Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Surgical Treatments for Menorrhagia (Hysteroscopy or Hysterectomy)

July 2017

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

Hysterectomy for menorrhagia is only commissioned for patients meeting **ALL of the following criteria:**

1. There has been an unsuccessful trial (6 months) with a levonorgestrel intrauterine system unless it is medically inappropriate or contraindicated
2. At least two of the following treatments have failed or are contra-indicated:
   Mefanamic acid ‖ Tranexamic acid ‖ Combined oral contraceptives ‖ Progestogen only contraceptives
3. Endometrial ablation has failed to relieve symptoms or is contra-indicated and myomectomy has been considered and offered as surgical alternative where appropriate.
4. The woman has been fully informed of the implications of this surgery (e.g. amenorrhoea and infertility) and wishes to proceed.

Hysteroscopy for the investigation of menorrhagia is commissioned where:

- Cancer or a structural abnormality is suspected (e.g. symptoms of persistent intermenstrual bleeding or post coital bleeding)
- Age 40 or over after simple (non-surgical) treatment fails
- Age 45 or over before treatment

Hysteroscopy is not normally funded for the management of menorrhagia alone, but may be appropriate for management of associated conditions which are contributing to HMB (eg. polyps/fibroids).

Further details are provided in Section 6 of this document, including arrangements for women unwilling to consider an intrauterine system

Note: The policy does not apply to other indications for hysterectomy including proven or high risk of malignancy, prolapse, chronic pain/endometriosis and large fibroids.

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Internal Review Date:	Documents will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made in light of published updates to local and national evidence of effectiveness and cost effectiveness and/or recommendations and guidelines from local, national and international clinical professional bodies. Date to Initiate Review: July 2020
Lead Executive/Director:	Chris Emerson, Director of Contracting
Name of originator/author:	Helen Bryant, Senior Commissioning Manager Fiona Bates, Medicines Management Commissioner and Public Health Liaison
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Equality & Diversity Impact Assessment	July 2017

Key individuals involved in developing the document:

Name	Designation	Version Reviewed
The original NHS England policy statement was developed in consultation with key clinicians		

Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	February 2016 onwards	V1.0
Mr A Thompson, Consultant Gynaecologist, Worcestershire Acute Hospitals NHS Trust	March 2016	V1.0
Ms J Kerr, General Manager, Worcestershire Acute Hospitals NHS Trust	March 2016	V1.0
Dr L Bramble, Worcestershire GP	March 2016	V1.0

Version Control:

Version No	Type of Change	Date	Description of change
1.0	Significant	March – June 2017	Introduction of local commissioning policy in line with NHS England policy statement, to clarify the treatment pathway for patients.

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1. Definitions

1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.2 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patients indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.3 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.4 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

1.5 ***Endometrial Hyperplasia*** is an abnormal thickening of the uterus (womb) lining.

1.6 ***Fibroids*** are non-cancerous growths that can develop inside the womb and can sometimes cause symptoms such as pain and heavy periods.

1.7 ***Hysterectomy*** is a surgical procedure (operation) to remove the womb (uterus). Pregnancy is not possible following this operation.

1.8 ***Hysteroscopy*** is a procedure that allows a doctor to look inside a patient's uterus in order to diagnose and treat causes of abnormal bleeding. Hysteroscopy is done using a hysteroscope, a thin, lighted tube that is inserted into the vagina to examine the cervix and inside of the uterus.

1.9 ***Intrauterine Adhesions*** are sections of scar tissue that can cause absent periods and infertility

1.10 ***Menorrhagia*** refers to heavy menstrual bleeding (periods).

1.11 ***Polyps*** are small growths that develop on the lining of the womb and can cause irregular and heavy periods

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 This policy applies to patients with heavy menstrual bleeding, for whom alternative management options (as outlined) have been exhausted.

2.4 The policy does not apply to other indications for hysterectomy including proven or high risk of malignancy, prolapse, chronic pain/endometriosis and large fibroids.

2.5 Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for Advice & Guidance should be considered as an alternative to a referral for clinical assessment.

2.6 There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria for surgery or is not considered clinically suitable for surgery. Such patients should be discharged without surgery.

2.7 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

3. Background

3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. This policy document outlines the arrangements for funding of this treatment for patients where local Clinical Commissioning Groups directly commissions this service.

3.4. Menorrhagia (heavy menstrual bleeding - HMB) is defined as excessive menstrual blood loss leading to interference with the physical, emotional, social and material quality-of-life of a woman, and which can occur alone or in combination with other symptoms. Although HMB has an adverse effect on the quality of life of many women it is not a problem associated with significant morbidity or mortality.

