NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10082 Technologies for the rapid diagnosis of endometriosis

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are for the rapid diagnosis of endometriosis. The technologies are assessed for early use. Early-use assessment considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

Using inclusive language in healthcare is important for safety, and to promote equity respect and effective communication with everyone. People with endometriosis may include women, trans men and non-binary people with endometriosis. NICE considers that healthcare professionals use their clinical judgement when implementing recommendations, taking into account the individual's circumstances, needs and preferences, and ensuring all people are treated with dignity and respect throughout their care.

2. The condition

Endometriosis is a chronic inflammatory disease defined as the presence of endometrial-like tissue (the womb lining) outside the uterus (womb). It is typically a disease of the reproductive years and although its exact cause is unknown, it is understood to be hormone mediated and typically associated with menstruation. Those with a first degree relative with endometriosis have a 7 to 10 fold increased risk of developing the condition (Endometriosis CKS, 2025).

Symptoms can vary depending on the extent and location of the endometrial tissue, but the most common symptom is chronic pelvic pain. Other symptoms include:

- period-related pain affecting daily activities and quality of life
- deep pain during or after sexual intercourse
- period-related or cyclical gastrointestinal symptoms, in particular, painful bowel movements
- period-related or cyclical urinary symptoms, in particular, pain passing urine or blood in the urine,
- subfertility or infertility in associated with 1 or more of the above
- fatigue (NG73, 2024).

Endometriosis can have a significant physical, sexual, psychological and social impact and affect ability to work. It is estimated that 10% of women in the UK of reproductive age have endometriosis (Endometriosis UK, 2024). With the prevalence of endometriosis in women with infertility estimated to be as high as 30 to 50% (Endometriosis UK, 2024). The symptoms of endometriosis can be frequent, chronic and severe.

3. Current practice

In the NHS, the referral, diagnosis and management of endometriosis follows:

- NICE Endometriosis diagnosis and management guideline (NG73, 2017 updated 2024)

Alongside:

- NICE Endometriosis Clinical Knowledge Summary (2025)
- NICE Endometriosis Quality standard (QS172, 2018)
- European Society of Human Reproduction and Embryology (ESHRE, 2022)
- Getting it right first time Maternity and Gynaecology report (GIRFT, 2024)
- NICE Chronic pain in over 16s guideline (NG193, 2021)
- NICE Heavy menstrual bleeding assessment and management guideline (NG88, 2018 updated 2021)

Endometriosis should be suspected in women (including those aged 17 and under) presenting with one or more symptoms or signs of endometriosis (NG73, 2024).

If endometriosis is suspected, a structured clinical assessment should be undertaken including a detailed history and examination, with consideration of risk factors, alternative gynaecological diagnoses and potential complications (CKS, 2024).

An abdominal and pelvic (internal vaginal) examination should be offered to identify abdominal masses and pelvic signs of endometriosis, such as reduced organ mobility and enlargement, tender nodularity in the posterior vaginal fornix, and visible vaginal endometriotic lesions. If an internal pelvic examination is not appropriate or declined, an abdominal examination should be carried out to exclude abdominal masses (NG73, 2024).

3.1 Diagnosis

Primary care should offer all women with suspected endometriosis a referral to imaging for transvaginal ultrasound scan, regardless of clinical examination findings. If a transvaginal ultrasound is declined or not suitable, a transabdominal ultrasound scan of the pelvis should be considered (NG73, 2024). In some cases, imaging investigations specialist pelvic ultrasound (transvaginal or transabdominal) or pelvic MRI (to assess the extent of deep

endometriosis) may inform diagnosis. However, experts acknowledge that the diagnostic performance of these investigations varies. This can be influenced by disease presentation and the training and experience of the healthcare professional carrying out the test and interpreting the results.

A referral to gynaecology services for further assessment and investigation should be considered if clinical suspicion remains or symptoms persist, even when abdominal or pelvic examinations and ultrasounds are normal, including:

- if the diagnosis is unclear
- for women with severe, persistent, or recurrent symptoms
- for women with pelvic signs of endometriosis
- if the initial management is not effective, not tolerated, or contraindicated (CKS, 2025).

A referral to a specialist accredited British Society for Gynaecological Endoscopy endometriosis centre should be made if there is suspected or confirmed:

- endometrioma (a type of ovarian cyst that forms when endometriosis affects the ovaries)
- endometriosis outside the pelvic cavity
- deep endometriosis involving the bladder, bowel or ureter (NG73, 2024).

