Commissioning Policy

NHS
Redditch and Bromsgrove
Clinical Commissioning Group

NHS
South Worcestershire
Clinical Commissioning Group

NHS
Wyre Forest
Clinical Commissioning Group

Reversal of Sterilisation (Men and Women)

January 2018

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

Following a review of the evidence and consideration of local circumstances, Worcestershire Clinical Commissioning Groups **do not support** the funding of surgery to reverse the effect of sterilisation or treatment to bypass the sterilisation for any patients, irrespective of gender.

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Lead Executive/Director:	Ms Christina Emerson - PMO Specialist Adviser
Name of originator/author:	Ms Christina Emerson – PMO Specialist Adviser, Mrs Fiona Bates – Medicines Management and Public Health Liaison Helen Bryant – Senior Contracts Mamager
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Key individuals involved in developing the document:

Name	Designation	Version Reviewed
Dr Sehar Umer	Public health GPTrainee	V1.2
Mrs Fiona Bates	Medicines Commissioning Team/Public Health Support	V1.2
Mrs Helen Bryant	Commissioning and IFR manager	V1.2

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	May 2014 January 2018	Version 1.2 Version 2.0

Version Control:

Version No	Type of Change	Date	Description of change
1.0	Policy update	May 14	Updated evidence review performed such that background, facts and policy altered
2.0	Policy Review	Jan 18	Review of evidence to ensure the policy reflects current practices Incorporation of management pathway

Table of Contents

1. Definitions

1.1 **Female Sterilisation** involves an invasive operation to cut, seal or block the fallopian tubes with the intention of becoming infertile. The surgery prevents the eggs from reaching the uterus (womb) where they could become fertilised, resulting in pregnancy.

1.2 **Male Sterilisation (Vasectomy)** is a minor operation that involves the cutting, blocking or sealing of the tubes that carry sperm from a man's testicles to the penis area with the intention of becoming infertile. This prevents sperm from reaching the seminal fluid (semen), which is ejaculated from the penis during sex. There will be no sperm in the semen, so a woman's egg cannot be fertilised.

1.3 **Infertility** is when a couple can't get pregnant (conceive) despite having regular unprotected sex.

1.4 **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.

1.5 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.

1.6 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.

1.7 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.

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 men and women who have been sterilised previously and who are considering a reversal of the sterilisation procedure in order to make them fertile again.

2.4 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.

2.5 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.

2.6 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. A key consideration for reversal of sterilisation is the process by which sterilisation occurs and influencing factors. Both female and male sterilisation are considered a permanent form of contraception.

3.4. The Royal College of Obstetricians and Gynaecologists issued the following guidance regarding consent to sterilisation in 2004 and it is expected that all services offering sterilisation procedures follow this guidance:

- All verbal counselling advice must be supported by accurate, impartial printed or recorded information (in translation, where appropriate and possible), which the person requesting sterilisation may take away and read before the operation.
- Men and women requesting sterilisation should be given information about other long-term reversible methods of contraception.
- Although people requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success

rates associated with reversal, should this procedure be necessary. They should be informed that reversal operations, *in vitro*fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) are rarely provided by the NHS.

3.5. **Failure rates:** People requesting sterilisation should be informed that tubal occlusion and vasectomy are associated with failure rates and that pregnancy can occur several years after the procedure. They should be told of the lifetime risk of failure in general for tubal occlusion, which is estimated at one in 200. They should also be made aware that the longest period of follow-up data available for the most common method used in the UK, Filshie clips, suggests a failure rate after ten years of two to three per 1000 procedures. The failure rate for vasectomy should be quoted as approximately one in 2000 after clearance has been given.

3.6. **Epidemiology:** The popularity of tubal occlusion appears to be on the decline in the UK, possibly because of the availability of equally effective alternatives. Vasectomy rates have remained unchanged and the UK has been one of the few countries where the incidence of sterilisation in men exceeds that in women. National statistics for 2008-2009 showed 16% of men between the ages of 16-69 had had a vasectomy. Worldwide, sterilisation is the most frequent form of contraception with over 190 million couples relying on female tubal occlusion and 33 million couples on vasectomies for contraception

4. Relevant National Guidance and Facts

4.1 The Royal College of Obstetricians and Gynaecologists issued the following recommendations in relation to reversal of sterilisation:

Recommendation 31 and 46: Although patients requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary.

Recommendation 32 and 47: Patient should be informed that reversal operations are rarely provided by the National Health Service

4.2 **Success Rates Following Reversal**

Tubal Occlusion: Literature reviews have established that the overall intrauterine pregnancy rates following reversal of sterilisation range between 31% and 92%. In selected patient groups, particularly those who were sterilised with clips or rings, successful reversal may be at the top end of this range. Most studies have shown that success rates are improved by using microsurgical techniques. Case series of laparoscopic reversal of sterilisation report pregnancy rates of 31–73% with an associated ectopic pregnancy rate of 0–7%. A successful outcome after surgical sterilisation reversal is influenced mainly by age of the woman and the preoperative length of the fallopian tubes.

Results from IVF studies do not report separately on women with previous tubal sterilisation. However, the cumulative live birth rate in women who had undergone IVF for tubal disease was reported to be 55.8%.

Vasectomy: There are at present no standardised or uniform criteria in reporting the results of vasectomy reversal. A wide range of success rates have been reported, from 52% to over 82%. This wide range of success rates may to some extent reflect variations in:

a. Time since vasectomy

b. Type of vasectomy being reversed (e.g. open-ended, sealed with suture, sealed with heat)
c. Type of reversal (vasovasostomy or vasoepididymostomy, unilateral or bilateral)
d. Technique used (macro surgical or microsurgical, one-layer or two-layer anastomosis)
e. Surgeon skill and experience
f. Presence or absence of other pathology (e.g. varicocele)
g. Presence or absence of sperm antibodies.

