1. **Service Specifications**

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| **Service Specification No.** | VAS/07/2015 V.1.0 9 2nd Window |
| **Service** | Minimally Invasive Vasectomy (Male Sterilisation) Services |
| **Commissioner Lead** | Coventry and Rugby (Lead CCG)South Warwickshire CCGWarwickshire North CCG |
| **Provider Lead** |  |
| **Period** |

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| Start date (Asap in 2018 to 31/3/20). Following original procurement in 2015. |

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| **Date of Review** | TBC |
| **1. Population Needs** |
| * 1. **National/local context and evidence base**

1.1.1 Vasectomy is indicated when a man wishes to make a permanent and irreversible decision that they should never subsequently conceive a child of their own. It is a voluntary act with the request coming from the man wishing to be rendered.1.1.2 Data from both England and Scotland show a downward trend in the number of vasectomies that were performed in a hospital setting between 2000 and 2010 with an increase in the number of procedures being carried out in other settings. Data also show that there has been a decline in the cumulative total of vasectomies performed over the same period in both countries. In England the total number of vasectomies performed in all health care settings was 41 100 in 2000/2001 and 18 000 in 2010/2011, a reduction of 56.2%. (Reference: Male and Female Sterilisation, Faculty of Sexual and Reproductive Healthcare, 2014: <http://www.fsrh.org/pdfs/MaleFemaleSterilisation.pdf>).1.1.3 Sterilisation can be an empowering decision for the right person at the right time however its intended permanency means that the onus is on the health care practitioners involved to ensure that the patient has all the information required about the relative benefits and risks associated with all types of contraception in order to make an informed choice. |
| **2. Outcomes** |
| Patients will receive an effective quality vasectomy procedure with low complications rates in a community location of their choice  |
| **3. Scope** |
| 2.1 Aims and objectives of service2.1.1 The service will provide a high quality minimally invasive vasectomy service (using local anaesthesia), in accordance with Faculty of Sexual and Reproductive Health guidelines, (FSRH), in a primary care setting to all adult males who request it, have capacity to make the decision, are not acting under external duress and who do not have any contraindications2.1.2 The main aims of the service are:* + To provide a high quality, cost effective, local community vasectomy service
	+ To provide services that comply with accepted best practice, relevant accreditation processes, relevant guidelines in clinical practice and robust governance arrangements.
	+ To provide a complete holistic patient focussed care package; including pre and post operative care, information, advice and counselling
	+ To provide an opportunity for men’s Health Promotion and for Making Every Contact Count (MECC)
	+ To ensure consistent and continuous care between health professionals, and effective and efficient communication.
	+ To improve access and convenience for patients
	+ To improve patient choice