If imaging findings are normal, surgical laparoscopy should be considered to diagnose endometriosis.

3.2 Management

Management options for endometriosis include pharmacological and surgical treatments. The diagnosis and referral for people with suspected or confirmed endometriosis may be done in conjunction with initial pharmacological treatment (NG73, 2024). The choice of treatment should be discussed in relation to symptoms, preferences and priorities with respect to pain

management or fertility or both. Endometriosis can affect women throughout, and sometimes beyond, their reproductive lives so discussion of management strategies should acknowledge the changes to priorities and preferences which may occur across this. Counselling services and support networks should also be discussed and signposted to (NG73, 2024).

Pharmacological treatments: To support the management of endometriosis related pain, healthcare professionals should first consider a short trial of paracetamol and or non-steroidal anti-inflammatory drug for the first-line management of pain. Hormonal treatment should be offered (for those not trying to conceive), including the combined oral contraceptive pill or a progestogen-only pill, implant, injectable, or levonorgestrel intrauterine system. If initial hormonal treatment is ineffective, not tolerated or contraindicated or earlier if symptoms are troublesome, they should be referred to a local gynaecology service (CKS, 2025).

Surgical treatment: Most often surgical treatment, in the form or laparoscopy is combined as a diagnostic and operative surgical procedure to remove endometriosis which is located. A previous Cochrane review reported laparoscopy can reduce pain and improve fertility but also has recurrence rates of approximately 40 to 50% at 5 years post-surgery (Nisenblat et al, 2016). In some cases, such as those with adenomyosis (when endometrial tissue grows in the muscle in wall of the womb) and heavy bleeding not responding to other treatments, a surgical hysterectomy could be indicated and discussed as a management option (CKS, 2025).

4. Unmet need

An All-Party Parliamentary Group (APPG) report on endometriosis, based on a survey of over 10,000 women, highlighted the significant unmet need within the current system (APPG, 2020). Average time to diagnosis in the UK is estimated to be 8 years and 10 months (Endometriosis UK, 2024). On average, people first seek help from a GP after 3 years and 9 months of symptoms, a delay understood to stem partly from societal perceptions that

pelvic pain and abnormal vaginal bleeding are normal (Endometriosis UK, 2024).

There are known limitations within the current diagnostic pathway. A Cochrane review reported that transvaginal ultrasound has moderate sensitivity but high specificity for some forms of endometriosis, including identifying endometriomas (Nisenblat et al, 2016). However, experts highlight considerable variation in sensitivity, influenced by differences in disease presentation such as volume of disease and operator training and experience. These factors may lead to not identifying disease and may contribute to inequities in access to specialist care. MRI can serve as an alternative diagnostic tool but typically does not identify superficial disease and is recommended mainly for diagnosing and assessing the extent of deep endometriosis (NG73, 2024). Diagnostic laparoscopy offers visual confirmation and therefore the definitive diagnosis of endometriosis, but it is an invasive and costly surgical procedure.

Multiple factors contribute to delays in achieving a diagnosis, including late initial presentation, delays in referral pathways, and limitations of current diagnostic tests. In the APPG survey, over half of respondents reported visiting their GP more than 10 times before receiving a diagnosis, and over half had attended an emergency department because of their symptoms (APPG, 2020). Many described these delays as contributing to increased suffering, prolonged ill health, and disease progression that can be more challenging to treat (Endometriosis UK, 2024). Additionally, 90% reported that they would have liked access to psychological support while managing symptoms and awaiting diagnosis, but said this was not offered (APPG, 2010).

Recent government responses to the Women and Equalities Committee (Department of Health & Social Care, 2025) acknowledge inadequacies in current management and recommend improving diagnostic times and increasing awareness of non-invasive diagnostic options. Minimally invasive

rapid diagnostic tests may offer the potential for earlier, less invasive diagnosis, with associated benefits for both individuals and the NHS.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions. All the included technologies are either currently or are expected to become available to the NHS by the publication of the guidance.

