included in this group.

Table 1: Treatment costs for short-term and long-term use of the different treatment options.

Treatment	Short-term use: Cost per patient for 3 months	Long-term use: cost per patient per year
Relugolix in fixed combination with ABT	n/a. *	€ 1,077.53
Linzagolix	€ 293.30	€ 1,173.21
Linzagolix + ABT	n/a*	€ 1,270.80
GnRH agonists	€ 277.70	€ 1,110.79
GnRH agonists + ABT	n/a*	€ 1,252.33

* All combinations with add-back therapy (ABT) are mainly used for long-term treatment.

The additional costs compared to the GnRH agonists are limited. The additional costs compared to relugolix in combination with add-back therapy (Ryeqo®) are close to €200 per patient per year. The price of linzagolix with add-back therapy should not be higher than the price of relugolix with add-back therapy.

Appropriate use

At the beginning of October 2024, the National Health Care Institute received a request from the physicians' association to revise the reimbursement condition for the oral GnRH antagonists for the indication of uterine fibroids. Following the assessment of this request, the reimbursement conditions previously established for relugolix/oestradiol/norethisterone acetate on the advice of the National Health Care Institute have lapsed². Therefore, the National Health Care Institute does not consider strict conditions regarding the use of linzagolix in this patient group to be appropriate.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Annexes:

- Assessment of interchangeability
- Pharmacotherapeutic report
- Budget impact analysis

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² <https://www.zorginstituutnederland.nl/documenten/2025/09/30/gvs-advies-vervallen-vergoedingsvoorswaarden-relugolix-icm-estradiol-en-norethisteronacetaat-ryeqo>