

# Heavy menstrual bleeding: assessment and management

NICE guideline

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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

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.

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This guideline replaces CG44.

This guideline is the basis of QS47.

## Overview

This guideline covers assessing and managing heavy menstrual bleeding (menorrhagia). It aims to help healthcare professionals investigate the cause of heavy periods that are affecting a woman's quality of life and to offer the right treatments, taking into account the woman's priorities and preferences.

### *Who is it for?*

- Healthcare professionals
- Commissioners and providers of heavy menstrual bleeding services
- Women with heavy menstrual bleeding, their families and carers

## Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [your care](#).

[Making decisions using NICE guidelines](#) explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

### 1.1 *Impact of heavy menstrual bleeding (HMB) on women*

- 1.1.1 Recognise that heavy menstrual bleeding (HMB) has a major impact on a woman's quality of life, and ensure that any intervention aims to improve this rather than focusing on blood loss. [2007]

### 1.2 *History, physical examination and laboratory tests*

#### History

- 1.2.1 Take a history from the woman that covers:
- the nature of the bleeding
  - related symptoms, such as persistent intermenstrual bleeding, pelvic pain and/or pressure symptoms, that might suggest uterine cavity abnormality, histological abnormality, adenomyosis or fibroids
  - impact on her quality of life
  - other factors that may affect treatment options (such as comorbidities or previous treatment for HMB). [2007, amended 2018]
- 1.2.2 Take into account the range and natural variability in menstrual cycles and blood loss when diagnosing HMB, and discuss this variation with the woman. If the woman feels that she does not fall within the normal ranges, discuss care options. [2007]
- 1.2.3 If the woman has a history of HMB without other related symptoms (see recommendation 1.2.1), consider pharmacological treatment without carrying

out a physical examination (unless the treatment chosen is levonorgestrel-releasing intrauterine system [LNG IUS]<sup>[1]</sup>). [2007, amended 2018]

## Physical examination

- 1.2.4 If the woman has a history of HMB with other related symptoms (see recommendation 1.2.1) offer a physical examination. [2007, amended 2018]
- 1.2.5 Carry out a physical examination before all investigations or LNG-IUS<sup>[1]</sup> fittings. [2007]

## Laboratory tests

- 1.2.6 Carry out a full blood count test for all women with HMB, in parallel with any HMB treatment offered. [2007]
- 1.2.7 Testing for coagulation disorders (for example, von Willebrand's disease) should be considered for women who:
- have had HMB since their periods started and
  - have a personal or family history suggesting a coagulation disorder. [2007]
- 1.2.8 Do not routinely carry out a serum ferritin test for women with HMB. [2007]
- 1.2.9 Do not carry out female hormone testing for women with HMB. [2007]
- 1.2.10 Do not carry out thyroid hormone testing for women with HMB unless other signs and symptoms of thyroid disease are present. [2007]

## 1.3 *Investigations for the cause of HMB*

### Before starting investigations

- 1.3.1 Consider starting pharmacological treatment for HMB without investigating the cause if the woman's history and/or examination suggests a low risk of fibroids, uterine cavity abnormality, histological abnormality or adenomyosis. [2018]
- 1.3.2 If cancer is suspected, see the NICE guideline on [suspected cancer: recognition and referral](#). [2007]

## Investigations

1.3.3 Take into account the woman's history and examination when deciding whether to offer hysteroscopy or ultrasound as the first-line investigation. [2018]

### *Women with suspected submucosal fibroids, polyps or endometrial pathology*

1.3.4 Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or
- they have risk factors for endometrial pathology (see recommendation 1.3.10). [2018]

1.3.5 Ensure that outpatient hysteroscopy services are organised and the procedure is performed according to best practice, including:

- advising women to take oral analgesia before the procedure
- vaginoscopy as the standard diagnostic technique, using miniature hysteroscopes (3.5 mm or smaller). [2018]

1.3.6 Ensure that hysteroscopy services are organised to enable progression to 'see-and-treat' hysteroscopy in a single setting if feasible. [2018]

1.3.7 Explain to women with HMB who are offered outpatient hysteroscopy what the procedure involves and discuss the possible alternatives. [2018]

1.3.8 If a woman declines outpatient hysteroscopy, offer hysteroscopy under general or regional anaesthesia. [2018]

1.3.9 For women who decline hysteroscopy, consider pelvic ultrasound, explaining the limitations of this technique for detecting uterine cavity causes of HMB. [2018]

1.3.10 Consider endometrial biopsy at the time of hysteroscopy for women who are at high risk of endometrial pathology, such as:

- women with persistent intermenstrual or persistent irregular bleeding, and women with infrequent heavy bleeding who are obese or have polycystic ovary syndrome

- women taking tamoxifen
- women for whom treatment for HMB has been unsuccessful. [2007, amended 2018]

1.3.11 Obtain an endometrial sample only in the context of diagnostic hysteroscopy. Do not offer 'blind' endometrial biopsy to women with HMB. [2018]

### ***Women with possible larger fibroids***

- 1.3.12 Offer pelvic ultrasound to women with HMB if any of the following apply:
- their uterus is palpable abdominally
  - history or examination suggests a pelvic mass
  - examination is inconclusive or difficult, for example in women who are obese. [2018]

