NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Linzagolix for treating symptoms of endometriosis

1 Recommendations

1.1 Linzagolix with hormonal add-back therapy can be used within its marketing authorisation as an option to treat symptoms of endometriosis in adults of reproductive age who have had medical or surgical treatment for their endometriosis.

What this means in practice

Linzagolix with hormonal add-back therapy must be funded in the NHS in England to treat symptoms of endometriosis in adults of reproductive age if it is considered the most suitable treatment option. Linzagolix must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that linzagolix with hormonal add-back therapy provides benefits and value for money, so it can be used routinely across the NHS.

Why these recommendations were made

Treatments for endometriosis aim to manage its symptoms but do not resolve the underlying condition. Options include surgery, gonadotropin-releasing hormone agonists (such as leuprorelin acetate) and relugolix–estradiol–norethisterone acetate (relugolix combination therapy [CT]).

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Clinical trial evidence shows that linzagolix with hormonal add-back therapy reduces dysmenorrhoea (painful periods) and non-menstrual pelvic pain compared with placebo. Indirect comparisons suggest that linzagolix with hormonal add-back therapy gives similar pain relief to leuprorelin acetate and relugolix CT.

The cost-effectiveness estimates for linzagolix with hormonal add-back therapy compared with surgery, leuprorelin acetate and relugolix CT are within the range that NICE considers an acceptable use of NHS resources. So, linzagolix with hormonal add-back therapy can be used.

For all the evidence, see the <u>committee papers</u>. For more information on streamlined evaluations, see NICE's manual on health technology evaluations.

2 Information about linzagolix

Marketing authorisation indication

2.1 Linzagolix (Yselty, Theramex) 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'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the <u>summary of product</u> characteristics for linzagolix (PDF).

Price

- 2.3 The list price for linzagolix is £80 for a pack of 28 200-mg tablets (BNF online, accessed April 2025). The list price for hormonal add-back therapy is £13.20 for a pack of 84 estradiol 1-mg norethisterone acetate 0.5-mg tablets (BNF online, accessed April 2025). At list price, 12 months of treatment would cost £1,100.
- 2.4 Costs may vary in different settings because of negotiated procurement discounts.

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3 Implementation

- 3.1 Section 7 of the National Institute for Health and Care Excellence

 (Constitution and Functions) and the Health and Social Care Information

 Centre (Functions) Regulations 2013 requires integrated care boards,

 NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.
- 3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.
- 3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has symptoms of endometriosis and the healthcare professional responsible for their care thinks that linzagolix is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered as a streamlined evaluation by the lead team of committee A, which includes the chair and three committee members.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

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NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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