2.2 Service description/care pathway2.2.1 Access to the service2.2.1.1 Providers should have local strategies in place for providing information to both service users and professionals on the choices available within the service and on access to the service.2.2.1.2 The service will be listed as a Provider on the Choose and Book system/equivalent (or working towards this) and accept all clinically appropriate referrals.2.2.1.3 The Provider will implement a standard referral form in agreement with commissioners, which will be available through local referral facilitation tools / websites, which will include specific patient focused health care questions that function as an initial triage system.2.2.1.4 Referrals which are not appropriate for a community service, should be discussed with the referring clinician and an appropriate referral made to other services (e.g. if there are clinical concerns, an urgent referral may be needed)2.2.1.5 The clinics will be provided to meet the needs of the service; this can be outside of usually GP practice surgery hours.2.2.1.6 The Service Provider shall ensure that the service offered is respectful and does not discriminate on grounds of age, gender identity/reassignment, sexuality, ethnicity, religion, disability, relationship or socio-economic status, or other personal circumstances. Services should be sensitive and accessible to the needs of clients whose first language is not English, and those with hearing, visual or other disability.2.2.1.7 Receipt and administration of all referrals will be the responsibility of the Provider.2.2.1.8 Clients should be seen within half an hour of their appointment time and flow through the clinic should be without undue delay.2.2.1.9 Referrers should indicate why sterilisation is required and provide evidence of previous obstetric history and use of contraception and give reasons and explanation of any intolerance.2.2.1.10 Providers should provide pathways of care from receipt of referral to discharge of patient including pathways if complications arise and indicating a clear route of referral into secondary care if appropriate. **2.2.1.11** All clients should be offered a chaperone for any examination. If the offer is declined this should be recorded in the client’s notes. If a chaperone is present a record should be made of the identity of the chaperone. All providers should have a chaperone policy. **2.2.1.12** All adult males who request it, have capacity to consent, are not acting under external duress and who do not meet any of the exclusion criteria should be considered for the procedure. It should be made clear to patients that the NHS, other than in exceptional individual circumstances, will NOT fund reversal of the procedure. **2.2.1.13** Marital breakdown, change of partner or remarriage is not unusual. Such events would not be considered sufficient grounds to give an individual priority for funding a sterilisation reversal. Vasectomy reversals have only been agreed to date when patients have clearly demonstrated that the vasectomy procedure was undertaken under duress or inadequate counselling (bearing in mind it is important to ascertain that request for reversal is also not under duress). The death of a child although rare and tragic would not be considered sufficient grounds for a reversal and should be discussed during the pre-vasectomy counselling within worst – case scenarios. 2.2.2 Support, Advice and Assessment Appointment2.2.2.1. The Provider will ensure that both verbal and written information about the procedure and follow up care is given to the patient (ideally assessment should be done with partner present). Pre-operative individualised assessment must include a process of counselling and consent. It will also include1:* + Taking a medical history
	+ A full range of information about access to all forms of contraception including long term reversible methods of contraception and tubal occlusion. Information should be provided on the advantages, disadvantages (including risks and complications) and relative failure rates of each method.1 Individuals should be informed that vasectomy is safer, quicker to perform and is associated with less morbidity than female sterilisation by laparotomy or laparoscopy. Individuals should be informed that vasectomy has an associated failure rate and that pregnancy can occur several years after vasectomy.
	+ Addressing myths and misconceptions associated with sterilisation.
	+ Reassurance that there is no increase in testicular cancer or heart disease associated with vasectomy. The association of an increased risk of prostate cancer is at present likely to be considered to be non-causative. Service Users will be informed of the risk of chronic testicular, scrotal, penile or lower abdominal pain after vasectomy, that is rarely severe and can be chronic in some men.
	+ Informing service users that reversal operations or intracytoplasmic sperm injections are rarely available on the National Health Service as they are considered low priority procedures and will only be considered in exceptional cases.
	+ Assessment of individuals for known predictors of regret (see 2.2.2.4) and highlight the possibility of regret associated with sterilisation
	+ A discussion related to sterilisation not conferring protection against sexually transmitted infections
	+ A discussion of the need to use contraception until sterilisation has been carried out and the need to continue use beyond the procedure. Condoms should be offered to all patients at the procedure appointment as a method of preventing STIs and contraception and the provider should ensure that service users know how to use them correctly.

2.2.2.2 The pre-operative assessment should be documented in clinical records and be carried out at a suitable interval (at least 2 weeks) prior to the procedure (and all will be shared with the patient’s own GP)2.2.2.3 Counselling will also take into account cultural, religious, psychosocial, psychosexual and other psychological issues, some of which may have implications beyond fertility. Healthcare professionals will concentrate on factual information and avoid persuasion or any act that may be deemed coercive, however clear the advantage of their recommended option appears to be.2.2.2.4 Additional consideration will be taken when counselling patients that;* Are under the age of 30 years
* Have few or no children already (few usually relates to two or fewer)
* Are not in a relationship/change of relationship status
* Death of a child
* Psychological/psychosexual issues
* Not in a mutually faithful relationship or in a crisis/unhappy relationship
* May be making the decision as a reaction to a loss of a relationship
* Who may be at risk of coercion by their partner, family or health or social welfare professional/who may be in an abusive relationship (safeguarding procedures should be followed)