### ***Women with suspected adenomyosis***

- 1.3.13 Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:
- significant dysmenorrhoea (period pain) or
  - a bulky, tender uterus on examination that suggests adenomyosis. [2018]
- 1.3.14 If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques. [2018]
- 1.3.15 Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on [endometriosis](#)). [2018]

### **Other diagnostic tools**

- 1.3.16 Do not use saline infusion sonography as a first-line diagnostic tool for HMB. [2007]
- 1.3.17 Do not use MRI as a first-line diagnostic tool for HMB. [2007]
- 1.3.18 Do not use dilatation and curettage alone as a diagnostic tool for HMB. [2007]



To find out why the committee made the 2018 recommendations on investigations for women with HMB and how they might affect practice, see [rationale and impact](#).

## 1.4 *Information for women about HMB and treatments*

1.4.1 Provide women with information about HMB and its management. Follow the principles in the NICE guideline on [patient experience in adult NHS services](#) in relation to communication, information and shared decision-making. [2018]

1.4.2 Provide information about all possible treatment options for HMB and discuss these with the woman (see section 1.5). Discussions should cover:

- the benefits and risks of the various options
- suitable treatments if she is trying to conceive
- whether she wants to retain her fertility and/or her uterus. [2018]

### Levonorgestrel-releasing intrauterine system (LNG-IUS)

1.4.3 Explain to women who are offered an LNG-IUS<sup>[1]</sup>:

- about anticipated changes in bleeding pattern, particularly in the first few cycles and maybe lasting longer than 6 months
- that it is advisable to wait for at least 6 cycles to see the benefits of the treatment. [2007]

### Impact of treatments on fertility

1.4.4 Explain to women about the impact on fertility that any planned surgery or uterine artery embolisation may have, and if a potential treatment (hysterectomy or ablation) involves loss of fertility then opportunities for discussion should be made available. [2007]

1.4.5 Explain to women that uterine artery embolisation or myomectomy may potentially allow them to retain their fertility. [2007]

## Endometrial ablation

- 1.4.6 Advise women to avoid subsequent pregnancy and use effective contraception, if needed, after endometrial ablation. [2007]

## Hysterectomy

- 1.4.7 Have a full discussion with all women who are considering hysterectomy about the implications of surgery before a decision is made. The discussion should include:

- sexual feelings
- impact on fertility
- bladder function
- need for further treatment
- treatment complications
- her expectations
- alternative surgery
- psychological impact. [2007]

- 1.4.8 Inform women about the increased risk of serious complications (such as intraoperative haemorrhage or damage to other abdominal organs) associated with hysterectomy when uterine fibroids are present. [2007]

- 1.4.9 Inform women about the risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy. [2007]

## 1.5 *Management of HMB*

- 1.5.1 When agreeing treatment options for HMB with women, take into account:

- the woman's preferences
- any comorbidities

- the presence or absence of fibroids (including size, number and location), polyps, endometrial pathology or adenomyosis
- other symptoms such as pressure and pain. [2018]

### Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis

1.5.2 Consider an LNG-IUS<sup>[1]</sup> as the first treatment for HMB in women with:

- no identified pathology or
- fibroids less than 3 cm in diameter, which are not causing distortion of the uterine cavity or
- suspected or diagnosed adenomyosis. [2018]

1.5.3 If a woman with HMB declines an LNG-IUS or it is not suitable, consider the following pharmacological treatments:

- non-hormonal:
  - tranexamic acid
  - NSAIDs (non-steroidal anti-inflammatory drugs)<sup>[2]</sup>
- hormonal:
  - combined hormonal contraception<sup>[3]</sup>
  - cyclical oral progestogens. [2018]

1.5.4 Be aware that progestogen-only contraception may suppress menstruation, which could be beneficial to women with HMB. [2018]

1.5.5 If treatment is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe, consider referral to specialist care for:

- investigations to diagnose the cause of HMB, if needed (see [section 1.3](#)) taking into account any investigations the woman has already had and
- alternative treatment choices, including:

- – pharmacological options not already tried (see recommendations 1.5.2 and 1.5.3)
- surgical options:
  - ◇ second-generation endometrial ablation
  - ◇ hysterectomy. [2018]

1.5.6 For women with submucosal fibroids, consider hysteroscopic removal. [2018]

### Treatments for women with fibroids of 3 cm or more in diameter

1.5.7 Consider referring women to specialist care to undertake additional investigations and discuss treatment options for fibroids of 3 cm or more in diameter. [2018]

1.5.8 If pharmacological treatment is needed while investigations and definitive treatment are being organised, offer tranexamic acid and/or NSAIDs<sup>[2]</sup>. [2007]

1.5.9 Advise women to continue using NSAIDs<sup>[2]</sup> and/or tranexamic acid for as long as they are found to be beneficial. [2007]

1.5.10 For women with fibroids of 3 cm or more in diameter, take into account the size, location and number of fibroids, and the severity of the symptoms and consider the following treatments:

- pharmacological:
  - non-hormonal:
    - ◇ tranexamic acid
    - ◇ NSAIDs<sup>[2]</sup>
  - hormonal:
    - ◇ ulipristal acetate (see recommendations 1.5.11 and 1.5.12)
    - ◇ LNG-IUS<sup>[1]</sup>
    - ◇ combined hormonal contraception<sup>[3]</sup>

- – ◇ cyclical oral progestogens
- uterine artery embolisation
- surgical:
  - myomectomy
  - hysterectomy. [2018, amended Nov 2018]

1.5.11 If ulipristal acetate<sup>[4]</sup> is the preferred treatment option, be aware of measures to reduce the risk of rare but serious liver injury:

- discuss the relative benefits and harms of ulipristal acetate with women, including recognising the signs and symptoms of liver injury, to enable an informed decision
- monitor liver function for the first 2 treatment courses, and as clinically indicated, in line with current prescribing guidance. [Nov 2018]

1.5.12 When ulipristal<sup>[4]</sup> is used for intermittent treatment in women who are not eligible for surgery, for example where the risks of surgery outweigh the benefits or where the woman declines surgical treatment:

- Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below.
- Consider ulipristal acetate 5 mg (up to 4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre. [Nov 2018]

1.5.13 Be aware that the effectiveness of pharmacological treatments for HMB (excluding ulipristal acetate) may be limited in women with fibroids that are substantially greater than 3 cm in diameter. [2018, amended Nov 2018]

1.5.14 Prior to scheduling of uterine artery embolisation or myomectomy, the woman's uterus and fibroid(s) should be assessed by ultrasound. If further information about fibroid position, size, number and vascularity is needed, MRI should be considered. [2007]

1.5.15 Consider second-generation endometrial ablation as a treatment option for

women with HMB and fibroids of 3 cm or more in diameter who meet the criteria specified in the manufacturers' instructions. [2018]

1.5.16 If treatment is unsuccessful:

- consider further investigations to reassess the cause of HMB (see [section 1.3](#)), taking into account the results of previous investigations and
- offer alternative treatment with a choice of the options described in recommendation 1.5.10. [2018]

1.5.17 Pretreatment with a gonadotrophin-releasing hormone analogue<sup>[5]</sup> or ulipristal acetate before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus. [2007, amended 2018, amended Nov 2018]

### Route and method of hysterectomy

1.5.18 When discussing the route of hysterectomy (laparoscopy, laparotomy or vaginal) with the woman, carry out an individual assessment and take her preferences into account. [2007, amended 2018]

1.5.19 Discuss the options of total hysterectomy (removal of the uterus and the cervix) and subtotal hysterectomy (removal of the uterus and retention of the cervix) with the woman. [2007, amended 2018]

### Removal of ovaries (oophorectomy) with hysterectomy

1.5.20 Only remove ovaries with hysterectomy with the express wish and informed consent of the woman, after discussion of all associated risks and benefits. [2007, amended 2018]

### Dilatation and curettage

1.5.21 Do not offer dilatation and curettage as a treatment option for HMB. [2007]

1.5.22 If dilatation is needed for non-hysteroscopic endometrial ablation:

- confirm that there is no evidence of uterine perforation or false passage

- use hysteroscopy before inserting the ablation device, to establish the condition of the uterus
- ultrasound may be used to ensure correct uterine placement of the ablation device; if the device uses a balloon, keep this inflated during the ultrasound scan. [2007, amended 2018]

To find out why the committee made the 2018 recommendations on management of HMB and how they might affect practice, see [rationale and impact](#).

<sup>[1]</sup> At the time of publication (March 2018), not all LNG-IUSs have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

<sup>[2]</sup> At the time of publication (March 2018), NSAIDs do not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

<sup>[3]</sup> At the time of publication (March 2018), not all combined hormonal contraceptives have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

<sup>[4]</sup> Ulipristal is indicated for 1 course (lasting up to 3 months) of pre-operative treatment for moderate to severe symptoms of uterine fibroids and for intermittent treatment (up to 4 courses) of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery. Use this recommendation in conjunction with the [summary of product characteristics](#).

<sup>[5]</sup> At the time of publication (March 2018), not all gonadotrophin-releasing hormone analogues have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing](#)

unlicensed medicines for further information.



## Recommendations for research

The guideline committee has made the following recommendations for research.

### *1 Hysteroscopy compared with ultrasound or empiric pharmacological treatment in the diagnosis and management of heavy menstrual bleeding (HMB)*

Is initial testing using hysteroscopy more effective than testing with pelvic ultrasound or empiric pharmacological treatment in the diagnosis and management of HMB?

#### Why this is important

There is no consensus about the best test-and-treat strategy for women with HMB, and empiric pharmacological treatment is often initiated as a first treatment without investigation. Parameters of diagnostic accuracy give useful information about a test's ability to detect a condition (or the absence of a condition). But accurate diagnosis does not automatically result in a better overall outcome for the woman, because this also depends on treatment decisions after the diagnosis is made. However, it is thought that optimal treatment depends on accurate diagnosis of the underlying pathology causing HMB.

