NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Policy title	**Heavy Menstrual Bleeding (menorrhagia) v1.1**
Policy position	**Surgical Interventions: Criteria Based Access Dilatation and Curettage: (D&C) Not Normally Funded**
Date of Forum recommendation	**June 2019**

This guidance relates to the care and management of Heavy Menstrual Bleeding (HMB) only. HMB with associated symptoms such as pelvic pain or intermenstrual bleeding (IMB) are outside the scope of this guideline and may need to be managed differently. For definitions of HMB, IMB, Dysfunctional Uterine Bleeding (DUB) and Endometrial Atypia Hyperplasia (EAH) please see Appendix 1.

Primary Care Management and Referral Criteria

Patients without red flags should be investigated and managed conservatively in primary care in the first instance, in accordance with the pathway 1.

Referral should usually only be made when there is either a red flag (urgent referral needed) or all acceptable conservative measures have been tried and blood loss is unacceptable or further specialist investigation or surgical treatment is required, as detailed in the pathway 1 on primary care management.

Pathway 1: Management of Heavy Menstrual Bleeding (HMB) in Primary Care

HMB - Clinical Presentation

Defined as excessive menstrual blood loss which interferes with a woman's physical, emotional, social, and/or material quality of life (QoL). Difficulties exist in defining 'normal' menstrual blood loss. Clinicians should take into account the range and natural variability in menstrual cycles and blood loss when diagnosing HMB. Interventions should focus on improving symptoms and QoL. In 40-60% of cases, no underlying cause is found. Patients may complain of passing large clots, feeling light headed, other symptoms of anaemia, quality of life impact. Measuring menstrual blood loss either directly or indirectly is not routinely recommended for HMB.

History - This should cover the nature of the bleeding, details of menstrual cycle (eg association with intermenstrual bleeding or pain), related symptoms that might suggest structural or histological abnormality, impact on quality of life and other factors that may determine treatment options (such as the presence of comorbidities). **Predisposing factors for endometrial neoplasia:** obesity; PCOS; unopposed oestrogen; age over 45; nulliparity; late menopause; Tamoxifen; family history of breast, colon, endometrial cance (these factors are particularly important if HMB of rapid onset or associated with IMB or prolonged bleeding. If endometrial neoplasia suspected patients should be referred on 2ww pathway).

Underlying causes of HMB include:

- Uterine and ovarian pathologies, such as fibroids, endometriosis, adenomyosis, polyps, endometrial hyperplasia, endometrial cancer, polycystic ovary syndrome
- Systemic diseases, such as coagulation disorders, hypothyroidism, liver or kidney disease
- Iatrogenic causes, such as anticoagulant treatment, chemotherapy, intrauterine contraceptive device
- A structural abnormality is suggested by associated symptoms, such as intermenstrual bleeding or prolonged menstrual bleeding, post-coital bleeding, pelvic pain, pressure symptoms

Consider presence of structural/histological abnormality

A physical examination and/or other investigations, e.g. ultrasound, should be performed if the history suggests the presence of structural or histological abnormality, e.g. any of the following associated symptoms: intermenstrual bleeding, postcoital bleeding, pelvic pain, pressure symptoms, lower abdominal distension

Examine the patient if structural abnormality suspected or prior to Levonorgestrel- releasing intra-uterine system fitting

If the woman has a history of HMB with other related symptoms, offer a physical examination
Examination should be carried out before all: levonorgestrel-releasing intrauterine system fitting; investigations for structural or histological abnormalities

Refer urgently to specialist care on suspected cancer pathway

RED FLAGS - suspected cancer

HMB with prolonged bleeding/IMB and obesity. Unusual at age <45 years other than in association with PCOS or hereditary cancer

Investigations

Laboratory tests:
Take a full blood count in all women with HMB
Coagulation is only indicated when women have had HMB since their periods started and have a personal/ FH suggestive of coagulation disorder
Imaging should be undertaken in the following circumstances – the uterus is palpable abdominally; vaginal examination reveals a pelvic mass of uncertain origin
Thyroid function is only indicated when other symptoms of disease exist

Possibility of structural abnormality

History suggests submucosal fibroids/ polyps/ endometrial hyperplasia/ carcinoma: persistent irregular bleeding, infrequent heavy bleeding, tamoxifen use, failure of treatment for HMB

History suggests large fibroids: abdominally palpable uterus, history or examination suggests pelvic mass or when examination is inconclusive