2.2.2.5 Scrotal examination should be carried out either at initial consultation or before commencing the procedure.2.2.2.6 Opportunities should be taken to identify vulnerable individuals (e.g. those with adult protection needs (robust safeguarding pathways should be in place), those experiencing domestic/sexual abuse, mental health problems, drug and alcohol misuse, or reporting risky sexual behaviours). Appropriate referrals should be made. Individuals should also be assessed for other lifestyle risks and signposted on (as part of Making Every Contact Count programme, which all staff should be trained to deliver).The Provider will ensure all staff have appropriate safeguarding training (safeguarding for both children and adults)The Provider will ensure that staff are aware of, and abide by The Care Act 2014 https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/366104/43380\_23902777\_Care\_Act\_Book.pdf guidance in relation to safeguarding vulnerable adults from abuse and harm, and should also ensure that all staff are aware of and abide by local adult safeguarding policies and procedures (SCIE Report: Safeguarding adults: multi-agency policy and procedure for the West Midlands - Home page)The Provider shall ensure that all staff are aware of and abide by the legislation on safeguarding children, and should also ensure that staff are aware of and abide local safeguarding children board policies and procedures, and have internal procedures in place which align with local safeguarding priorities2.2.3 Vasectomy Procedure2.2.3.1 The operating doctor will need to ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the patient does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution.2.2.3.2 All vasectomies will be performed under local anaesthetic. Consideration may be given to warming local anaesthetic to approximately 37°C before infiltration to reduce pain associated with injection. Local anaesthetic with or without adrenaline (epinephrine) can be used during vasectomy (outside product licence for bupivicaine with adrenaline). Local anaesthetic should be administered via infiltration of the subcuticular tissue and by direct injection to the vas deferens and be administered using a fine-gauge needle to reduce pain.2.2.3.3 It is expected that single use disposable equipment will be used wherever possible. The clinic environment should be suitable for delivery of an invasive procedure.2.2.3.4 Cauterisation followed by division of the vas deferens, with or without excision, is associated with the lowest likelihood of early recanalisation (failure) when compared to other occlusion techniques.2.2.3.5 Division of the vas deferens on its own is not an acceptable technique because of its failure rate. It should be accompanied by ligation and fascial interposition or diathermy. Clips will not be used for occluding the vas, as failure rates are unacceptably high.2.2.3.6 Excised portions of the vas deferens will only be sent to histological examination if there is any doubt about their identity.2.2.3.7 The Provider will offer a one stop approach only if the patient requests it and it is deemed appropriate for that patient following a comprehensive telephone consultation by the surgeon. A two week cooling off period between pre-operative information / assessment and the procedure must still be enforced.2.2.3.8 In order to maintain continuity of service to patients, existing service providers performing scalpel only procedures are allowed a maximum of 6 months from the date of service commencement under this Service Specification to retrain to perform the non- scalpel method. If the Provider is unable to find a suitable training within this timeframe he/she must contact the lead commissioner, Coventry & Rugby Clinical Commissioning Group as soon as possible.2.2.3.9 A Certificate in Local Anaesthetic Vasectomy is required for all professionals providing this service. Training requirements (developed by the FSRH) can be found at: http://www.fsrh.org/pdfs/VasectomyLogbook.pdf. If a doctor has no prior vasectomy surgical experience then they will be supervised for a minimum of 15 procedures. Doctors with relevant prior surgical experience will perform a minimum of eight supervised procedures as part of training. .2.2.3.10 A doctor who wishes to supervise trainees needs to meet the requirements outlined by the Faculty of Sexual and Reproductive Health at: <http://www.fsrh.org/pdfs/VasectomyLogbook.pdf>2.2.3.11 All doctors performing vasectomies also need to meet the revalidation requirements set out in the training document above2.2.3.12 Intraoperative complications relating to identification of the vas, and other intraoperative complications, should be managed as per FSRH guidelines.2.2.3.13 Details of the procedure will be kept as part of the clinical record and shared with the patient’s GP.2.2.3.14 All Serious Incidents Requiring Investigation (SIRIs) should be reported to commissioners within 24 hours, according to the local CCG Incident Policy.2.2.4 Post Procedure Care2.2.4.1 The Provider will ensure that post vasectomy care includes provision of emergency contact numbers (when and who to contact), pain relief, wound care advice, information about resuming normal activities including sexual intercourse, provision of contraception prior to clearance and provision of sampling equipment for seminal analysis. Information regarding all of these elements of care should be given to all patients both verbally and in writing (in a variety of languages and formats).