NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Interventional procedure HTG10470 (IP1774/2) Ultrasound-guided transcervical and transvaginal radiofrequency ablation for symptomatic uterine fibroids

Final scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is ultrasound-guided transcervical and transvaginal radiofrequency ablation for symptomatic uterine fibroids. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This assessment is a review of existing NICE HealthTech guidance on transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids, but the remit has been broadened to also include transvaginal procedures. The scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

2 Summary of the procedure

Uterine fibroids are non-cancerous growths that develop in or around the womb (uterus). They can cause symptoms including heavy periods, bleeding between periods, pelvic pressure or pain, and urinary incontinence. They can be associated with fertility problems and miscarriage.

In this procedure, which can be done under sedation, local, regional or general anaesthetic, a device is inserted through the vagina (transvaginal) or cervix (transcervical). Ultrasound imaging is used to guide the device to the fibroid. One or more needle-like electrodes are advanced from the device into the fibroid being treated. The device delivers heat (radiofrequency) energy to destroy the fibroid tissue (ablation). The aim is to reduce symptoms and shrink the fibroid over time. The procedure may be repeated depending on the number and size of fibroids being treated.

3 The condition

Uterine fibroids are non-cancerous growths that develop in or around the muscle of the uterus, including on the cervix. Most people with fibroids are asymptomatic, but they can cause symptoms. These include heavy menstrual bleeding, bleeding between periods, pelvic pressure or pain, and urinary incontinence. They can be associated with fertility problems and miscarriage.

The incidence of uterine fibroids increases with age during the reproductive years, peaks in the perimenopausal years, and declines after menopause. Around 66% of women develop at least 1 uterine fibroid during their lifetime and around 33% of women will develop symptoms from uterine fibroids (NICE). Risk factors for developing uterine fibroids include age up to menopause, family history, not having given birth, obesity, high blood pressure, diabetes, and Black African ethnicity.

Fibroids are generally classified by their location using the International Federation of Gynaecology and Obstetrics (FIGO) system according to their location within or outside the uterine wall. Submucosal fibroids (FIGO types 0

to 2) grow in the muscle layer beneath the uterus's inner lining and grow into the uterine cavity. Intramural fibroids (FIGO types 3 to 4) grow within the muscular uterine wall. Subserosal fibroids (FIGO types 5 to 7) develop outside of the uterus and grow into the pelvis. FIGO type 8 fibroids occur in other sites such as the cervix or may be parasitic fibroids (fibroids that have detached from the uterus and developed an alternative blood supply).

Fibroids can coexist with other conditions such as adenomyosis, which can affect the outcome of treatment.

4 Current practice

In most cases, fibroids do not cause symptoms or interfere with pregnancy and no treatment is needed. Someone with mild symptoms may be monitored to see if the fibroids grow. Treatment might be needed when fibroids are large enough to have an effect on pregnancy or fertility, or cause symptoms.

The treatment pathway for symptomatic uterine fibroids differs depending on treatment aims and patient characteristics, including the size and location of the fibroid, and the desire for future pregnancy. Treatment is generally aligned with NICE's guideline on heavy menstrual bleeding: assessment and management.

Pharmacological treatment can include a levonorgestrel-releasing intrauterine system, drugs to control bleeding or pain (such as tranexamic acid and non-steroidal anti-inflammatories) or hormonal treatment (such as combined hormonal contraception, cyclical oral progestogens and gonadotrophin-releasing hormone analogues). If these do not control symptoms, are not suitable or fibroids are 3 cm or larger then procedures can be considered. Procedures include:

- uterine artery embolisation (injecting small particles into the uterine arteries with the aim of blocking off the blood supply to the fibroids, done as a catheter-based procedure)

- myomectomy (surgical removal of fibroids, done using a hysteroscopic, laparoscopic, robotic or open abdominal approach)
- hysterectomy (removal of the uterus, done using a laparoscopic, robotic, open abdominal or vaginal approach)
- endometrial ablation (destroys lining of uterus, usually done with a transcervical approach).

In addition to the procedure options listed in the NICE guideline, magnetic resonance image-guided transcutaneous focused ultrasound is a non-surgical uterus-preserving intervention, which is done with the person lying prone inside an MRI scanner. This procedure aims to destroy the fibroid tissue using high-intensity ultrasound pulses.

Fibroids vary widely in number, size and distribution. Some treatments are only suitable for certain types of fibroid. For example, hysteroscopic approaches may be unsuitable for transmural, multiple or deeper intramural fibroids. Myomectomy is typically offered for large symptomatic fibroids (more than 6 cm), while smaller fibroids are typically managed with hormonal therapy.