In the absence of clinical trials, decision analytical economic models evaluating all possible outpatient testing algorithms have indicated that using ultrasound or hysteroscopy for initial diagnostic testing for women with HMB are the most effective diagnostic strategies. Pelvic ultrasound has been most commonly used because it has been more widely available and is considered less intrusive than hysteroscopy. However, advances in technology mean that the hysteroscopy is well tolerated in the outpatient setting, and it can potentially be performed outside the traditional hospital environment in a community setting. Moreover, in contrast with ultrasound, hysteroscopy allows concomitant treatment of intrauterine pathologies such as submucosal fibroids and endometrial polyps. It also facilitates the fitting of levonorgestrel-releasing intrauterine systems (LNG-IUS).

A test-and-treat randomised controlled trial with cost-effectiveness analysis could help to answer the crucial question of whether hysteroscopy improves outcomes for women and results in more effective use of NHS resources.

## *2 Effectiveness of the progestogen-only pill, injectable progestogens, or progestogen implants in alleviating HMB*

How effective are the progestogen-only pill, injectable progestogens or progestogen implants in alleviating HMB?

### **Why this is important**

Many women use LNG-IUS as the first-line pharmacological treatment for HMB, but it is not acceptable to all women. Combined oral contraceptives have also been shown to be effective for treating HMB, but their use is contraindicated in some women. Other progestogens used for contraception have far fewer contraindications than combined contraceptives, but their effectiveness as a treatment for HMB has not been studied.

A randomised controlled trial or cohort prospective observational study could compare the effectiveness of progestogens with other pharmacological treatments for HMB.

## *3 Long-term outcomes of pharmacological and uterine-sparing surgical treatments for HMB associated with adenomyosis*

What are the long-term clinical outcomes of pharmacological and uterine-sparing surgical treatments in women with HMB associated with adenomyosis?

### **Why this is important**

Adenomyosis is common, and the symptoms cause significant morbidity, including restriction of daily activities. A wide range of incidences have been suggested, but most studies report a prevalence of between 20 and 35%. Despite this, there is little evidence about the impact of adenomyosis on symptoms of HMB or the best treatment for this condition. Optimising treatment can lead to better patient satisfaction and the avoidance of unnecessary investigations and treatments. In order to do this, a better understanding of the impact of adenomyosis in causing HMB, pain and subfertility is needed.

A prospective clinical registry would allow long-term clinical outcomes such as patient satisfaction and re-intervention for refractory symptoms, to be recorded after pharmacological and uterine-sparing surgical treatments for women with adenomyosis.

## *4 Hysteroscopic removal of submucosal fibroids compared with other uterine-*

## *sparing treatments for HMB*

Is hysteroscopic removal of submucosal fibroids more effective and cost-effective than other uterine-sparing treatments for the management of HMB?

### **Why this is important**

HMB is thought to be caused by submucosal fibroids in around 15% of women. Such fibroids are amenable to minimally invasive surgical removal ('hysteroscopic myomectomy'), avoiding the need for surgical incision. Non-comparative data have reported improvement in HMB symptoms and the avoidance of further pharmacological or surgical treatment in 70 to 80% of women treated with hysteroscopic myomectomy.

Specific hysteroscopic surgical skills are necessary to optimise surgical success and minimise complications. However, recent advances in endoscopic technologies have made hysteroscopic myomectomy potentially safer and more feasible.

A randomised controlled trial comparing this technique with long-term pharmacological therapy or more invasive surgical intervention would provide information on long-term outcomes.

## *5 Second-generation endometrial ablation for HMB associated with myometrial pathology*

Are outcomes after second-generation endometrial ablation for women with HMB associated with myometrial pathology (adenomyosis and/or uterine fibroids) equivalent to those for women without myometrial pathology?

### **Why this is important**

With the wider availability of high-resolution transvaginal pelvic ultrasound, adenomyosis and fibroids have been recognised as 2 of the most common uterine pathologies in women presenting with HMB. Pharmacological treatments appear to be less effective in the presence of these conditions, making referral to specialist care for surgery more likely.

Second-generation endometrial ablation is a minimally invasive, uterine-sparing surgical procedure, but its effectiveness in women with adenomyosis or uterine fibroids is unclear. Thus women with these conditions may be denied second-generation endometrial ablation and undergo unnecessary invasive surgery such as hysterectomy. On the other hand, women may be subjected to ineffective second-generation endometrial ablation that delays more effective treatment such as

hysterectomy. It is therefore important to evaluate the effectiveness of second-generation endometrial ablation in women with these conditions, and a cohort controlled study is suggested as the best approach for doing this.

## Rationale and impact

### *Investigations for the cause of HMB*

Recommendations 1.3.1 to 1.3.14

#### Why the committee made the recommendations

##### *Before starting investigations*

The committee agreed that investigation is not necessary before starting treatment when history and examination do not suggest structural abnormalities or endometrial pathology.

##### *Investigations*

The choice of first-line investigation should depend on the woman's history and examination findings. The committee made recommendations for using hysteroscopy or ultrasound that were based on the available evidence for diagnostic accuracy.

