Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Linzagolix (Yselty) for treating symptoms of endometriosis [NICE TA1067]		
Available at	https://www.nice.org.uk/guidance/ta1067		
Date of issue	04 June 2025	**Implementation deadline**	02 September 2025

Medicine details[1]	
Name and brand name	Linzagolix (Yselty)
Manufacturer	Theramex
Mode of action	Linzagolix is a selective, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist that inhibits endogenous GnRH signalling by binding competitively to GnRH receptors in the pituitary gland, thereby modulating the hypothalamic-pituitary-gonadal axis.
Licenced indication	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
Formulation	Film-coated tablet (100mg & 200mg)
Dosage	200mg daily to be taken with concomitant hormonal Add Back Therapy (ABT)
Comparison of NICE TA with Summary of Product Characteristics (SmPC)	Recommended as per NICE guidance *This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.*

NICE TA recommendations

Recommendations

1. Recommendation

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.

NICE has produced tools and resources to support the implementation of this guidance.

Why this recommendation was 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]).

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.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of 90 days
- The implementation deadline is 02 September 2025

Clinical effectiveness

- 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.

Patient safety

- The product should be used in line with recommendations made by NICE.
- ▼ This is a Black Triangle drug – this medicinal product is subject to reporting of all suspected adverse drug reactions to the MHRA. This will allow timely identification of new safety information.

www.medicines.org.uk – Yselty 200mg film-coated tablet – Summary of Product Characteristics (SmPC)

- Women should be informed that treatment with linzagolix usually leads to a significant reduction in menstrual blood loss and often leads to amenorrhoea, which may reduce the ability to recognise the occurrence of a pregnancy in a timely manner. Pregnancy testing should be performed if pregnancy is suspected, and treatment should be discontinued if pregnancy is confirmed
- Linzagolix with or without concomitant ABT has not been demonstrated to provide contraception. Women of childbearing potential at risk of pregnancy have to use effective non-hormonal contraception while on treatment with linzagolix
- Linzagolix should be avoided in women with severe hepatic impairment (Child-Pugh C). No dose adjustment is necessary in women with mild or moderate hepatic impairment (Child-Pugh A or B)
- Caution should be exercised in patients who have known cardiovascular disease, family history of QT prolongation or hypokalaemia, and in concomitant use with medicinal

products known to prolong the QT interval. Caution should also be exercised in patients with co-existing disorders leading to increased linzagolix plasma levels
- Linzagolix should be avoided in women with moderate (eGFR = 30– 59 mL/min), severe renal impairment (eGFR < 30 mL/min) or end-stage renal disease
- Increases in lipid levels were observed with linzagolix treatment. These increases were generally of no clinical relevance. However, in women with pre-existing elevated lipid profiles monitoring of lipid levels is recommended.
- Patients with known depression or history of depression should be carefully monitored during treatment. Treatment should be discontinued if depression recurs to a serious degree.

Patient factors

- An additional treatment option would be valued by patients.
- This is an oral treatment
- Convenience for patients
- Potential improved adherence
- Long-term control of symptoms
- Potential non-surgical treatment option
- GnRH antagonists provide immediate suppression of follicle-stimulating hormone (FSH) and luteinising hormone (LH) secretion with rapid reversibility.
- Linzagolix should preferably be started in the first week of the menstrual cycle and should be taken continuously once daily.
- Pregnancy should be ruled out prior to starting treatment
- In patients with risk factors for osteoporosis or bone loss a DXA scan is recommended prior to starting treatment with linzagolix.
- DXA scan is recommended after 1 year of treatment for all women to verify that the patient does not have an unwanted degree of BMD loss.
- Thereafter, BMD assessment is recommended annually or at a frequency determined by the treating physician based on the woman's individual risk and previous BMD assessment

Environmental impact

- Packaging waste would be additional to usual municipal waste recycling or landfill.
- Discharge into the wastewater system (post-metabolism) from an individual patient is unlikely to have a significant impact short term, however the long-term impact to the water ecosystem is unknown.

Equality & diversity

www.nice.org.uk

Age

- Licensed for treating symptoms of endometriosis in adult women of reproductive age.
- Negative impact for patients under 18 years of age with symptoms of endometriosis

Sex

- Heavy menstrual bleeding and endometriosis affect women.
- Although linzagolix 200 mg plus ABT is expected to be indicated for the symptomatic treatment of endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis, this should not prevent the use of linzagolix by people with endometriosis who do not identify as a woman.

Place in therapy relative to available treatments

First-Line Treatments (Pain Management & Hormonal Suppression) in line with CKS

a) NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- Purpose: Reduce inflammation and pain.
- Considerations: Should be taken at the onset of menstruation for best results. GI side effects may occur.

b) Neuromodulators
- Purpose: For neuropathic pain

c) Combined Hormonal Contraceptives (CHCs)
- Purpose: Suppress ovulation and reduce endometrial growth.