5 Unmet need

Uterine fibroids are common, affecting up to two-thirds of women during their lifetime, and they can have a substantial effect on quality of life. Fibroids are estimated to cost the NHS around £86 million a year in direct healthcare expenditure, with additional economic losses from sickness absence and reduced productivity (RCOG).

Drug treatments can be used to control symptoms or to temporarily shrink fibroids, but they can cause side-effects and may be unsuitable for people who are trying to conceive. Myomectomy is the most common procedure option used to treat fibroids when fertility is a consideration. But it may need laparoscopic, robotic or open surgery and complications include excessive bleeding, infection, injury to adjacent organs, adhesions, a need for total

hysterectomy, and fibroid recurrence. In addition, clinicians may advise a delay between myomectomy and pregnancy because of concerns about uterine rupture. Endometrial ablation is unsuitable for people who are trying to conceive or wish to preserve their fertility. Uterine artery embolisation can be done as a fertility sparing option, but it is associated with an increased risk of early or premature menopause and second trimester loss.

Hysteroscopic resection is generally suitable only for submucosal fibroids that protrude into the uterine cavity. Some people with certain types of fibroid, including deeper intramural or multiple fibroids may have limited minimally invasive treatment options. A hysterectomy is the only definitive treatment for removing fibroids, but it is an invasive procedure and can lead to early menopause even when ovaries are conserved.

Ultrasound-guided transvaginal or transcervical radiofrequency ablation is a minimally invasive uterus-preserving intervention that can be done as a day case or outpatient procedure and has a fast recovery time. It can be used to treat intramural, submucous and subserosal fibroids depending on fibroid size, location. It may be an option when medical management is not appropriate and more invasive surgery is unsuitable because of factors such as high surgical risk or previous lower abdominal surgery. It may also offer an option to people for whom general or regional anaesthetic is unsuitable. The transvaginal approach does not need cervical dilation and may be of particular benefit to someone with trauma or difficult cervical access. Normal pregnancy outcomes at term have been reported after the procedure.

6 The procedure

Ultrasound-guided transcervical and transvaginal radiofrequency ablation for symptomatic uterine fibroids offers another option to treat long-term smaller symptomatic fibroids. It can be done under sedation, regional or general anaesthetic. The transcervical procedure can also be done under local anaesthetic. Details of the procedure may vary according to the system being used.

For some technologies, the ultrasound probe is separate to the radiofrequency electrodes. Here, an ultrasound probe is inserted into the vaginal canal or an abdominal ultrasound is used to locate the fibroid and to monitor the ablation throughout the procedure. Where the ultrasound probe and radiofrequency electrode are integrated into a single device, the cervix is dilated to allow the device to be passed into the uterus through the cervix.

All systems use needle-like radiofrequency electrodes which are advanced into the fibroid. Energy is applied to ablate the fibroid tissue, or to disrupt the local blood supply to the fibroid. For technologies that use a separate ultrasound device, the electrode is advanced directly into the fibroid through the anterior or posterior vaginal fornix (in front of or behind the cervix; transvaginal approach) or passed into the uterus through the cervix (transcervical approach). It can also be done hysteroscopically. In both approaches, multiple small ablation zones can be created within 1 fibroid, using a 'moving shot' technique, or a single ablation can be done according to the size and shape of the fibroid. For the integrated device, the treatment and safe zones are calculated before the ablation starts, according to the size and depth of the fibroid. The device has inbuilt measurement of temperature and time. An introducer is advanced to the centre of the fibroid and needle electrodes are deployed into the fibroid. Radiofrequency energy is applied for 1 to 7 minutes, depending on the size of the fibroid.

Multiple fibroids of varying types and locations can be treated within 1 session. The aim is to improve symptoms and reduce the fibroid volume over time. The procedure may be unsuitable for very large fibroids or for fibroids that protrude on the outer surface of the uterus.

6.1 Innovative aspects of the procedure

The proposed innovative aspects of the procedure are that it has a short procedure time and is a relatively simple incisionless uterus-preserving technique with a quick recovery. It may allow targeted treatment of fibroids while minimising tissue disruption. The uterine muscle remains intact, and the

procedure aims to avoid damage to the endometrium. It has the potential to be done as a day case or outpatient procedure and can be repeated if necessary.

Some systems have additional features that calculate the radiofrequency treatment and safety zone, according to the size and depth of the fibroid. This could potentially allow more accurate targeting of the fibroid.

Normal pregnancy outcomes at term have been reported after the procedure.

6.2 Current known use of the procedure

According to the hospital episode statistics, there were 306 finished consultant episodes and 95 outpatient attendances for 'radiofrequency ablation of lesion of uterus' (Q16.7) in the financial year 2024 to 2025. It is unknown if this includes any procedures that used a transvaginal or transcervical approach.