##### *Women with suspected submucosal fibroids, polyps or endometrial pathology*

Outpatient hysteroscopy is recommended for women with HMB if uterine cavity abnormalities or endometrial pathology are suspected because:

- the evidence showed that it is more accurate (higher sensitivity and specificity) in identifying them than pelvic ultrasound
- it is safe and has a low risk of complications
- it is acceptable to women if done according to best practice guidelines
- women can have submucosal fibroids and polyps removed during the procedure, and targeted biopsy if needed
- it is cost-effective as part of a diagnosis and treatment strategy.

For women who decline outpatient hysteroscopy, the committee agreed that hysteroscopy under general or regional anaesthetic should be offered, because the benefits of accurate identification outweigh the risks of anaesthesia.

Pelvic ultrasound can be considered for women who decline hysteroscopy, provided that they

understand and accept that it is less accurate in detecting uterine cavity abnormalities and endometrial pathology.

Endometrial biopsy should only be taken in the context of hysteroscopy and only from women who have a high risk of endometrial pathology, to avoid unnecessary and painful biopsies. 'Blind' endometrial biopsy is not recommended because it may not identify treatable lesions.

### ***Women with possible larger fibroids***

Hysteroscopy is not able to detect abnormalities outside the uterine cavity, such as subserous or intramural fibroids, or adenomyosis. If an examination suggests a large fibroid or several fibroids, pelvic ultrasound (transvaginal or transabdominal) is recommended instead of hysteroscopy and is likely to be particularly cost-effective in this context.

The committee agreed that if abdominal or vaginal examination is difficult to perform or inconclusive (for example, because the woman is obese), pelvic ultrasound would be helpful to identify any abnormalities that might have otherwise been suggested by examination.

### ***Women with suspected adenomyosis***

The evidence showed that transvaginal ultrasound is more accurate than transabdominal ultrasound or MRI for detecting adenomyosis. Although transvaginal ultrasound is more intrusive than the other investigations, the committee's experience suggests that many women find it acceptable. It is also widely available in secondary care, and sometimes in primary care.

Transvaginal ultrasound may not be acceptable to or suitable for some women, such as women who have not been sexually active or women with female genital mutilation. The committee agreed that transabdominal ultrasound or MRI can be considered for these women, provided that they understand and accept that they are less accurate for detecting adenomyosis.

## **How the 2018 recommendations might affect practice**

### ***Hysteroscopy***

Hysteroscopy, in preference to pelvic ultrasound, is recommended for women with HMB who are suspected of having submucosal fibroids, polyps or endometrial pathology based on their history and examination. This change in practice will have a resource impact on service organisation and training.

Ultrasound is available through direct booking in primary care, whereas hysteroscopy is not. Changes to services will be needed to allow direct access booking into one-stop hysteroscopy services and ideally to increase delivery in community-based clinics. Specialists could offer more services in the community, or GPs and nurses could be trained to perform hysteroscopy in primary care. However, there should be ongoing savings because the number of unnecessary investigations is reduced and women are offered effective treatment as a result of more accurate diagnosis.

To ensure that outpatient hysteroscopy is acceptable to women, it is essential that the procedure is done according to best practice guidelines, including techniques and equipment to minimise discomfort and pain in women; adequately sized, equipped, and staffed facilities; staff with necessary training, skills and expertise; and the need for audit and benchmarking of outcomes.

### ***Ultrasound***

Transvaginal and transabdominal ultrasound are already widely available in secondary care and sometimes in primary care.

The committee noted that clinicians might need additional training and experience in interpreting transvaginal ultrasound scans to identify signs of adenomyosis.

For full details of the evidence and the committee's discussion see [evidence review A: diagnostic test accuracy in investigation for women presenting with heavy menstrual bleeding](#).

## ***Management of HMB***

### ***Recommendations 1.5.1 to 1.5.15***

#### **Why the committee made the recommendations**

The committee emphasised the importance of talking to the woman about her needs and preferences when deciding on treatments for HMB. This includes any plans for pregnancy and whether she wants to retain her uterus or fertility. The committee also highlighted that the cause of HMB and other symptoms should be taken into account. This is to ensure that the most appropriate management strategy is offered to the woman.

#### ***Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis***

In current practice LNG-IUS is a first-line treatment for HMB in these women. Evidence supported

this, showing that it is as effective as, or more effective than, other treatments in improving health-related quality of life and satisfaction with treatment. It also offered the best balance of benefits and costs. However, the committee agreed that more research is needed to determine the benefit to women of investigations before treatment with LNG-IUS as a management strategy (see research recommendation 1).

The available evidence did not show clinically important differences in effectiveness and acceptability among the other pharmacological treatments, so there are several options that may be considered if a woman declines LNG-IUS or it is not suitable.

For women with severe symptoms and those for whom initial treatment is unsuccessful, the committee agreed that referral to specialist care may be considered, because some women may benefit from further investigations (in particular those who started treatment without investigations) or from specialist management.

There was a lack of evidence about second-line treatment, so a choice of pharmacological and surgical options can be considered.

The committee agreed that women who decline pharmacological treatment and ask for surgery as a first treatment may be referred to specialist care for consideration of further investigations and surgical treatment. The evidence showed that reduction in blood loss and satisfaction with treatment was greater for hysterectomy and second-generation endometrial ablation techniques than for first-generation endometrial ablation.