**2.2.4.2** Postoperative complications (bleeding/haematoma, infection and early failure, late failure and chronic post-vasectomy pain) should be managed as per FSRH guidelines, to include pre-operative skin cleansing and decision to shave scrotum as per local protocols. Bleeding and infection rates should be less than 2%, optimal failure rates should be less than 1% (with late failures after clearance has been given being 1 in 2000 or 0.05%), and chronic post-vasectomy pain should occur in between 1-14%. **2.2.4.3** Seminal analysis to be carried out at a recognised laboratory and funded by the provider. **2.2.4.4** Men must be advised to continue to use effective contraception until azoospermia has been confirmed. Irrigation of the vas deferens during vasectomy does not reduce failure rates or time to clearance. **2.2.4.5** The Provider will advise patients in how to comply with seminal analysis and supply all necessary equipment in advance of the 12 week target (for initial semenology test). **2.2.4.6** The Provider will inform patients that they will require at least one clear seminal analysis results at 3 months post vasectomy before the vasectomy is considered successful. A routine second post-vasectomy seminal analysis (PVSA) is not required if azoospermia is found in the first sample. **2.2.4.7** In a small minority of men, non-motile sperm persist after vasectomy. In such cases ‘special clearance’ to stop contraception may be given when fewer than 100,000/ml non motile sperm are found in a fresh specimen post-vasectomy, as no pregnancies have yet been reported under these circumstances. **2.2.4.8** If motile sperm are observed in a fresh sample 7 months post-procedure, the vasectomy should be considered a failure. **2.2.4.9** The Provider will forward seminal analysis results to the patient and their General Practitioner **2.2.4.10** A register of failed vasectomies will be maintained.**2.2.4.11** A register of post-operative complications will be maintained. **2.2.4.12** Active follow up regarding making sure patient has undertaken seminology tests etc will be undertaken by provider. **2.2.4.13** Urgent clinical assessment and emergency admission must be available if necessary. **2.2.4.14** Staff should be secured to stay beyond their contractual hours, where necessary, and this must be incorporated into the overall unit cost. **2.2.5 Confidentiality** **2.2.5.1** The service must be, and be known to be, strictly confidential. A written Confidentiality Policy should be prominently displayed and made available to service users. Staff should be able to demonstrate an understanding of the Policy and process and be able to communicate this to clients using the service. **2.2.5.2** Confidentiality must be maintained throughout the patients visit, including the minimal use of names in public areas, such as the reception or waiting areas. Communication sent to the patient should be through the methods consented to by the patient. Care should be taken to ensure that information is not shared with anyone else, including the clients General Practitioner, without the client’s consent (although it should be expressed that communication with GPs is routine practice). Issues of child protection overrule the right to confidentiality in certain circumstances please see local children’s safeguarding policies for guidance, however the client should be informed if other agencies are to be involved. **2.2.5.3** The Service Provider will be expected to demonstrate that the collection, storage and transfer of information to other services, including that in electronic format is secure and complies with any data protection requirements. **2.2.6 Consent** **2.2.6.1** The Service Provider will be expected to operate a policy for obtaining consent that complies with FSRH guidance (2014). Interpreting services will be used where appropriate. **2.2.6.2** Competent consent is understood in terms of the client’s ability to understand the choices and their consequences, including the nature, purpose and possible risk of any treatment (or non-treatment). **2.2.6.3** The consent form will include a statement of indemnity which relieves the Provider of any responsibility if a pregnancy occurs because the patient fails to comply with seminal analysis. Consent (including discussions had) should also be documented in the clinical notes. **2.2.6.4** Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent (see FSRH guidance, 2014) to a procedure that will permanently remove their fertility **2.2.7 Service user experience** Feedback from service users is essential to developing quality contraceptive and vasectomy services. The specification aims to ensure that feedback from service users, together with other information, is used to assist performance management and improve service delivery. **2.2.7.1** All patients using the vasectomy service should be asked to complete an anonymous post treatment satisfaction survey within a timescale agreed between the Commissioner and the Provider. The survey results should be forwarded to the Commissioner on a quarterly basis so that they can be used for performance management and service planning. Consideration should be given to supporting patients with a disability to complete surveys, if required. **2.2.7.2** The Service Provider will respond positively to any other comments offered about the standard of service they provide, for example from other members of the local sexual health community, or from the public. **2.3 Population covered** **2.3.1** The Provider shall provide services to all Service Users registered with a General Practitioner in Coventry and Warwickshire, for whom the Commissioners are responsible for funding healthcare services. **2.4 Any acceptance and exclusion criteria (please see UK Medical Eligibility Criteria for Contraceptive Use 2009 (or updated criteria):** [**http://www.fsrh.org/pdfs/UKMEC2009.pdf**](http://www.fsrh.org/pdfs/UKMEC2009.pdf)**)** **2.4.1 Referrals will be accepted from:** * GPs
* Sexual Health Services
* Any other relevant agencies/clinicians
* Self referrals

