

# Clinical Commissioning Policy

# **CMICB\_Clin106** Male sterilisation - secondary care management

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

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## Last Reviewed: May 2025

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 The vast majority of men requesting a vasectomy can safely (and relatively painlessly) be managed using a local anaesthetic administered by the relevant community provider.
- 1.2 Referral to a secondary care urologist for specialist management of vasectomy (or appropriately commissioned clinical setting) is not routinely commissioned unless one of the following conditions applies:
  - 1.2.1 History of a hypersensitivity reaction or contraindication to the local anaesthetic

#### OR

1.2.2 History of fainting easily

#### OR

1.2.3 Coagulation disorder

#### OR

1.2.4 Previous refusal at procedure with local anaesthetic

#### OR

1.2.5 Difficulty in palpation of the vas deferens

#### OR

1.2.6 Unusual scrotal sensitivity

#### OR

1.2.7 Previous scrotal surgery (e.g. orchidopexy) OR cryptorchidism

#### OR

1.2.8 Scrotal injury

OR

1.2.9 Inguinal hernia.

## 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.

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- 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 <u>NHS England gender</u> <u>services programme</u> - <u>https://www.england.nhs.uk/commissioning/spec-services/npccrg/gender-dysphoria-clinical-programme/</u>

## 4. Rationale behind the policy statement

- 4.1 There is general agreement in the literature that the vast majority of men can be managed in primary care using a local anaesthetic.
- 4.2 The list of contraindications (when a general anaesthetic may be required) is consistent with guidelines from the American & Canadian Urological Associations, the Faculty of Sexual and Reproductive Healthcare and also the Royal College of Obstetricians and Gynaecologists.

## 5. Summary of evidence review and references

- 5.1 Since 2013, local authorities have had the mandatory responsibility for commissioning and delivering all community and pharmacy contraceptive services. However, CCG's are responsible for commissioning vasectomy and female sterilisation services.<sup>1</sup>
- 5.2 Male sterilisation is effected by performing a vasectomy which is a technique which involves interruption of the *vas deferens* (the tube which carries sperm from the testicle to the urethra). <sup>2</sup> A variety of techniques is available to occlude the vas deferens but excision and ligation are the most common methods. The failure rate lies between zero 2% and most frequently, it is quoted as <1%. Complications are relatively uncommon with <3% of cases requiring medical attention usually for haematoma, bleeding, infection, acute and chronic pain and congestive epididymitis.<sup>3</sup>
- 5.3 Various guidelines have recommended that vasectomy should be performed in most men under local anaesthetic only. <sup>2,4-6</sup> It has been suggested that reluctance to undergo this operation under a local anaesthetic is partially related to patient expectation that the procedure is painful. However, a detailed survey compared this expectation to the real-life experiences of vasectomy in 509 men. The authors concluded that the real-life pain experienced by men was significantly less their pre-procedure expectation. <sup>7</sup>