3.5. Hysterectomy is a major surgical procedure with significant physical and emotional complications as well as social and economic costs. It is one of the most commonly performed operations, with menstrual disorders being one of the leading indications. However, there are now many other treatments available in the management of HMB including drugs, intrauterine devices, procedures to remove the endometrium (the inner lining of the uterus) as well as other surgical procedures. Hysterectomy should therefore not be used as a first-line treatment solely for HMB, unless in the presence of large fibroids, malignancy, or other symptoms.

3.6. Women should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Although the CCGs respect that autonomy and individual choice are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.

4. Relevant National Guidance and Facts

4.1 The National Institute for Health and Clinical Excellence (NICE) has produced a number of guidance documents that have been used to inform this policy, listed in section 5 of this document.

4.2 Menorrhagia is a very common problem. In 2000/2001, about 45,000 hysterectomies and 17,000 therapeutic endoscopic uterine procedures were carried out in England (Hospital Episode Statistics; ungrossed for missing data; Department of Health). About half of these are likely to be for heavy menstrual bleeding.

4.3 A **hysterectomy** is used to treat conditions that affect the female reproductive system such as heavy periods (Menorrhagia), long-term pelvic pain, non-cancerous tumours, fibroids and cancer of the ovaries, the womb, the cervix or the fallopian tubes. Other treatments may be appropriate before a hysterectomy for heavy periods (Menorrhagia) is considered, e.g. Mirena, Endometrial Ablation.

There are different types of hysterectomy operation, the main types are:

- **Total hysterectomy**: the most commonly performed operation where the womb and cervix (neck of the womb) are removed.
- **Subtotal hysterectomy**: the womb is removed leaving the cervix (neck of the womb) in place.
- **Total hysterectomy with bilateral salpingo-oophorectomy**: the womb, cervix, fallopian tubes (salpingectomy) and the ovaries (oophorectomy) are removed.
- **Radical hysterectomy**: the womb and surrounding tissues are removed including the fallopian tubes, part of the vagina, ovaries, lymph glands and fatty tissues.

4.4 A **hysteroscopy** can be used to diagnose cases when a patient's symptoms suggest there could be a problem with their womb (e.g. irregular periods, bleeding between periods, bleeding after intercourse, bleeding after the menopause, pelvic pain, unusual vaginal discharge, repeated miscarriage, infertility. An endometrial biopsy can be taken for the diagnosis of endometrial pathology e.g. hyperplasia or cancer. Those patients who meet the criteria for the 2 week wait pathway should be referred for more urgent assessment.

4.5 A **hysteroscopy** can be used to remove abnormal growths from the womb, such as, fibroids, polyps, intrauterine adhesions and endometrial hyperplasia. This procedure has taken over from Dilation & Curettage (D&C) which is no longer recommended.

5. Evidence Review

5.1 This evidence review is primarily based on recommendations with the following NICE Clinical Guideline:
Heavy menstrual bleeding (CG44, January 2007) http://www.nice.org.uk/CG044

5.2 Other guidance considered include:

- Laparoscopic laser myomectomy (IPG23, November 2003) http://guidance.nice.org.uk/IPG23
- Photodynamic endometrial ablation (IPG47, March 2004) http://guidance.nice.org.uk/IPG47
- Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding (TAG78, April 2004) http://guidance.nice.org.uk/TA78
- Endometrial cryotherapy for menorrhagia (IPG157, March 2006) http://guidance.nice.org.uk/IPG157

6. Patient Eligibility

6.1 The Commissioner will fund **Hysterectomy** for heavy menstrual bleeding only when:

- There has been an unsuccessful trial (of at least 6 months) with a levonorgestrel intrauterine system (e.g. Mirena®) unless it is medically inappropriate or contraindicated[1].

Notes:

i. Patients should be fully informed of the risks and benefits of this, less invasive, management option when compared with those associated with other surgical options and should be strongly encouraged to try this method prior to those more invasive methods (see section 3.6).

ii. It is suggested that a "cooling off" period is allowed for patients less willing to consider an intrauterine system (IUS), during which time they may consider the risks and benefits of different interventions. NHS Choices provides a good overview of the different treatment options and includes a tool that allows the pros and cons of different options to be compared. http://www.nhs.uk/Conditions/Periods-heavy/Pages/Treatment.aspx#close

iii. Patients unwilling to trial a levonorgestrel IUS are required to trial a progestogen only contraceptive (in addition to 2 additional other treatments, see below)

AND

- At least two of the following treatments have failed or are contra-indicated (3 treatments including a progestogen only contraceptive for patients unwilling or contra-indicated (including where medically inappropriate) to an IUS, see above):
    - Mefanamic acid 500mg TDS
    - Tranexamic acid 1-1.5g TDS
    - Combined oral contraceptives
    - Progestogen only contraceptives

AND

- Endometrial ablation has failed to relieve symptoms or is contra-indicated and myomectomy has been considered and offered as surgical alternative where appropriate.