History suggests adenomyosis: Significant dysmenorrhoea or bulky, tender uterus on examination. If a woman declines TV ultrasound or it is not suitable for her, consider transabdominal or MRI, explaining limitations

Start pharmacological therapy when there is low risk of structural abnormality

In HMB without other related symptoms consider pharmacological treatment without carrying out a physical examination (unless the treatment chosen is levonorgestrel-releasing intrauterine system).
Non-hormonal treatment options: Tranexamic acid or NSAIDs (non-steroidal anti-inflammatory drugs)
Hormonal treatment options:· Levonorgestrel-releasing intrauterine system – provided long-term (at least 12 months) use is anticipated· Combined hormonal contraception· Cyclical oral progestogens
Take a full blood count in all women with HMB.

Management whilst awaiting investigations

If pharmaceutical treatment is required while investigations and definitive treatment are being organised, either tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) should be considered. Advise women these treatments are symptomatic and will not affect the underlying cause.

Request pelvic ultrasound

Submucosal fibroids/ polyps/ endometria hyperplasia

Fibroids > 3cm in diameter:
The following treatment options should be considered in light of the severity of symptoms and patient wishes:
Non hormonal: tranexamic acid, NSAIDs
Hormonal: combined hormonal contraception, cyclical oral progestogens
NB: Fitting LNG-IUS is not recommended in primary care in the context of large fibroids. This could be offered following hysteroscopy, if normal uterine cavity confirmed

No structural or histological abnormality is present or fibroids are <3cm in diameter or suspected or diagnosed adenomyosis

Pharmaceutical management:
1st line: LNG-IUS, 2nd line: non-hormonal/ hormonal
If bleeding is very heavy consider tranexamic acid/ norethisterone

No response to pharmaceutical treatment

Refer to gynaecology

Refer to ultrasound

Consider further investigations or referral

Monitor and review treatment response

If initial treatment is ineffective (and treatment was complied with):

- Consider a second pharmaceutical treatment rather than immediate referral to surgery.
- Consider adding on an additional drug, e.g. a non-steroidal anti-inflammatory drug which can be combined with tranexamic acid; or combined oral contraceptive

Secondary care management of patients with Fibroids >3cm:

Pharmaceutical treatments:

RESTRICTIONS to the use of Ulipristal Acetate (Esmya) for the Treatment of Fibroids

Ulipristal acetate (Esmya): **suspension of the licence due to risk of serious liver injury**.

In February 2018, the Medicines & Healthcare products Regulatory Agency (MHRA) issued a safety alert for Ulipristal Acetate (Esmya) due to reports of serious liver injury in women using the medication for uterine fibroids. Temporary safety measures, including no new patients to be prescribed Esmya, were put in place, pending the completion of an European Medicines Agency (EMA) review to investigate the link between Esmya and these cases of severe liver injury. The EMA review concluded that Esmya may have contributed to the onset of some of the cases of severe liver injury and finalised with a number of measures to minimise this risk. In August 2018, in accordance with this, the MHRA issued an update advising restricted indications, new contraindications and advice on liver function monitoring. In March 2020, following a further case of liver injury requiring transplant despite safety measures in place, the EMA has started a further review. To protect public health, marketing authorisations have been suspended in the UK for the duration of the review. The MHRA issued the following update:

Advice for healthcare professionals:

- contact patients currently being treated with Esmya as soon as possible and stop their treatment; discuss alternative treatment options for uterine fibroids as appropriate
- do not start any new patients on Esmya
- advise recent users to seek immediate medical attention if they develop signs and symptoms of liver injury (nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia or jaundice)
- perform liver function tests 2–4 weeks after stopping Esmya as recommended in the product information
- report suspected adverse drug reactions without delay to the Yellow Card Scheme
- there are no concerns with emergency contraceptive ellaOne (ulipristal acetate 30mg single dose) at this time

Advice to give to patients

- stop taking Esmya and contact your doctor for advice about other possible treatments for uterine fibroids
- attend appointments for liver function testing after stopping Esmya treatment as advised by your doctor
- seek medical advice immediately if you develop symptoms of liver injury such as abdominal pain, yellowing of the skin or eyes, dark urine, tiredness, loss of appetite, and nausea and vomiting, even if 1–2 months after stopping Esmya treatment
- there are no concerns with emergency contraceptive ellaOne (ulipristal acetate 30mg, single-dose) at this time

Surgical Treatments:
Surgical procedures for the treatment of HMB will normally be funded only when all first- and second-line medical treatments have been exhausted, or are contraindicated, as per the pathways 1 and 2. Shared decision making should be used in the decision for surgical treatment (see Appendix).