**2.4.2 Surgery should be delayed if the following conditions are present:** * Scrotal skin infection
* Active sexually transmitted disease
* Balanitis
* Epididymitis
* Orchitis
* Systemic infection/gastroenteritis

**2.4.3** Surgery should be undertaken with caution (extra preparations, precautions and counselling) if the following are present: * Diabetes
* Young age (<30 years)
* No offspring
* Depressive disorders

**2.4.4** Exclusion criteria (may be referred to specialist provider for consideration) * Previous scrotal surgery/injury
* BMI>35
* Drug or alcohol misuse
* Varicocoele/Hydrocoele
* Filariasis/Elephantiasis
* Intrascrotal mass
* Lack of consent/capacity
* Inguinal hernia
* Cryptorchidism
* Anticoagulant therapy
* Coagulation disorders
* Mental instability
* A history of an allergy to local anaesthetic
* A history of fainting easily
* Patient refusal of local anaesthesia
* Those deemed unsuitable for local anaesthetic
* AIDS using antiretrovirals

**2.5 Response time, detail and prioritisation** **2.5.1** The Provider will offer an appointment within two weeks of receipt of the referral. **2.5.2** The Provider will offer an appointment for the procedure no earlier than 2 weeks and usually no later than 4 weeks after the pre-operative assessment (up to 6 months in the patient requires) to ensure a cooling off period is allowed **2.5.3** The Provider will complete an initial triage assessment of the referral to ensure the patient appears suitable for a community vasectomy service within one week of receipt of the referral **2.5.4** Referrals which are not appropriate for a community service, should be discussed with the referring clinician and an appropriate referral made to other services (e.g. if there are clinical concerns, an urgent referral may be needed) **2.5.5** The service provider will not cancel appointments except in exceptional circumstances. Where exceptional circumstances do occur the provider will inform the Commissioners in writing within 7 days of the event. **2.6 Discharge Criteria** **2.6.1** If azoospermia is achieved, patient is discharged back to own GP. **2.6.2** If after 3 tests over a 7 month period the operation has not been successful, patient will be discharged back to own GP for further management **2.6.3** If patient does not attend andrology appointments, they will be discharged back to own GP, with advice that cannot assume operation has been successful. **2.7 Discharge Procedure (Care Transfer)** See 2.6 **2.8 Promotion and support of self-care** **2.8.1** The service will promote a culture of encouraging informed decisions regarding healthcare. The aim will be to facilitate self-care and patient / carer empowerment. **2.8.2** Signposting arrangements will be in place to direct service users to other services such as General Practitioners, Support Groups, Pharmacy, Dieticians, Physiotherapists, Citizens Advice Bureau, Social Care, Mental Health Services, Sexual Health Services, Sexual Assault and Domestic Violence Services, Drug and Alcohol Services, other Lifestyle services (some of this signposting will occur through delivering the Making Every Contact Count programme) etc. **2.9 Information provided to patients and carers** **2.9.1** Patients and carers will receive information on what they can expect from the provider, details of appointments, chaperone facilities, confidentiality issues and contact details for the clinicians. **2.9.2** Patients and carers will be informed of the vasectomy procedure, the implications, the possible benefits and risks involved. **2.9.3** Patients will be informed of the rationale for all onward referrals ensuring patients maintain their right to make choices. **2.9.4** All information will be available in a variety of communication formats to ensure that all those with visual or hearing difficulties or whose first language is not English will not be disadvantaged. Professional interpreters will be used as appropriate. **2.5 Interdependencies with other services** * Key services that the provider will be expected to develop effective links with include:
* General Practitioners