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- 5.4 More specifically, the American Urological Association (AUA) suggests that vasectomy should be performed with local anaesthesia with or without oral sedation. If the patient declines local anaesthesia or if the surgeon believes that local anaesthesia with or without oral sedation will not be adequate, then vasectomy may be performed with intravenous sedation or general anaesthesia.<sup>4</sup> Further, the Association recommends a preoperative physical examination to identify patients who may not be good candidates for local anaesthesia because of unusual scrotal sensitivity, patients who are too uncomfortable or too anxious to tolerate vasectomy or patients whose vasa are especially difficult to palpate.
- 5.5 The Canadian Urological Association guideline on vasectomy suggests some patients who are anxious or those with complicating factors such as a previous orchidopexy, or other scrotal surgery may require sedation or a general anaesthetic.<sup>5</sup> The UK-based Faculty of Sexual and Reproductive Healthcare also suggests that local anaesthetic is contraindicated if there is a history of allergy and/or the presence of a medical comorbidity where it is clinically inappropriate to use a local anaesthetic such as those with impaired cardiac function or cardiovascular disease.<sup>2</sup>
- 6.5 Finally, in 2004, the Royal College of Obstetricians and Gynaecologists guideline on male and female sterilisations, repeated the assertion that most men will tolerate vasectomy under local anaesthesia because this is both safer and less expensive than a general anaesthetic. However, the College expanded the contraindications to vasectomy under local anaesthesia by adding a history of fainting easily or patient refusal of local anaesthesia. Specialist referral may be necessary for cases of previous scrotal injury, large varicocoeles or large hydrocoele (in which case the vas may be difficult or impossible to locate). Specialist referrals may also be required in patients with cryptorchidism, inguinal hernia and coagulation disorders.<sup>6</sup>
- 5.6 It is worth highlighting that as part of the work in the development of the American Urological Association guideline (2012), the researchers specifically sought published evidence on the indications for using general anaesthesia for vasectomy. Clearly, no evidence was forthcoming.<sup>4</sup> Similarly, the Faculty of Sexual and Reproductive Healthcare (2014) had located a limited quantity of evidence which examined the most appropriate anaesthesia for vasectomy. No RCTs were identified. The Faculty's recommendation was vasectomy should be performed under local anaesthesia wherever possible.<sup>2</sup>
- 5.7 In conclusion, there is a general agreement in the literature that the vast majority of men can be managed in primary care using a local anaesthetic. Only in rare circumstances, will a secondary referral be required. Neither Mersey nor Shropshire CCGs have policies in this area. However, both Greater Manchester and North Staffordshire CCGs are both "not routinely commissioned" policies which are qualified by some ill-defined exceptions. These include "unless there is a clinical reason why the patient needs a general anaesthetic" and "referral to secondary care may be required in some circumstances."

#### REFERENCES

- 1. Contraceptive services for under 25s. Public health guideline. London: National Institute for health and care excellence, 2014:PH 51.
- 2. Faculty of sexual and reproductive healthcare clinical guidance: Male and female sterilisation. London: Clinical effectiveness unit, Faculty of sexual and reproductive healthcare, 2014.
- Cook LA, Van Vliet H, Lopez LM, et al. Vasectomy occlusion techniques for male sterilization. *Cochrane Database of Systematic Reviews* 2014(3) doi: 10.1002/14651858.CD003991.pub4
- 4. Vasectomy: AUA guideline. *American Urological Association* 2012
- 5. CUA guideline : vasectomy. *Canadian Urological Association Journal* 2016;**10**(7-8):5.
- 6. Male and female sterilisation: Evidence-based clinical guideline number 4. London: Royal College of obstetricians and gynaecologists, 2004.

 Sooltangos A, Al-Ausi M. Local anaesthetic vasectomy is not as painful as patients expect. BMJ Sexual and Reproductive Health 2020;46(3):234-35. doi: 10.1136/bmjsrh-2019-200462

## 6. Advice and Guidance

#### 6.1 Aim and Objectives

- 6.1.1 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.
- 6.1.2 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- 6.1.3 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.
- 6.1.4 At the time of publication, the evidence presented per procedure/treatment was the most current available.
- 6.1.5 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.
- 6.1.6 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

- 6.2.1 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)

- 6.3.1 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.
- 6.3.2 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: <u>https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-</u> <u>ifr/</u>

#### 6.4 Cosmetic Surgery

- 6.4.1 Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.
- 6.4.2 Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.
- 6.4.3 A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: <u>Cosmetic procedures - NHS</u>

#### 6.5 Diagnostic Procedures

- 6.5.1 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.
- 6.5.2 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

6.6.1 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) None.
- 9.2 International classification of diseases (ICD-10) None.

## **Document Control**

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#### **Version History**

Version 0.2 - 13 October 2021

Combines 17.4a Male sterilisation under local anaesthetic and 17.4b male sterilisation under general anaesthetic.

The intervention is "referral to a urologist" who will decide whether a general anaesthetic is indicated or perhaps a local anaesthetic under sedation. The new list of indications is evidence-based whereas the current policies are not supported by any references.

However, the new list of indications is specific yet complements the existing policies and there is no anticipated increase in demand.

Version 0.3 - 27th April 2023

On suggestion of GP Place Director changed "be managed in primary care or in the community using a local anaesthetic" to "be managed using a local anaesthetic administered by the relevant community provider." (J. Hampson, Consultant in Public Health)

Version 0.4 – July 2024 Re-formatting

Version 0.5 - May 2025 – This policy was part of a public engagement exercise, there was no feedback received.