NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Reversal of Male Sterilisation

Category 1 Intervention - Not routinely commissioned –

Ref:	CMICB_Clin040
Version:	1
Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
Supersedes:	Previous Clinical Commissioning Group (CCG) Policy
Author (inc Job Title):	
Ratified by: (Name of responsible Committee)	ICB Board
Cross reference to other Policies/Guidance	
Date Ratified:	1 April 2023
Date Published and where (Intranet or Website):	1 April 2023 (Website)
Review date:	1 April 2026
Target audience:	All Cheshire & Merseyside ICB Staff and Provider organisations

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Document control:		
Date:	**Version Number:**	**Section and Description of Change**
April 2023	1	Policy ratified by Cheshire & Merseyside ICB

1. Introduction

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

1.2 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 in Appendix 1.

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

2. Purpose

2.1 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.

3. Policy statement

3.1 Reversal of vasectomy is not routinely commissioned.

4. Exclusions

4.1 None

5. Rationale

5.1 Vasectomy is considered to be irreversible, and men will have been told this during the consent process.

5.2 It is widely accepted that vasectomy reversal is not usually available throughout the NHS.

5.3 Although reversal is technically feasible, the average success rate of achieving a pregnancy is around 50% but this is heavily influenced by many factors.

6. Underpinning evidence

6.1 Reversal of a vasectomy involves (one way or another) removal or bypassing the vas *deferens* occlusion thus allowing transport of sperm from the testicle into the urethra. There are 2 main techniques: - *vasovasostomy* which involves re-joining the severed ends of the vas deferens and *vasoepididymostomy* (epididymovasostomy) which is an anastomosis of a single epididymal tubule to the lumen of the vas deferens. [1]

6.2 Success rates following reversal have variously been reported as up to 82%.[2] Many factors are thought to contribute to the success or otherwise of achieving a pregnancy and these have been cited as: -

- time since vasectomy,
- type of vasectomy being reversed,
- type of reversal (see above),

- surgical technique (e.g., microsurgical or macro surgical),
- surgeon skill and experience,
- presence of other pathology e.g., varicocoele and
- presence of sperm antibodies.

6.3 In addition to vasectomy reversal, some couples may seek sperm retrieval combined with in vitro fertilisation (IVF) and/or intracytoplasmic sperm injection (ICSI) or use of cryopreserved sperm. Overall, as a rule of thumb, pregnancy with live birth occurs in approximately 50% of couples who attempt these techniques. This pregnancy rate is less than the pregnancy rate in couples in whom the male partner hasn't had a vasectomy.[3]

6.4 In its guideline (2004) [2], although the Royal College of Obstetricians and Gynaecologists (RCOG) recommend that men requesting vasectomy should understand that the procedure is intended to be permanent, they should, however, be given information on the success rates associated with reversal. RCOG also recommends that men should be informed that reversal operations or intracytoplasmic sperm injection is rarely provided by the NHS. In its more recent guidance (2014), the Faculty of Sexual and Reproductive Healthcare (FSRH) stresses the importance of noting that the NHS doesn't currently offer vasectomy reversal routinely.[1]

6.5 On NICE's Clinical Knowledge Summaries (CKS) website on male sterilisation, practitioners are recommended to provide information on reversal and its success rates. Patients should also be advised that the NHS doesn't routinely offer reversal operations. In addition, on the NHS's patient- facing website on vasectomy, patients should be told that reversal is considered to be permanent as it is very difficult to reverse. Also, vasectomy reversal isn't usually available on the NHS.

6.6 It is concluded that the general consensus within the NHS is that the vasectomy procedure is considered irreversible. Whilst technically, the procedure can be reversed, the effectiveness depends on many factors but principally it is most effective as soon as possible after the original procedure. It is not unreasonable to infer that all men will have been told during the consent process for their vasectomy that the procedure is a permanent one and funding for a reversal is unlikely to be permitted under the NHS.

6.7 Finally, it is worth pointing out that vasectomy reversal is not routinely commissioned by all of the neighbouring CCGs.

REFERENCES

1. Faculty of sexual and reproductive healthcare clinical guidance: Male and female sterilisation. London: Clinical effectiveness unit, Faculty of sexual and reproductive healthcare, 2014.
2. Male and female sterilisation: Evidence-based clinical guideline number 4. London: Royal College of obstetricians and gynaecologists, 2004.
3. Vasectomy: AUA guideline. *American Urological Association* 2012

7. Force

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.

8. Coding

8.1 Office of Population Censuses and Surveys (OPCS)
N18.1 Reversal of bilateral vasectomy in primary position

8.2 International classification of diseases (ICD-10)
None

9. Monitoring and Review

9.1 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

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

10. Quality and Equality Analysis

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

Appendix 1 - Core Objectives and Principles

Objectives

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.

Principles

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.

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.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

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 wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

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

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.

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.

Clinical Exceptionality

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.