No evidence was found about hysteroscopic removal of submucosal fibroids, but the committee agreed that it is an effective treatment that is acceptable to many women. It can be done at the same time as diagnostic hysteroscopy if facilities are available.

### ***Treatments for women with fibroids of 3 cm or more in diameter***

The committee emphasised the importance of taking into account the size, number and location of fibroids, and severity of symptoms, when treating fibroids of 3 cm or more in diameter. This is because women with fibroids that are substantially greater than 3 cm in diameter may benefit from more invasive treatment, such as uterine artery embolisation or surgery. Therefore, referral to specialist care to discuss all treatment options with the woman should be considered.

There was limited evidence that did not favour any one treatment over others for women with fibroids of 3 cm or more in diameter. However, the evidence for pharmacological treatment options



was mainly for fibroids not substantially greater than 3 cm in diameter, whereas the evidence for interventional or surgical treatments was mainly for fibroids substantially greater than 3 cm in diameter. The committee agreed that pharmacological treatment is not always the best option for fibroids that are substantially greater than 3 cm in diameter because of their physical effect on the uterine cavity. In addition, some women may prefer not to have pharmacological treatment. Therefore uterine artery embolisation and surgery are included as first-line treatment options.

Evidence on ulipristal acetate was not reviewed as part of this guideline update, but the committee agreed that it is an option for these women.

The committee agreed that second-generation endometrial ablation may be suitable for some women with fibroids that are substantially greater than 3 cm in diameter in the absence of associated pressure-related fibroid symptoms. They were unable to define criteria for eligibility, because these differ for the different techniques (in terms of the size, shape, uniformity and integrity of the uterine cavity) and are specified by the manufacturers.

There was a lack of evidence about specific second-line treatments, so the committee agreed that alternative pharmacological and surgical options should be considered if initial treatment is unsuccessful, after reviewing whether further investigation is needed.

## How the 2018 recommendations might affect practice

The committee noted that the recommendations should reinforce current best practice and help to reduce variation in clinical practice for the treatment of HMB.

In current practice, hysterectomy is a second-line treatment strategy for heavy menstrual bleeding, for which women need to have tried first-line treatment strategies, and for these to be unsuccessful, before being offered a hysterectomy. Offering hysterectomy as a first-line treatment option may result in an increase in hysterectomies. However, only a small group of women are expected to choose the procedure as first-line treatment.

For full details of the evidence and the committee's discussion see [evidence review B: management of heavy menstrual bleeding](#).

## Putting this guideline into practice

NICE has produced [tools and resources](#) to help you put this guideline into practice.

Some issues were highlighted that might need specific thought when implementing the recommendations. These were raised during the development of this guideline. They are:

- facilities and staffing for hysteroscopy services in community settings
- providing hysteroscopy in line with best practice guidelines.

Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed. Implementing change is most effective when aligned with local priorities.

Changes recommended for clinical practice that can be done quickly – like changes in prescribing practice – should be shared quickly. This is because healthcare professionals should use guidelines to guide their work – as is required by professional regulating bodies such as the General Medical and Nursing and Midwifery Councils.

Changes should be implemented as soon as possible, unless there is a good reason for not doing so (for example, if it would be better value for money if a package of recommendations were all implemented at once).

Different organisations may need different approaches to implementation, depending on their size and function. Sometimes individual practitioners may be able to respond to recommendations to improve their practice more quickly than large organisations.

Here are some pointers to help organisations put NICE guidelines into practice:

1. **Raise awareness** through routine communication channels, such as email or newsletters, regular meetings, internal staff briefings and other communications with all relevant partner organisations. Identify things staff can include in their own practice straight away.
2. **Identify a lead** with an interest in the topic to champion the guideline and motivate others to support its use and make service changes, and to find out any significant issues locally.
3. **Carry out a baseline assessment** against the recommendations to find out whether there are gaps in current service provision.

4. **Think about what data you need to measure improvement** and plan how you will collect it. You may want to work with other health and social care organisations and specialist groups to compare current practice with the recommendations. This may also help identify local issues that will slow or prevent implementation.

5. **Develop an action plan**, with the steps needed to put the guideline into practice, and make sure it is ready as soon as possible. Big, complex changes may take longer to implement, but some may be quick and easy to do. An action plan will help in both cases.

6. For **very big changes** include milestones and a business case, which will set out additional costs, savings and possible areas for disinvestment. A small project group could develop the action plan. The group might include the guideline champion, a senior organisational sponsor, staff involved in the associated services, finance and information professionals.

7. **Implement the action plan** with oversight from the lead and the project group. Big projects may also need project management support.

8. **Review and monitor** how well the guideline is being implemented through the project group. Share progress with those involved in making improvements, as well as relevant boards and local partners.

NICE provides a comprehensive programme of support and resources to maximise uptake and use of evidence and guidance. See our [into practice](#) pages for more information.

Also see Leng G, Moore V, Abraham S, editors (2014) [Achieving high quality care – practical experience from NICE](#). Chichester: Wiley.

## Context

Heavy menstrual bleeding (HMB) is defined as excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms.

HMB is one of the most common reasons for gynaecological consultations in both primary and secondary care. About 1 in 20 women aged between 30 and 49 years consult their GP each year because of heavy periods or menstrual problems, and menstrual disorders comprise 12% of all referrals to gynaecology services.

