NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin075
Fibroids (myoma, leiomyoma), uterine artery embolization (UAE)

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 Patients requiring uterine artery embolisation (UAE) in the management of heavy bleeding due to fibroids (leiomyoma) which are greater than 3 cm in diameter, should be referred to a specialist for consideration of this and other potential treatments and/or investigations.

1.2 Patients with fibroids <3 cm in diameter can normally be managed by a levonorgestrel–releasing intrauterine system (LNG–IUS), tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDs), combined hormonal contraception or cyclical oral progestogens.

2. Exclusions

2.1 None.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 This policy statement is in line NICE guidance (NG 88).

5. Summary of evidence review and references

5.1 Uterine fibroids, which are also known as leiomyomas or myomas, are usually benign and are one of the most common pelvic neoplasms in women. They may be asymptomatic or may cause symptoms such as heavy uterine bleeding, urinary incontinence, feeling of pelvic pressure or pain.[1] It has been estimated that they can be symptomatic in up to 35% of women [2] and surveys have shown that work, social life and physical activities are hindered by fibroid symptoms.[3]

5.2 Treatments include hormonal, nonhormonal, minimally invasive or full-scale surgery (e.g. hysterectomy).[2] One such minimally invasive option is uterine arterial embolisation (UAE), a technique which involves injection of small particles through a catheter into the artery supplying the fibroids in order to cause thrombosis and subsequent fibroid infarction.[1] UAE may be considered first-line therapy in women who are finished with childbearing and require a minimally invasive uterine sparing therapy.[4]

5.3 The current Cheshire CCG policy recommends UAE "in line with NICE guidance" and cites interventional procedure guidance, IPG 367, as the underpinning evidence .[1] Because this was published in 2010, a rapid literature review, over the last 10 years, was conducted to ascertain whether any significant changes have occurred since this time.

5.4 A recent review (published in 2020) suggested that UAE (introduced in the 90s) has emerged as a less invasive option for women which is effective in the short – midterm with similar improvements in symptoms-related quality-of-life versus surgery, but with reduced hospital stays and cost. However, in the longer term, re-treatment may be necessary.[2] Other studies have demonstrated the apparent superiority of UAE over high intensity focused ultrasound [5] and the technique itself has been refined such as the trans-radial approach rather than the more usual transfemoral path. [6]

5.5 From RCTs, the most common complications were discharge and fever (4%), bilateral UAE failure (4%) and post-embolisation syndrome (2.9%) which is characterised by fever, abdominal pain and leucocytosis after embolisation. Less frequent complications included DVT (0.3%), severe vasovagal event (0.3%) and haematometra (0.3%). The authors of this review concluded that UAE has a significantly lower rate of major complications relative to surgery, but this comes at the cost of increased risk of re-intervention in the future. [7] Other rare adverse effects include uterine necrosis which sometimes occurs following UAE, but this is more common in patients with comorbidities such as diabetes. [8]

5.6 Perhaps one of the greatest concerns is the potential impact of UAE on fertility. Reviews have shown that pregnancy rates following UAE are around 50% – 69% which is lower than other techniques and with higher miscarriage rates [9,10] Other authors have noted that pregnancies following UAE have been sporadically reported but the actual fertility rate remains uncertain. Conversely, low birth weight, miscarriage and prematurity have all been associated with UAE.[8] The theoretical problem is unintended embolisation of the utero-ovarian circulation which could lead to reduction in ovarian blood supply and subsequent impairment of ovarian reserve. The topic remains controversial which is underlined by another study which found no impact on ovarian reserve (as measured by anti-Mullerian hormone (AMH) levels) following UAE. [11]

5.7 IPG 367 (2010) [1] on uterine artery embolisation for fibroids recommends that UAE is efficacious in the short–medium term for a substantial proportion of patients with no major safety concerns. Therefore, the procedure may be used provided normal arrangements are in place for governance/audit. However, patients should be warned that symptom relief may not be achieved in some women and further procedures may be required. Women should also be informed of the uncertainties on fertility and patient selection should be carried out by a multidisciplinary team including a gynaecologist and an interventional radiologist.

5.8 In 2018, NICE published its guideline, NG 88, on heavy menstrual bleeding – assessment and management. [12] This reaffirms the requirement in IPG 367 that the impact of treatment (including UAE) on fertility should be explained to patients. However, the principal recommendation of NG 88, in the management of heavy menstrual bleeding, is that UAE is one of many considerations for the treatment of fibroids of 3 cm or more in diameter. More specifically, clinicians should take into account the size, location and number of fibroids, and the severity of symptoms when considering treatments which could include pharmacological, hormonal, UAE or surgical management. In this context, NICE's rationale is that the larger fibroids (>3 cm) are likely to benefit from more invasive treatment (such as UAE) whereas the smaller fibroids will respond to a levonorgestrel releasing intrauterine system (LNG–IUS) or other pharmacological management. The main recommendation, therefore, for women with large fibroids is referral to specialist care and discussion of potential treatment options.

5.9 The new policy statement has been amended to align more closely with the most up-to-date NICE guidance on this topic (NG 88). None of the neighbouring CCGs have specific policies on UAE. This is with the exception of Mersey CCG whose policy repeats verbatim all of the recommendations in NG 88.

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6. Advice and Guidance

6.1 **Aim and Objectives**

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms ‘men’ and ‘women’ are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 **Core Principles**

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the ‘NHS Choice’ framework.
  - Commissioning decisions will give ‘due regard’ to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 **Individual Funding Requests (Clinical Exceptionality Funding)**

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 **Cosmetic Surgery**

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 **Diagnostic Procedures**

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**

L71.3 Percutaneous transluminal embolisation of artery With
Y53 Approach to organ under image control OR
Y68 Other approach to organ under image control

9.2 **International classification of diseases (ICD-10)**

D25.0 Submucous leiomyoma of uterus
D25.1 Intramural leiomyoma of uterus
D25.2 Subserosal leiomyoma of uterus
D25.9 Leiomyoma of uterus, unspecified

Document Control

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