5.1 DotEndo (DotLab)

DotEndo is an in vitro diagnostic test intended to be used in women aged 18 to 49 years with unexplained pelvic pain, suspected endometriosis or both. Using a blood sample the test reviews microRNA biomarker levels with a machine-learning algorithm to identify whether endometriosis is likely to be present or not. The test is intended to be used alongside standard clinical practice to support the diagnosis, referral and management. It is not intended to be used as a standalone diagnostic test.

The technology is currently not available for use in the NHS and does not yet have regulatory approval in the UK.

5.2 Endotest (ZIWIG)

Endotest is an in vitro diagnostic test intended to be used in people aged 18 to 43 years with symptoms suggestive of endometriosis. The test uses a saliva sample to analyse salivary microRNA to provide a descriptive diagnosis. The saliva sample can be collected in either primary or specialist care settings and is sent to a laboratory for molecular analysis. The result is returned to the healthcare professional. Endotest is intended to be used alongside standard practice to support diagnosis, referral and management.

The technology is not yet in use in the NHS. It is regulated as a class C device under IVDR.

5.3 Endosure (Endosure Inc 3CPM)

Endosure is a diagnostic test that analyses the gastrointestinal myoelectric signal collected by the Electrogastrogram or Electroviscerogram. The system software analyses gastric, gastrointestinal and intra-abdominal myoelectrical activity signal data to identify patterns that are suggestive of endometriosis. It can be used for people of all ages. The technology may be used in primary care setting and specialty gynaecology consultant setting or a combination of both. The technology should only be used by healthcare professionals. Endosure is intended to be used alongside standard practice to support diagnosis, referral and management.

The technology is currently in use within the NHS in a research context. It is regulated as a class IIa medical device.

6. The place of technologies in the care pathway

The technologies are proposed to be used within primary care settings. They are intended for people with recurrent symptoms of suspected endometriosis, but with normal clinical examination and either negative imaging results for endometriosis or no imaging results because imaging is unacceptable. Testing should be overseen by a healthcare professional with expertise in endometriosis diagnosis and management to ensure appropriate use and interpretation of results.

6.1 Innovative aspects

The included technologies each use different techniques to detect endometriosis. Two include the use of biomarker-based methods from saliva or blood samples and a third uses myoelectrical data to produce an electroviscerogram.

All of the technologies provide innovation in offering a less invasive and faster approach to diagnosing endometriosis. Earlier decision-making in the diagnostic pathway supported by these tests may reduce delays to diagnosis and avoid some unnecessary investigations because of uncertainty in diagnosis. This could reduce the need for invasive diagnostic laparoscopy for

some people, with potential benefits for symptom burden, patient experience and NHS capacity.

7. Comparator

The key comparator for this assessment is current NHS practice, which includes clinical examination and imaging without the technologies. The assessment will compare the diagnostic accuracy, clinical outcomes, and cost-effectiveness of the new technologies in scope against this standard practice.

8. Patient and healthcare professional issues and preferences

Minimally invasive testing has the potential to enable earlier diagnosis of endometriosis, addressing a key unmet need. This would support recognition and validation of symptoms, reducing uncertainty and stress for people managing their condition.

Tests being minimally or less invasive supports care being accessible to as many people as possible, providing a more acceptable experience to women seeking a diagnosis than alternative internal transvaginal clinical examinations and transvaginal ultrasounds.

A positive result from minimally invasive testing may enable faster referral to secondary care, allowing earlier diagnosis and treatment. However, false positive test results could lead to unnecessary treatment.

9. 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.

Endometriosis is a chronic condition of the female reproductive system. Diagnosis is often delayed and access to care is unequal, particularly for certain population groups.

- Sex and gender identity: people who do not identify as female, including trans men and non-binary people, may experience distress or exclusion when accessing care through specialist women's health services, potentially delaying diagnosis and treatment (Endometriosis UK, 2024)
- Ethnicity: NICE Clinical Knowledge Summaries identify people with white ethnicity as presenting with a higher prevalence of endometriosis (NICE, CKS, 2025). However, evidence from the Royal College of Obstetricians and Gynaecologists suggests this may reflect research and diagnostic bias rather than true biological differences. People from ethnic minority backgrounds report additional barriers, including:
    - misdiagnosis (for example, black women being more frequently diagnosed with fibroids)
    - cultural barriers to discussing menstrual health
    - pain symptoms being more likely to be dismissed or minimised.