The focus of this guideline is on women of reproductive age (after puberty and before the menopause) with HMB, including women with suspected or confirmed fibroids, and women with suspected or confirmed adenomyosis. The guideline does not primarily cover women with gynaecological bleeding other than HMB (for example, intermenstrual bleeding or postcoital bleeding) or with gynaecological conditions in which HMB is not the main symptom (such as endometriosis).

Since the publication of the original guideline in 2007, equipment and software for transvaginal ultrasound have improved. Outpatient hysteroscopy has become more widely available, and is more acceptable to women with the advent of modern equipment such as miniature hysteroscopes. Therefore the relative clinical and cost effectiveness of diagnostic strategies have changed. Improvements in diagnostic imaging in recent years have resulted in an increase in the reported prevalence of adenomyosis. Adenomyosis, which is associated with abnormal uterine bleeding, pelvic pain and infertility, was not included in the previous version of the guideline.

This guideline makes recommendations on a range of pharmacological and surgical treatment options for HMB. Outpatient management comprising insertion of a levonorgestrel-releasing intrauterine system (LNG-IUS) has increased in popularity in recent years, and there has been a reduction in surgical procedures. However, some endometrial ablation techniques (such as microwave endometrial ablation) are no longer available in the UK.

The guideline aims to help healthcare professionals advise each woman with HMB about the treatments that are right for her, with a clear focus on the woman's choice. It should be borne in mind that it is the woman herself who decides whether a treatment has been successful.

## More information

You can also see this guideline in the NICE Pathway on [heavy menstrual bleeding](#).

To find out what NICE has said on topics related to this guideline, see our web pages on [endometriosis and fibroids](#) and [gynaecological conditions](#).

For full details of the evidence and the committee's discussions on the 2018 recommendations, see the [evidence reviews](#). Evidence for the 2007 recommendations is in the [full version](#) of the 2007 guideline. You can also find information about [how the guideline was developed](#), including details of the committee.

## Update information

**November 2018:** References to ulipristal acetate (Esmya) were reinstated after the European Medicines Agency completed its review on the use of Esmya for uterine fibroids, and more information on shared decision making and monitoring for side effects has been included. The accompanying visual summary has also been updated.

The recommendations are marked as:

- **[Nov 2018]** if the evidence was reviewed in November 2018
- **[2018, amended Nov 2018]** if the evidence was reviewed in 2018, but changes were made to the recommendation wording in November 2018 that changed the meaning
- **[2007, amended 2018, amended Nov 2018]** if the evidence was reviewed in 2018, but changes were made to the recommendation wording in March 2018 and November 2018 that changed the meaning.

**March 2018:** This guideline is an update of NICE guideline CG44 (published January 2007) and replaces it.

New recommendations have been added on investigations for heavy menstrual bleeding (HMB) and management.

The recommendations are marked as:

- **[2018]** if the evidence was reviewed in 2018
- **[2016]** if the evidence was reviewed in 2016
- **[2007]** if the evidence was reviewed in 2007
- **[2007, amended 2018]** if the evidence was reviewed in 2007, but changes were made to the recommendation wording in 2018 that changed the meaning.

References to ulipristal acetate (Esmya) were removed from this guideline because the European Medicines Agency was reviewing the use of Esmya for uterine fibroids and had introduced temporary safety measures.

### Amended recommendation wording (change to meaning)

Recommendation in 2007 guideline	Recommendation in current guideline	Reason for change
<p>Initially, a history should be taken from the woman. This should cover the nature of the bleeding, related symptoms that might suggest structural or histological abnormality (see recommendation 1.2.4), impact on quality of life and other factors that may determine treatment options (such as presence of comorbidity). (1.2.1)</p>	<p>Take a history from the woman that covers:</p> <ul style="list-style-type: none"> <li>• the nature of the bleeding</li> <li>• related symptoms, such as persistent intermenstrual bleeding, pelvic pain and/or pressure symptoms, that might suggest uterine cavity abnormality, histological abnormality, adenomyosis or fibroids</li> <li>• impact on her quality of life</li> <li>• other factors that may affect treatment options (such as comorbidities or previous treatment for HMB). [2007, amended 2018] (1.2.1)</li> </ul>	<p>Symptoms related to HMB have been added here instead of cross-referencing to a later recommendation for clarity. 'Persistent' was added because occasional intermenstrual bleeding is quite common but if it is persistent it might indicate an underlying problem.</p> <p>'Structural abnormality' has been replaced by 'uterine cavity abnormality' because this is a more precise term.</p> <p>Adenomyosis has been added, because diagnosis and treatment of this condition is now covered in the guideline update.</p> <p>Fibroids have been added to include fibroids outside the uterine cavity.</p> <p>Previous treatment for HMB was added because it is important to know if any treatment has failed previously.</p>

