

Transvaginal laser therapy for urogenital atrophy

Interventional procedures guidance

Published: 26 May 2021

www.nice.org.uk/guidance/ipg697

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 The evidence on transvaginal laser therapy for urogenital atrophy does not show any short-term safety concerns. Evidence on long-term safety and efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research should be appropriately powered randomised controlled trials and report details of patient selection, treatment protocols, and long-term safety and efficacy including patient-reported outcomes.
- 1.3 NICE encourages further research into transvaginal laser therapy for urogenital atrophy and may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

- 2.1 Urogenital atrophy most often happens during or after the menopause. Lack of the hormone oestrogen leads to thinning of the tissues around the vaginal area and reduction in the number of mucus-producing glands. The most common symptoms affect the vulva and vagina including dryness, pain on sexual intercourse, itching and vaginal discharge. There is increased vulnerability to inflammation, trauma and infection. Urogenital atrophy can also result in urinary

symptoms, such as urgency to urinate and urinary tract infections.

Current treatments

- 2.2 [NICE's guideline on diagnosis and management of menopause](#) describes the management of menopausal symptoms. The main treatments for urogenital atrophy are vaginal oestrogen, and non-hormonal lubricants and moisturisers.

The procedure

- 2.3 Transvaginal laser therapy for urogenital atrophy is done as an outpatient procedure and can be done without anaesthetic. A laser-probe device is inserted into the vagina to apply laser energy to the vaginal wall. The laser causes controlled thermal injury, which is claimed to make the tissue remodel, improve tissue elasticity and stimulate the production of new collagen. Treatment typically consists of 3 sessions at 4 to 6 weeks apart. The aim is to reduce the symptoms of urogenital atrophy.
- 2.4 There are different types of lasers used for this procedure, including carbon dioxide (CO₂) and erbium-doped yttrium aluminium garnet (Er:YAG) lasers. The type of laser and the energy level used have different tissue penetration and can cause different types of thermal injury.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 14 sources, which was discussed by the committee. The evidence included 3 systematic reviews, 6 randomised controlled trials, 1 non-randomised comparative study and 3 case series. In addition, there are

data from a survey of 535 sites with 113,174 patients. The evidence is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in symptoms of dryness or atrophy, dyspareunia, itching or burning, measures of vaginal health and sexual functioning, and patient satisfaction.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: vaginal discharge, ulceration, scarring, de novo urge incontinence, and fistula.
- 3.4 Two commentaries from patients who have had this procedure were discussed by the committee.

Committee comments

- 3.5 There was a lack of high-quality comparative studies with sufficient numbers of patients and long-term follow up to make a definitive evaluation on the long-term safety and efficacy of this procedure. Urogenital atrophy is a common condition. These considerations underpinned the committee's request for more data collection.
- 3.6 The committee was informed that the procedure may have a role for patients who are unable to use topical oestrogen.
- 3.7 The committee was informed that patients may need repeated courses of treatment at regular intervals.

ISBN: 978-1-4731-4140-7

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).