  These factors contribute to poorer experiences and outcomes for some ethnic minority groups (RCOG, 2024).
- Age: adolescents and young people often face difficulties accessing diagnosis, as symptoms may not be taken seriously and there are limited age-appropriate referral pathways. This can result in significant delays in diagnosis at an early stage of disease (NG73, 2024).
- People with a learning disability or who are neurodivergent may have difficulties in communicating their symptoms and may find transvaginal ultrasound unacceptable, potentially delaying diagnosis and treatment
- Socioeconomic status: two of the technologies (Endosure and Endotest) for rapid diagnosis of endometriosis are currently available only in the private healthcare sector.

- Specialist centre locations: the limited number of specialist endometriosis services may mean that some people may need to travel long distances to access specialist management which may be particularly challenging for, disabled people, people living in rural areas, people experiencing homelessness, people with financial constraints, caring responsibilities, or inflexible work commitments may struggle to attend multiple appointments or specialist clinics, leading to delayed diagnosis. Local variation in service provision may also result in longer delays to diagnosis in some areas.

Personal reasons:

- some individuals may feel uncomfortable with invasive diagnostic testing including transvaginal examination or transvaginal ultrasound testing. This may be for a range of reasons and is likely to affect some groups more, including young people, survivors of abuse, people from certain faith groups or ethnic backgrounds, trans men and non-binary people.
- women who have decided not to have children are reported to feel their symptoms, concerns and management may be taken less seriously (Endometriosis UK, 2024).

No groups were identified as being disadvantaged by the introduction of these technologies.

10. Guidance type

The technologies for the rapid diagnosis of endometriosis are assessed for early use. This approach to guidance development is proposed because:

- the assessed technologies have limited or no current use in the NHS
- limited evidence is available for all technologies
- the technologies have the potential to address a high unmet need in the NHS
- the technologies have recent, ongoing or upcoming appropriate regulatory approval for use in the UK.

11. Decision problem

The key decision questions for this assessment are:

- Does offering these tests have the potential to be clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?

Table 1: Decision problem

Type of assessment	Early use assessment
Population	People who have or have had female reproductive organs (including women, trans men and non-binary people) with recurrent symptoms of suspected endometriosis with normal clinical examination and either negative imaging results for endometriosis or no imaging results because imaging is unacceptable. If the evidence allows, the following subgroups may be considered: • Young people and adolescents • Perimenopausal and postmenopausal people • People who have fertility as a priority • People with higher body mass index • People who find transvaginal ultrasound unacceptable
Interventions	• Endosure • Dot Endo • Endo test
Comparator	Current practice including clinical examination and imaging without the technologies
Setting	• Primary care

Outcomes and costs (may include but are not limited to)	**Clinical outcomes:**
	• Diagnostic accuracy
	  ○ Test sensitivity
	  ○ Test specificity
	  ○ Positive and negative predictive values
	• Time taken from initial presentation to referral to specialist services
	• Impact of false positives
	• Time taken to diagnosis
	• Time taken to starting treatment

	• Number of hospital attendances including admissions and emergency department attendances
	• Number of primary care consultations
	• Number of referrals for laparoscopy
	
	Patient-reported outcomes:
	• Overall pain
	• Symptom burden
	• Quality of life
	• Level of daily function
	• Patient experience
	• Ease of use and acceptability for patients and carers
	
	Other
	• Adverse events
	
	Costs and resource use:
	• Costs of equipment,
	• Costs of staff and associated training
	• Cost of testing, including time requesting, reviewing and communicating results
	• Cost of follow up appointments, including
	  ○ Further investigations
	  ○ Further treatment
	• Costs of appointments, investigations and treatments avoided

Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

12. Other issues for consideration

12.1 Validation of biomarkers

The European guidance published in 2022 (ESHRE, 2022) concluded that there was insufficient evidence at the time to support the diagnostic use of

biomarkers from endometrial tissue, blood, menstrual fluid or uterine fluid and therefore recommended that they should not be used in routine clinical practice. Although the evidence base in this area is evolving, experts remain cautious about the robustness of validation studies and the extent to which findings can be generalised to routine care.

12.2 Potential implementation issues

Implementation of biomarker tests would require laboratory analysis, with implications for integration within existing clinical pathways. Considerations include workforce requirements, including training for healthcare professionals involved in requesting, interpreting and acting on test results, as well as for laboratory staff and pathologists supporting delivery of the tests.

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