Generally for fibroids more than 3cm uterine artery embolization or myomectomy should be considered as a treatment option before hysterectomy. However, it is important for clinical judgement to be applied to this guidance on surgical treatments.

Uterine artery embolisation:
Uterine artery embolisation (UAE) is a uterine-preserving procedure for the treatment of fibroids that involves injecting small particles into the blood vessels that take blood to the uterus, via the groin. The aim is to block the blood supply to the fibroids to relieve symptoms and reduce their size. Approximately 1 in 3 women require further intervention within 5 years.

UAE for the treatment of symptomatic large (>3cm) or multiple fibroids will normally be funded only when all first- and second-line medical treatments have been exhausted, or are contraindicated, as per the pathways 1 and 2.

UAE (put in up to 4 courses) should be offered as an alternative to hysterectomy for the treatment of symptomatic, large (>3cm) or multiple fibroids. Women should be encouraged to balance their desire for uterus preservation with the higher likelihood of re-intervention.

Secondary care management of fibroids <3cm or normal uterus

Pharmacological treatments:
First line and second line medical treatments (as per Pathway 1) should have been exhausted, or contraindicated, before surgery is considered.

Surgical treatments
Surgical procedures for the treatment of HMB will normally be funded only when all first- and second-line medical treatments have been exhausted, or are contraindicated, as per the pathways 1 and 2. For fibroids less than 3cm endometrial ablation should generally be considered as a treatment option before hysterectomy. However, it is important for clinical judgement to be applied to this guidance on surgical treatments.

Endometrial ablation
Endometrial ablation is a uterine-preserving surgical procedure for the treatment of HMB, which destroys most of the lining of the uterus. Endometrial ablation should be offered as an alternative to hysterectomy for the treatment of HMB to women who:

- wish to preserve their uterus
  and
- have no desire to conceive,
  and
- have a small uterus (<10-12 gestational weeks) or small fibroids (<3cm).

No more than two ablation procedures will normally be funded. Other indications must be approved on a case-by-case basis through local Individual Funding Request (IFR) process.

Other indications must be approved on a case-by-case basis through local IFR process.

Dilatation and Curettage: D&C **should not be used** for **diagnosis or treatment** for HMB in women because it is clinically ineffective[1].

Hysterectomy

Hysterectomy is an effective treatment of menorrhagia, but the widespread use should be balanced against its potential mortality and morbidity and should usually therefore be considered to be a last resort option in the light of evidence that the patient has been offered conservative treatments in the first instance, and if appropriate, other secondary care interventions as described above.

Hysterectomy should be offered to women only when:

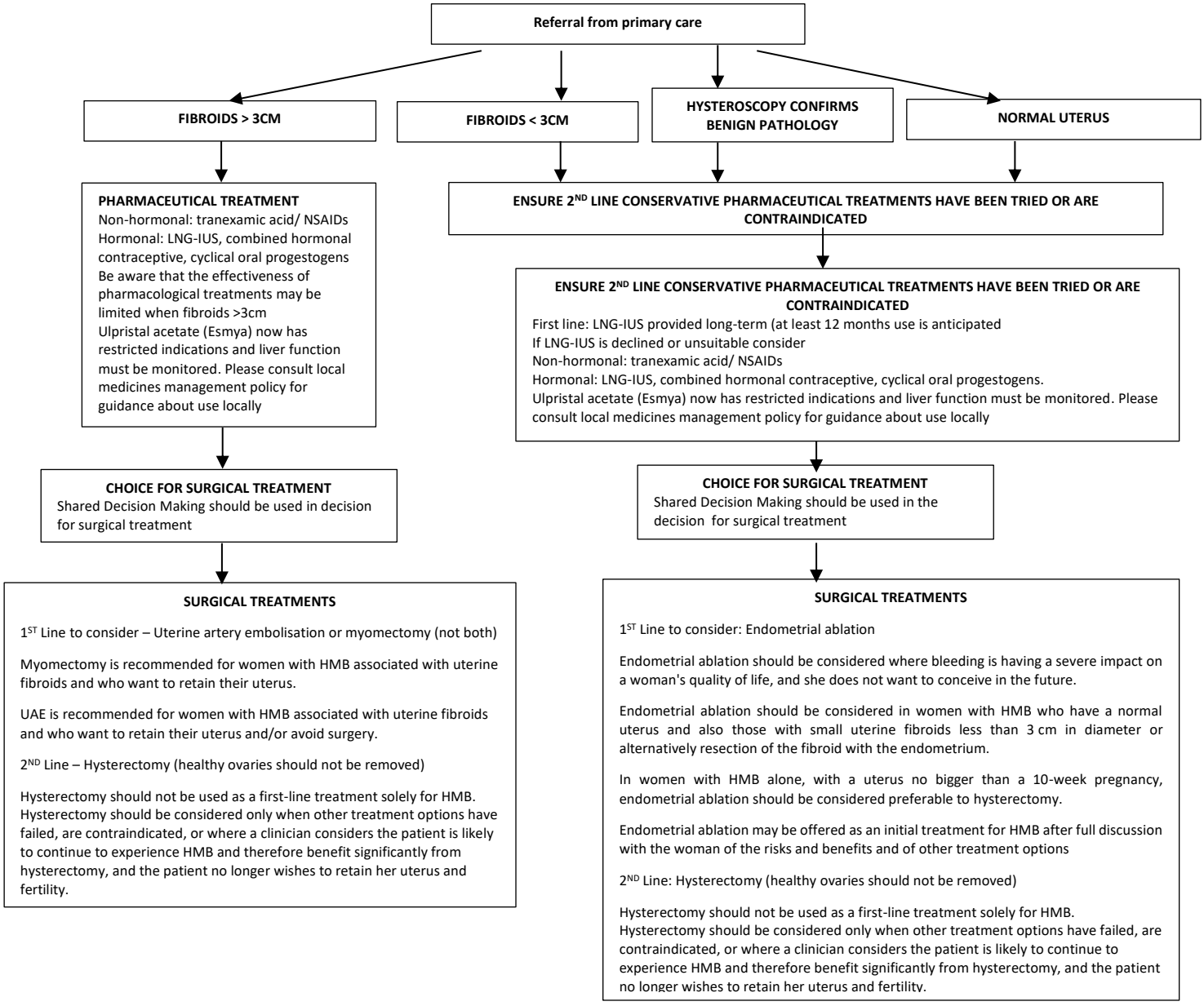
- there is a wish for amenorrhoea
  and
- the woman no longer wishes to retain her uterus
  and

the woman has no desire to conceive

For all surgical interventions the patient should have been informed of the advantages and disadvantages of surgery, and alternatives, as part of an informed consent and a shared decision making process (see Appendix 2)

[1] NHSE (2019) Evidence-Based Interventions: Guidance for Clinical Commissioning Groups (CCGs)

Pathway 2 – Management of Heavy Menstrual Bleeding in Secondary Care



***While this is the desirable pathway for the treatment of patients with HMB clinical judgement and a patient's informed decisions must be considered in making treatment decisions. HMB with associated symptoms such as pelvic pain or intermenstrual bleeding are outside the scope of this guideline and may need to be managed differently.

Appendix 1 – DEFINITIONS:

Heavy Menstrual Bleeding (HMB) / menorrhagia

NICE defines HMB as "excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms. Any interventions should aim to improve quality of life measures".

Intermenstrual Bleeding (IMB)

IMB refers to vaginal bleeding (other than postcoital) at any time during the menstrual cycle other than during normal menstruation. It can sometimes be difficult to differentiate true IMB from metrorrhagia (irregularly frequent periods)[1].

Patients who have HMB and IMB should be referred to secondary care for specialist assessment, if all other benign causes have been ruled out, and the patient has had appropriate investigations in primary care (including infection screening and pregnancy testing).

Dysfunctional Uterine Bleeding (DUB)

DUB is defined as the occurrence of irregular or excessive uterine bleeding in the absence of pregnancy, infection, trauma, new growth or hormone treatment. DUB:

- usually presents as menorrhagia without an underlying cause
- is a diagnosis of exclusion and all other appropriate investigations should be carried out
- occurs more commonly in adolescents and perimenopausal women[2]

If DUB causes a patient to have HMB the HMB pathways in Annexe A and B should be followed.