The longer the time from vasectomy to a reversal operation, the lower the pregnancy rates. Up to ten years, the rates vary between 32% and 80%; over ten years the rates vary between 9% and 35%.

5. Patient Eligibility

5.1 Whilst reversal of sterilisation can be an effective procedure, sterilisation is undertaken with permanent intent. The Commissioner will neither fund surgery to reverse the effect of sterilisation or treatment to bypass the sterilisation for males or females; consequently referrals for consideration of sterilisation will not be supported.

5.2 Requests for funding based on exceptional circumstances are expected to be rare. Being divorced or separated and in a new relationship does not constitute an exceptions case. An example of exceptionality would be that of a couple/individual who have lost a child under the age of 16 through illness or accident and have no other children either in the current or from any previous relationship

6. 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
- The Royal College of Obstetricians and Gynecologists "Evidence Based Clinical guidance : Male and Female Sterilisation in 2004"
- " Sterilisation: Female sterilisation and Vasectomy" Patient.co.uk

7. Equality Impact Assessment

Organisation	NHS Redditch & Bromsgrove CCG, NHS South Worcestershire CCG, NHS Wyre Forest CCG		
Department	Public Health	Name of lead person	Dr Sehar Umar Supported by Jennifer Weigham, Equality Lead, NHS Arden CSU
Piece of work being assessed	Reversal of Sterilisation (Men and Women)		
Aims of this piece of work	To provide guidance on the commissioning stance for the NHS funding of reversal of sterilisation surgery for Worcestershire patients		
Date of EIA	26/06/2014 Reviewed Jan 2018	Other partners/stakeholders involved	Clinical Commissioning Policy Collaborative
Who will be affected by this piece of work?	Patients, GPs and specialist clinicians		

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	The policy covers all patients, irrespective of gender. It is noted that evidence suggests that the success rates of reversal is higher in males, than females.	Yes
Race	From the research paper reference below the following information was presented "In an analysis using the 2002 National Survey of Family Growth (NSFG), black women were more likely to be sterilized compared with white women after controlling for important socioeconomic confounders such as age, insurance status, marital status, education, parity, religion, and income (2). Women with no or public insurance were also more likely to have undergone sterilization compared with women with private insurance. While tubal sterilization is a highly effective method of contraception, it has the potential downside of being permanent. Although few women seek reversal for	Yes

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
	the procedure, the prevalence of post sterilisation regret ranges from 0.9% to 26% and varies by the length of time since the procedure (3,4). Studies examining risk factors for post sterilisation regret show that young age at the time of the sterilizing procedure is the strongest predictor for expressing regret (4-9). Non-white race has also been found to be associated with post sterilisation regret, but these analyses did not assess the independent effect of race/ethnicity after adjusting for important socioeconomic characteristics (4-8). To determine whether an increased rate of sterilization among black women and women with public or no insurance is associated with increased post sterilisation regret, we used the 2002 NSFG database to examine the independent effects of race/ethnicity and insurance status on desire for sterilization reversal". https://www.researchgate.net/publication/5962041_Race_insurance_status_and_desire_for_tubal_sterilization_reversal Success rates are not considered to be affected by an individual's ethnicity or heritage.	
Disability	There is no evidence to suggest that those individuals with any form of disability will be more affected by this policy. Individuals with a disability are not considered more or less likely to require a reversal. However, there is the issue of the small amount of people for specialised reasons that are sterilised due to their learning disability or incapacity or the danger of harm to themselves of having a child.	No
Religion/ belief	An individual's religion or belief is not considered to directly impact on their requirement for reversal of sterilisation; however it is acknowledged that any form of contraception is not always approved of by certain religions	No
Sexual orientation	An individual's sexual orientation is not believed to impact on their requirement to reversal of sterilisation. However, the CCG acknowledges that there could be instances where an individual has been sterilised due to personal reasons related to their sexual orientation and circumstances can change throughout an individual's life.	No
Age	The age of an individual is not considered to be a factor in their requirement for reversal of sterilisation. However, the time span from when sterilisation happened is important as the longer the time since sterilisation the less successful the reversal will be for conception.	Yes
Social deprivation	For those who require reversal of sterilisation their socio-economic status may be a factor if self-funding becomes pertinent.	Yes
Carers	An individual's carer status is not considered to make them more affected by this policy.	No
Human	Will this piece of work affect anyone's human rights?	No

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
rights	Whilst the CCG acknowledges that individuals may feel that it is their right to have a family life this does not extend to technically having a child and therefore the reversal of sterilisation to facilitate this.	

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Gender	Inclusive policy and success rates	N/A It is a biological/clinical factor that cannot be influenced	N/A	N/A	N/A
Race	Research suggests that different ethnic groups may different access rates to surgery due to social factors	The CCG acknowledges that these factors can influence sterilisation and reversal. Patients are given a thorough explanation of process and consequences when sterilised and are given a number of options and counselling. And ultimately advised that it is a permanent technique.	Monitor IFR's	N/A	N/A
Age	Length of time from sterilisation reduces success rates.	N/A It is a biological/clinical factor that cannot be influenced	Monitor IFR's	N/A	N/A
Social Deprivation	If reversal is not funded may be an issue for those on low income etc not able to afford private treatment.	Whilst the CCG acknowledges that not funding reversal will impact more on those unable to afford private treatment they refer back to the fact that patients are given a thorough explanation of process and consequences when sterilised and are given a number of options and counselling. And ultimately advised that it is a permanent technique.	Monitor IFR's	N/A	N/A