- Considerations: Often used continuously (without breaks) to avoid withdrawal bleeding. Not suitable for women with contraindications (e.g., migraines with aura, history of thrombosis) or those wishing to conceive.

Second-Line Treatments (When First-Line Fails)

a) Progestogens
- Purpose: Thin the endometrial lining and reduce lesions.

b) Gonadotropin-Releasing Hormone (GnRH) Agonists/Antagonists
- Purpose: Induce a temporary menopause-like state to suppress endometriosis.

Linzagolix with ABT would be second line after treatment failure on first-line therapies.

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

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The drug cost per Place according to NICE resources does not exceed £100,000.

Linzagolix with or without hormonal ABT is cost effective, but only when it is intended to be used for longer-term treatment (normally for more than 6 months). It is not recommended for people who need short-term treatment, for example, before planned surgery. The economic analysis for short-term use did not compare linzagolix against all relevant comparators, so the committee was unable to determine whether linzagolix was cost effective in this population. So, it is only recommended for longer-term use.

Section 1: cost of the technology

Annual cost per patient (or complete course if shorter)

NICE approved medicine	Pack size/cost per	Annual cost
Linzagolix (Yselty) 200mg film coated tablets	28 tablets - £80.00	£1,042 per year (assuming 13 treatment packs required) **Note that if required a patient would also be prescribed hormonal add-back therapy (ABT).**

Availability of CAP/PAS price:
- No.

Price relative to comparable medicines:

GNRH antagonists

Comparators	Pack size/cost per	Annual cost
Relugolix –estradiol-norethisterone (Ryeqo®)	28 tablets - £72.00	£938.57 **Note hormonal add-back therapy (ABT) is included as part of this treatment.**

GnRH agonists *[BNF accessed 02.05.2025]*

These treatments are licensed for 6 months but are used for longer in clinical practice. Additional administration costs in LCS in primary care.

Medicine	Pack size/cost per pack	**Annual cost excl. VAT** *[BNF accessed on 02.05.2025]*
Leuprorelin acetate (Prostap® SR DCS) 3.75mg (Takeda UK Ltd)	Pre-filled disposable injection £75.24	(every month) £980.80* Calculation made for 28 days treatment for comparison to goserelin
Leuprorelin acetate (Prostap® 3 DCS) 11.25mg (Takeda UK Ltd)	Pre-filled disposable injection £225.72	(every 3 months) £978.12* Calculation made for treatment every 12 weeks for comparison to goserelin
Goserelin acetate 3.6mg (Zoladex®) (Astra Zeneca Ltd)	Pre-filled disposable injection £70.00	(every 28 days) £912.50
Triptorelin pamoate (Decapeptyl SR 11.25mg) Ipsen Ltd	Powder and solvent for injection £207.00	(Every 3 months) £828.00
Triptorelin acetate (Decapeptyl SR 3mg) Ipsen Ltd	Powder and solvent for injection £69.00	(Every 4 weeks) £897.00
Triptorelin acetate (Gonapeptyl Depot 3.75mg) Ferring Pharmaceuticals Ltd	Powder and solvent for injection £81.69	(Every 4 weeks) £1061.97
Nafarelin by intranasal administration	Nasal Spray £52.43	60 dose container X 12 £629.16

Section 2: NICE resource impact statement and template

NICE resource impact report and template

The assumptions in the resource template for Surrey Heartlands patients, eligible for treatment with linzagolix do not reach the £100,000/place/year threshold.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

Recommended traffic light status and rationale:

BLUE (with specialist initiation)

- Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement.

Implementation

Actions to implement

Primary care

- Continue to prescribe treatment as recommended by the specialist team.

Secondary care

- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- Specialist teams will be required to arrange a DXA scan prior to treatment in patients with risk factors for osteoporosis.
- DXA scan is recommended after 1 year of treatment for all women and this will be arranged by the specialist team.
- Thereafter, BMD assessment is recommended annually or at a frequency determined by

the treating physician based on the woman's individual risk and previous BMD assessment

ICS

- This technology is commissioned by Surrey Heartlands ICB who are required to comply with the recommendation in the NICE TA within the time set in the publication.

PAD and Joint Formulary

- Add linzagolix as a treatment option for treating the symptoms of endometriosis

References:

1 Summary of Product Characteristics. emc. Available at: www.medicines.org.uk Accessed <07/07/2025>

2 NICE Technology Appraisal Guidance: Available at: www.nice.org.uk/guidance/ta1067 (Linzagolix for treating symptoms of endometriosis) Accessed <07/07/2025>

3 NICE Resource Impact Template: Available at: (Linzagolix for treating symptoms of endometriosis) https://www.nice.org.uk/guidance/ta1067/resources Accessed <07/07/2025>

Declaration of interest: None

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Clare Johns	Lead Pharmacy Technician (Surrey Heartlands ICB)	07/07/2025	None
Supported by				
Reviewed by	Tejinder Bahra	Lead MRU Pharmacist	07/07/2025	None