Endometrial Atypia Hyperplasia (EAH)

Endometrial hyperplasia is defined as irregular proliferation of the endometrial glands with an increase in the gland to stroma ratio when compared with proliferative endometrium.

The most common presentation of endometrial hyperplasia is abnormal uterine bleeding. This includes heavy menstrual bleeding, intermenstrual bleeding, irregular bleeding, unscheduled bleeding on hormone replacement therapy (HRT) and postmenopausal bleeding.

According to RCOG guidance women with EAH should be offered a total hysterectomy in consultation with a specialist because of the risk of underlying malignancy or progression to cancer[3].

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[1] Patient.info Professional Reference [online]. *'Intermenstrual and Postcoital Bleeding'*. Available from: http://patient.info/doctor/intermenstrual-and-postcoital-bleeding [Accessed 13.02.2017]

[2] GP Notebook [online]. *'Dysfunctional Uterine Bleeding'*. Available from: http://www.gpnotebook.co.uk/simplepage.cfm?ID=-1670709232 [Accessed 05.01.2017]

[3] Royal College of Obstetricians and Gynaecologists. *'Green-top Guideline No. 67'*. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/green-top-guidelines/gtg_67_endometrial_hyperplasia.pdf [Accessed 05.01.2017]

Appendix 2

Shared Decision Making

Deciding what to do about heavy menstrual bleeding (menorrhagia)

This short decision aid is to help you decide what to do about your heavy menstrual bleeding (menorrhagia). You can use it on your own, or with your doctor, to help you make a decision about what's right for you at this time.

There are five main options for treating heavy menstrual bleeding. The choices are:

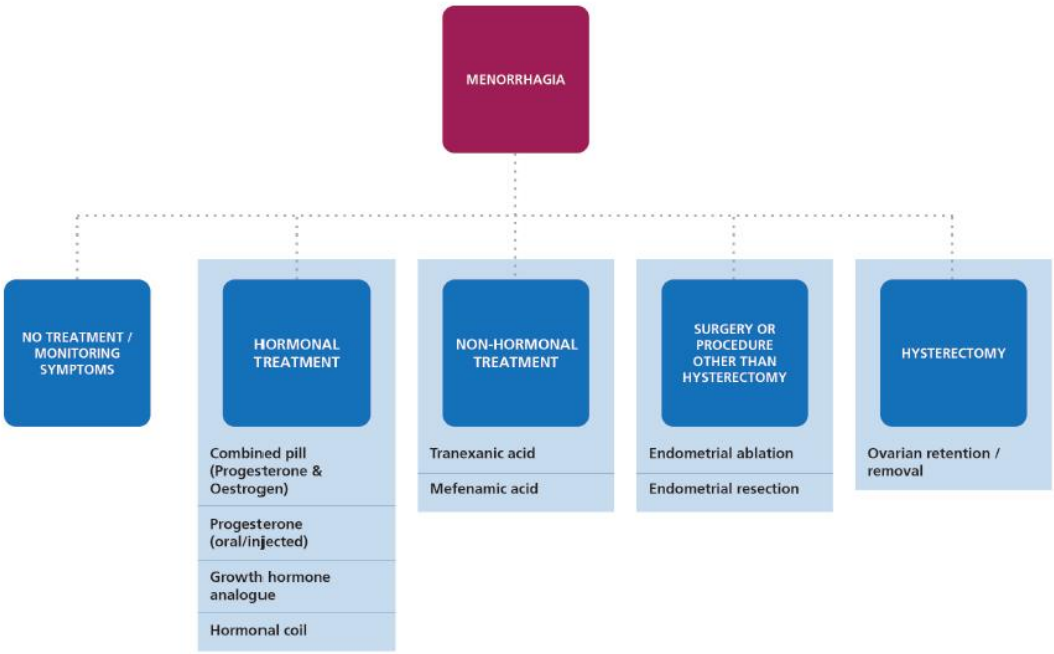
- **Monitoring**. This means checking your symptoms to see if they change. You can monitor your symptoms yourself (self-monitoring) or with your health care team. You can choose to have other treatments later if you decide you want them.

- **Hormone treatments**. These are tablets, injections, or a small device fitted inside your womb (the hormonal coil). These are treatments to reduce your bleeding.

- **Non-hormone treatments**. These are medicines that don't contain hormones that reduce your bleeding.

- **Surgery or procedure other than hysterectomy**. This is an operation to remove the lining of your womb, or reduce the blood supply to your womb. This makes the blood flow lighter.