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- There is a higher incidence of fibroids in Black women compared to other racial groups. They often experience earlier onset and have more severe symptoms (Caribbean and African Health Network). There is disproportionate use of hysterectomy as a treatment option and longer postoperative recovery periods for Black women.
- Some people with uterine fibroids may not identify as female, including non-binary people or trans men. Gender reassignment is a protected characteristic under the Equality Act 2010. The use of inclusive language and clinician awareness that transvaginal procedures may trigger gender dysphoria may be important for patient experience and engagement.

- Some treatments for fibroids are unsuitable for people who are pregnant and some interventions can have a negative effect on fertility and future pregnancy. Conversely, treating fibroids may enable a person to become pregnant.
- Uterine fibroids are common in people between 25 to 45 years of age and most common toward the end of the reproductive years, although they can occur at any age.
- People with uterine fibroids may be covered under disability in the Equality Act 2010 if their symptoms have a substantial adverse effect on day to day activities for longer than 12 months. Uterine fibroids are more common in people with obesity, which has a higher prevalence in more deprived socioeconomic groups.
- Access to specialist fibroid services and treatment options may vary because of differences in local service provision and referral pathways.

8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of ultrasound-guided transcervical and transvaginal radiofrequency ablation for symptomatic uterine fibroids to determine whether it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

Population	People with symptomatic uterine fibroids If the evidence allows the following subgroups may be considered: • FIGO type 2 submucosal fibroids • Multiple fibroids
Intervention	Ultrasound-guided transvaginal or transcervical radiofrequency ablation. Mechanisms for radiofrequency ablation may be considered separately depending on available evidence.
Key efficacy outcomes (may include but are not limited to)	• Reduction in menstrual bleeding

	• Rate of reintervention, including hysterectomy • Reduction of uterine fibroid symptoms • Durability of symptom improvement • Reduction in fibroid or uterine volume • Subsequent pregnancy rates • Subsequent live birth rates • Regrowth of uterine fibroids • Time to return to usual activities • Quality of life, using generic and fibroid specific tools (such as EQ-5D and UFS-QoL) • Patient satisfaction • Length of hospital stay
Key safety outcomes (may include but are not limited to)	• Tolerability of procedure • Anaesthetic related adverse events • Allergic reaction to device materials • Pain or discomfort • Bowel or bladder perforation • Unintended injury to the uterus, cervix or vaginal vault, adjacent organs or tissue • Conversion to surgery • Readmission rates • Adhesions • Fibroid regrowth • Electrical shock • Post-ablation inflammatory symptoms • Nausea or vomiting • Skin burn • Infection • Bleeding • Dysmenorrhoea • Thrombotic events • Fibroid sloughing or expulsion • Outcome of any subsequent pregnancy • Risk of treating or seeding undiagnosed malignancy

9 NICE team

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July 2026

Appendix A: Related evidence or guidance

Relevant registries or emerging key trials

None identified

Related NICE guidance, standards or indicators

NICE HealthTech guidance

- Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids (2021) NICE HealthTech guidance 572 – **current guidance**. Recommendation: special arrangements. This guidance is being updated and the expected publication date is to be confirmed (GID-HTG10470).
- Hysteroscopic mechanical tissue removal (hysteroscopic morcellation) for uterine fibroids (2021) NICE HealthTech guidance 590. Recommendation: special arrangements.
- Laparoscopic removal of uterine fibroids with power morcellation (2021) NICE HealthTech guidance 589. Recommendation:
  - For people who are postmenopausal or over 50, this procedure should not be used.
  - For people who are premenopausal or 50 or under, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- Ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic uterine fibroids (2019) NICE HealthTech guidance 523. Recommendation: special arrangements.
- Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids (2011) NICE HealthTech guidance 277. Recommendation: normal arrangements.
- Uterine artery embolisation for fibroids (2010) NICE HealthTech guidance 240. Recommendation: normal arrangements.

- Magnetic resonance (MR) image-guided percutaneous laser ablation of uterine fibroids (2003) NICE HealthTech guidance 12. Recommendation: special arrangements.

NICE clinical guidelines

Heavy menstrual bleeding: assessment and management (2018 updated 2021) NICE guideline NG88

NICE technology appraisal guidance

Linzagolix for treating moderate to severe symptoms of uterine fibroids (2024) NICE technology appraisal guidance 996

Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids (2022) NICE technology appraisal guidance 832

Other related documents

Non-NICE clinical guidelines

Chen I, Kives S, Randle E et al. (2025) Guideline No. 461: The Management of Uterine Fibroids. Journal of Obstetrics and Gynaecology Canada 47(8):102970. doi: 10.1016/j.jogc.2025.102970.