<p>If the history suggests HMB without structural or histological abnormality, pharmaceutical treatment can be started without carrying out a physical examination or other investigations at initial consultation in primary care, unless the treatment chosen is levonorgestrel-releasing intrauterine system (LNG IUS) (see recommendation 1.2.6). (1.2.3)</p>	<p>If the woman has a history of HMB without other related symptoms (see recommendation 1.2.1), consider pharmacological treatment without carrying out a physical examination (unless the treatment chosen is levonorgestrel-releasing intrauterine system [LNG IUS]). [2007, amended 2018] (1.2.3)</p>	<p>To avoid repetition and to add clarity 'structural or histological abnormality' was replaced by 'other related symptoms (see recommendation 1.2.1)'. The verb has been changed to 'consider' in line with current NICE style and the management recommendations. 'Or other investigations at initial consultation in primary care' has been taken out to avoid overlap with another recommendation (1.3.2) that covers investigation. Text has been moved to clarify the meaning.</p>
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<p>If the history suggests HMB with structural or histological abnormality, with symptoms such as intermenstrual or postcoital bleeding, pelvic pain and/or pressure symptoms, a physical examination and/or other investigations (such as ultrasound) should be performed. (1.2.4)</p>	<p>If the woman has a history of HMB with other related symptoms (see recommendation 1.2.1) offer a physical examination. [2007, amended 2018] (1.2.4)</p>	<p>List of symptoms has been taken out and added to an earlier recommendation instead (see recommendation 1.2.1). The verb has been changed to 'offer' in line with current NICE style. 'And/or other investigations (such as ultrasound) should be performed' has been taken out because this section covers physical examination and investigations are covered in section 1.3.</p>
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<p>If appropriate, a biopsy should be taken to exclude endometrial cancer or atypical hyperplasia. Indications for a biopsy include, for example, persistent intermenstrual bleeding, and in women aged 45 and over, treatment failure or ineffective treatment. (1.2.13)</p>	<p>Consider endometrial biopsy at the time of hysteroscopy for women who are at high risk of endometrial pathology, such as:</p> <ul style="list-style-type: none"> <li>• women with persistent intermenstrual or persistent irregular bleeding, or women with infrequent heavy bleeding who are obese or have polycystic ovary syndrome</li> <li>• women taking tamoxifen</li> <li>• women for whom treatment for HMB has been unsuccessful. [2007, amended 2018] (1.3.10)</li> </ul>	<p>The committee amended this recommendation to reflect current practice by:</p> <ul style="list-style-type: none"> <li>• using the verb 'consider' for consistency with current style</li> <li>• specifying endometrial biopsy for clarity</li> <li>• adding 'at the time of hysteroscopy', for consistency with the updated recommendations about diagnosis</li> <li>• changing 'hyperplasia' for 'pathology' for consistency with other recommendations</li> <li>• removing the age cut-off, because it is no longer relevant</li> <li>• amending the groups of women who are at higher risk of endometrial pathology, to ensure that women at risk are correctly identified and offered appropriate investigations.</li> </ul>
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<p>Pretreatment before hysterectomy and myomectomy with a gonadotrophin-releasing hormone analogue for 3 to 4 months should be considered where uterine fibroids are causing an enlarged or distorted uterus. (1.7.8)</p>	<p>Pretreatment with gonadotrophin-releasing hormone analogue before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus. [2007, amended 2018] (1.5.17)</p>	<p>Ulipristal acetate was added as a pretreatment, reflecting the 2016 recommendations on ulipristal acetate, but was removed before publication. See information on <a href="#">EMA review and temporary safety measures</a>.  The length of treatment was deleted, because this would depend on the agent.</p>
<p>Taking into account the need for individual assessment, the route of hysterectomy should be considered in the following order: first line vaginal; second line abdominal. (1.8.6)</p>	<p>When discussing the route of hysterectomy (laparoscopy, laparotomy or vaginal) with the woman, carry out an individual assessment and take her preferences into account. [2007, amended 2018] (1.5.18)</p>	<p>The comparison between different routes of hysterectomy was out of the scope of the protocol. The committee agreed the old recommendation is no longer valid, because the laparoscopic route is usually preferable. However, they agreed to place the emphasis on women's choice.</p>
<p>Removal of ovaries should only be undertaken with the express wish and consent of the woman. (1.9.2)</p>	<p>Only remove ovaries with hysterectomy with the express wish and informed consent of the woman, after discussion of all associated risks and benefits. [2007, amended 2018] (1.5.20)</p>	<p>The committee did not review removal of ovaries with hysterectomy, but agreed it is essential to specify that a full discussion of risks and benefits is needed.</p>

<p>Where dilatation is required for non-hysteroscopic ablative procedures, hysteroscopy should be used immediately prior to the procedure to ensure correct placement of the device. (1.2.21)</p>	<p>If dilatation is needed for non-hysteroscopic endometrial ablation:</p> <ul style="list-style-type: none"> <li>• confirm that there is no evidence of uterine perforation or false passage</li> <li>• use hysteroscopy before inserting the ablation device, to establish the condition of the uterus</li> <li>• ultrasound may be used to ensure correct uterine placement of the ablation device; if the device uses a balloon, keep this inflated during the ultrasound scan. [2007, amended 2018] (1.5.22)</li> </ul>	<p>The recommendation has been amended by the committee to reflect the latest guidance from the Medicines and Healthcare products Regulatory Agency (MHRA).</p>
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## Accreditation