- **Hysterectomy**. This is an operation to remove your womb. Your ovaries and fallopian tubes may be removed as well.



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What are my options?

	Monitoring	Medicines	Non-hormone treatment	Hysterectomy	Surgery or procedure other than hysterectomy
What is the treatment?	Monitoring involves having no immediate treatment. Women can have regular checks to see if their symptoms change, but they can choose not to have any treatment unless they get new symptoms or their symptoms get worse. Women can monitor symptoms themselves (self-monitoring) or with their health care team.	Hormone treatments include tablets, injections, and the hormonal coil. These reduce menstrual bleeding. The hormonal coil is a small plastic device that is fitted inside the womb where it slowly releases a hormone called progestogen. Hormone tablets (the pill) contain either the hormone progesterone, or progesterone and oestrogen combined. Progesterone can also be taken as an injection for heavy menstrual bleeding. Injections of another type of hormone treatment, gonadotropin-releasing hormone analogues, help heavy periods.	Non-hormone treatments are tablets that are taken orally to help heavy menstrual bleeding. They don't contain hormones. Non-hormone treatments won't affect a woman's chances of getting pregnant. Tranexamic acid, works by helping the blood in the womb to clot.[1] Mefenamic acid, which is a type of painkiller called a non-steroidal anti-inflammatory drug (NSAID), can help with painful periods as well as heavy menstrual bleeding. [2] A doctor might suggest taking either tranexamic acid or mefenamic acid, or taking both treatments together.	This is an operation to remove the womb. Sometimes, the cervix, the ovaries, and the fallopian tubes are removed during the same operation. Women can discuss this with their surgeon before the operation. Total hysterectomy is where the womb and the neck of the womb (the cervix) are removed. Sub-total hysterectomy is where the womb is removed but the cervix is left in place.	Surgery treatment for heavy menstrual bleeding involves having an operation to remove the womb lining (the endometrium), or to block the blood supply to the womb. An operation to remove the lining of the womb is called endometrial ablation, or endometrial resection. If heavy periods are caused by growths in the womb called fibroids, an operation called uterine artery embolisation can be chosen.[3] This operation reduces the blood supply to the womb and causes the fibroid to shrink. This should help make periods lighter.

	Monitoring	Medicines	Non-hormone treatment	Hysterectomy	Surgery or procedure other than hysterectomy
What is the effect on bleeding?	It's difficult to predict what will happen with monitoring. Women who are older and approaching the menopause are more likely to get better without treatment. In one group of women aged 40 to 44, four in 100 women said their bleeding became lighter within two years, without treatment. In a group of women aged 50 to 54, 25 in 100 women said their bleeding became lighter within two years, without treatment.[4]	Having hormone treatment can help heavy menstrual bleeding. The hormonal coil, the combined pill, and the progesterone pill can all help make periods lighter.[5] We don't know if having injections of progesterone or gonadotropin-releasing hormone analogues can make bleeding lighter.[6]	Non-hormone treatment can help heavy menstrual bleeding. Between 60 and 70 women in 100 who have non-hormone treatment for heavy menstrual bleeding have lighter periods.[7]	Having a hysterectomy can help heavy menstrual bleeding. If a woman has a hysterectomy to remove the womb, it means she won't have any menstrual periods at all.	Having surgery to remove or thin the lining of the womb can help heavy menstrual bleeding. Around 90 in every 100 women who have their womb lining removed using endometrial ablation have lighter periods or no periods afterwards.[8][9]

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	Monitoring	Medicines	Non-hormone treatment	Hysterectomy	Surgery or procedure other than hysterectomy
What is effect on whether you can get pregnant?	Monitoring isn't likely to have any effect on whether a woman can get pregnant. Contraception should be used if a woman wants to avoid pregnancy. If heavy menstrual bleeding is caused by fibroids, women can choose to have other treatments to improve their fertility.[10]	Hormone treatments might affect whether a woman can get pregnant. Hormone treatments have variable contraceptive effects. This means that they may prevent a woman from getting pregnant while they are having treatment. This effect is not permanent. If a woman stops having hormone treatment, she will be able to get pregnant in the future.	Non-hormone treatments won't have any effect on whether a woman can get pregnant. Contraception should be used if a woman wants to avoid pregnancy.	Having a hysterectomy will affect whether a woman can get pregnant. A hysterectomy is an operation to remove the womb. Some women may also have their ovaries and their fallopian tubes removed during the operation. This means that after the operation, they will not be able to get pregnant. This is effect is permanent.	Surgical treatment can affect whether a woman can get pregnant. Surgical treatment means having an operation to remove the lining of your womb. It removes the tissue that bleeds during a period and most of the tissue that makes up the surface lining of the womb. This can mean that after having treatment, some women are less likely to be able get pregnant. This effect may be permanent. If a woman becomes pregnant after endometrial ablation, there can be complications. So, if a woman does want to become pregnant in the future, this may not be a suitable treatment. Therefore contraception should be used to prevent the possibility of pregnancy.[11]