* Walk in Centres
* Secondary care vasectomy service providers
* Accredited Andrology Services
* Sexual Health Services
* Sexual Assault and Domestic Violence Services
* Drug and Alcohol Services
* Mental Health Services
* Other Lifestyle Services
* Social Care and Local Safeguarding Boards
* Third Sector Services
* Interpreters and Translation services
* Any other appropriate service
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| **4. Applicable Service Standards** |
| **3.1 Applicable national standards e.g. NICE, Royal College** * Faculty of Sexual and Reproductive Health
* Royal College of Obstetricians and Gynaecologists
* National Institute for Health and Care Excellence
* The Health and Social Care Act 2008: Code of Practice for the Prevention and Control of Infections. (The environment for the procedure must include completion of the Infection Prevention Society Quality Improvement Tool (QIT) for treatment rooms on a biannual basis: <http://www.ips.uk.net/professional-practice/quality-improvement-tools/quality-improvement-tools/> Furthermore, all providers should have an infection control policy consistent with NHS Professional CG1 Standard Infection Prevention and Control Guidelines 2013, or updated guidance)
* CQC registration for Surgical procedures.

**3.2 Applicable local standards** * 100% of Independent GPs performing the procedure will be registered as a GP with Special Interests (GPwSI) with NHS England Unit responsible for Coventry and Warwickshire.
* The Provider must have been trained to perform Vasectomy procedures to the standard advocated by the Faculty of Sexual and Reproductive Health (FSRH)
* The Provider shall have CRB Clearance
* Each professional shall undertake a minimum of 40 procedures annually and undertake at least one operating list per month. They will also conduct audits of their own complication and failure rates.
* The Provider shall have in place and operate effective management systems for prevention and control of healthcare associated infections (HCAIs)

 Standards relevant to premises requirements include: * A procedure for cleaning of the environment must be in place and audited
* Hand hygiene training of staff involved
* Equipment cleaning protocol must be in place
* A clear process for decontamination and sterilization of re-useable instruments (if applicable) should be demonstrated.
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| **5. Applicable quality requirements and CQUIN goals** |
| Quality Requirements - See schedule 4CQUIN Goals – Not Applicable |
| **6. Location of Provider Premises** |
| The Provider’s Premises are located at: To be confirmed.Waiting areas should have sufficient seating to accommodate the number of clients and their partners. Such areas should take into account the comfort of those waiting for others as they may experience an extended wait during a consultation or procedure.Specific aspects of clinic acceptability, such as ease of access, privacy & dignity, comfort and “room for improvement” should be actively reviewed in consultation with service users on an annual basis. Please note that costs associated with premises and equipment need to be met within the tariff price quoted, and appropriate premises and equipment needs to be available from the start of the contract.  |