AND

- The woman has been fully informed of the implications of this surgery, (e.g. amenorrhoea and infertility) and wishes to proceed.

6.2 The Commissioner will only fund a **Hysteroscopy** for the investigation of menorrhagia, where:

- Cancer or a structural abnormality is suspected (e.g. symptoms of persistent intermenstrual bleeding or post coital bleeding)
- Age 40 or over after simple (non-surgical) treatment, as noted in 6.1 above, fails
- Age 45 or over before treatment

[1] Contraindications to the levonorgestrel intrauterine system are:
- Severe anaemia, unresponsive to transfusion or other treatment, whilst a levonorgestrel intrauterine system trial is in progress
- Large fibroids (uterine size >12 weeks) or distorted/small uterine cavity (with proven ultrasound measurements)
- Genital malignancy or Active trophoblastic disease
- Pelvic inflammatory disease
- Established or marked immunosuppression

6.3 **Hysteroscopy** is not normally funded for the management of menorrhagia alone, but may be appropriate for management of associated conditions which are contributing to HMB (eg. polyps/fibroids) and should be considered in advance of a hysterectomy unless clinically inappropriate (eg. large fibroids).

Note: It is recognised that hysteroscopy may be required to confirm placement of devices for ablative procedures, but it is anticipated that this will not attract additional funding to the ablative procedure itself.

7. Supporting Documents

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Constitution, updated 27th July 2015
- NHS Dudley CCG (Black Country Collaborative) Procedures of Limited Clinical Value Policy

8. Equality Impact Assessment

Organisation	NHS Redditch & Bromsgrove CCG, NHS South Worcestershire CCG, NHS Wyre Forest CCG		
Department	Contracting/Medicines Commissioning	Name of lead person	Helen Bryant and Fiona Bates
Piece of work being assessed	Surgical Treatment for Menorrhagia		
Aims of this piece of work	To provide guidance to patients and clinicians in both primary and secondary care on the medical/clinical requirements against which surgical treatment for menorrhagia will be funded on the NHS within Worcestershire		
Date of EIA	30/03/2017	Other partners/stakeholders involved	Clinical Commissioning Policy Collaborative
Who will be affected by this piece of work?	Patients, GPs and Consultants		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	Menorrhagia is an exclusively female condition. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history.	No
Race	There is some evidence that some of the underlying conditions that may give rise to menorrhagia (e.g. uterine fibroids) are more common in women of African Caribbean descent. (NICE Clinical Guideline 44). The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so an individual's race should not be a factor in the decision making process or the application of the policy.	No
Disability	There is no evidence to confirm whether having a disability increases the risk of menorrhagia. A disability may make the symptoms of menorrhagia more difficult to manage without treatment but the range of available treatments and likely effectiveness remain the same. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so having a disability should not be a factor in the decision making process or the application of the policy.	No
Religion/ belief	There is no evidence to confirm whether being part of a specific religion or belief system increases the risk of menorrhagia. However, it is recognised that treatment options that affect regular menstruation may not	No

	be favourably considered by some women as in some cultures regular menstruation is considered important. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so an individual's beliefs should not be a factor in the decision making process or the application of the policy.	
Sexual orientation	There is no evidence to confirm whether an individual's sexual orientation increases the risk of menorrhagia. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so an individual's sexual orientation should not be a factor in the decision making process or the application of the policy.	No
Age	There is some evidence that some of the underlying conditions that may give rise to menorrhagia (e.g. uterine fibroids) are more common in women who are older. (NICE Clinical Guideline 44). In addition, it was recognised that the suitability of treatment may depend on the individual's proximity to menopause (as fibroids often reduce in size following onset). The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so an individual's age should not be a factor in the decision making process or the application of the policy.	No
Social deprivation	There is no evidence to confirm whether there is a link between social deprivation and an increased risk of menorrhagia. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so their social deprivation should not be a factor in the decision making process or the application of the policy.	No
Carers	There is no evidence to confirm whether being a carer increases the risk of menorrhagia. The CCG policy endorses the provision of NHS funded surgery based on the individual's disease history, so being a carer should not be a factor in the decision making process or the application of the policy.	No
Human rights	The CCG policy does not seek to impact on an individual's human rights.	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Not Applicable					