	Monitoring	Medicines	Non-hormone treatment	Hysterectomy	Surgery or procedure other than hysterectomy
What other consequences does this treatment have?	Having monitoring probably won't make much difference to daily life. Symptoms may get worse or may not improve, which can impact on daily life and what women can do. Choosing monitoring involves having occasional GP appointments to check the symptoms. Some women may need to go to hospital for tests to find out what's causing the symptoms. We don't know whether monitoring will improve quality of life. There aren't many studies that have looked at this.	We don't know if hormone treatment helps women go about their daily life in the same way as they would normally. Some women find medical treatment improves their symptoms. This may mean they are able to do more. Having hormone treatment involves going to the GP surgery or the hospital, depending on the type of hormone treatment a woman has. Having hormone treatment can improve quality of life. [12]	We don't know if non-hormone treatment helps women to go about their daily life in the same way as they would normally. Some women find non-hormone treatment improves their symptoms. This may mean they are able to do more. Non-hormone treatments need to be taken every day during a period. Some women may need to see a GP, nurse, or pharmacist to get repeat prescriptions for non-hormone treatments. Non-hormone treatment for heavy menstrual bleeding can improve quality of life. [13]	It may take up to two months to recover after having a hysterectomy. Once better, women are able to go about their daily life in the same way as they normally would. Some women find having a hysterectomy can improve your symptoms. This may help them to do more. Having an operation to remove the womb is likely to affect quality of life.[18]	The operation to remove the womb lining doesn't take long, and most women go home from hospital on the same day. Women should be able to get back to normal life within two to three weeks.[14] In one group of women who had an operation to remove the lining of their womb, they found they were able to do more daily activities after treatment.[15] Having an operation to remove the lining of the womb can improve quality of life.[16][17]

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	Monitoring	Medicines	Non-hormone treatment	Hysterectomy	Surgery or procedure other than hysterectomy
What side effects or complications does this treatment have?	Monitoring is not likely to cause side effects. If a woman chooses not to have treatment, symptoms may not improve or get worse.	Having hormone treatment can cause side effects.[19] How common the side effects are, and what kinds of side effects, depends on the type of hormone treatment a woman has. Not all side effects need treatment and some will go away on their own.	Non-hormone treatment can cause side effects.[20] The most common side effects are indigestion, diarrhoea, and headaches. These affect around one in 1,000 women. Around one in 10,000 women have bleeding or swelling in the stomach, ulcers, or breathing problems.[21]	Having a hysterectomy can cause side effects.[24] The most common side effect is an infection. This affects around one in 100 women. [25] Other side effects, like bleeding, damage to other parts of the body, blood clots, and dying during the operation, happen less often and affect fewer women.[26]	Surgical treatment can cause side effects.[22] The most common side effects are vaginal discharge, period pains or cramps, feeling sick, vomiting, or a fever. These affect around one in 100 women. Other side effects, like an infection, bleeding, or damage to the womb, happen less often and affect fewer women.[23] Not all side effects need treatment and some will go away on their own.

NOTE:

- This policy will be reviewed in the light of new evidence or new national guidance e.g. from NICE
- Where a patient does not meet the policy criteria or the intervention is not normally funded by the NHS, an application for clinical exceptionality can be considered via the ICB's Individual Funding Request (IFR) Policy and Process

Clinical Coding:

ICD 10
N920 - Excessive and frequent menstruation with regular cycle
N921 - Excessive and frequent menstruation with irregular cycle
N922 - Excessive menstruation at puberty
N924 - Excessive bleeding in the premenopausal period
Procedure code (INNF)
Q103 Dilation of cervix uteri and curettage of uterus NEC

Key words: HMB, heavy menstrual bleeding, menorrhagia, dilatation and curettage, D&C