

<b>Service Specification No.</b>	
<b>Service</b>	<b>Community Vasectomy Service</b>
<b>Commissioner Lead</b>	<b>NHS Lancashire &amp; South Cumbria Integrated Care Board</b>
<b>Provider Lead</b>	<b>Irwell Medical (EL) Witton Medical Centre (BwD) Stepping Stone Practice (BwD)</b>
<b>Period</b>	<b>1<sup>st</sup> April 2023 – 31<sup>st</sup> March 2024</b>
<b>Date of Review</b>	<b>Annually</b>

<p><b>1. Population Needs</b></p> <p><b>1.1 National/local context and evidence base</b></p> <p>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 infertile and the procedure may be offered irrespective of age or marital status.</p> <p>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 in order to make an informed choice.</p> <p>Discussion of sterilisation is a routine part of contraceptive advice offered by health professionals.</p> <ul style="list-style-type: none"> <li>• <i>Royal College of General Practitioners (2018) Framework to support the governance of General Practitioners with Extended Roles</i></li> <li>• Department of Health (November 2010). <i>Healthy Lives, Healthy People: Our Strategy for public health in England.</i></li> <li>• Royal College of Obstetricians and Gynaecologists (RCOG) (2004) Male and Female Sterilisation, Evidence-based clinical guideline number 4</li> </ul>
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<p><b>2. Outcomes</b></p> <p><b>2.1 NHS Outcomes Framework Domains &amp; Indicators</b></p> <table border="1"> <tr> <td><b>Domain 1</b></td> <td><b>Preventing people from dying prematurely</b></td> <td></td> </tr> <tr> <td><b>Domain 2</b></td> <td><b>Enhancing quality of life for people with long-term conditions</b></td> <td></td> </tr> <tr> <td><b>Domain 3</b></td> <td><b>Helping people to recover from episodes of ill-health following injury</b></td> <td></td> </tr> <tr> <td><b>Domain 4</b></td> <td><b>Ensuring people have a positive experience of care</b></td> <td><b>X</b></td> </tr> <tr> <td><b>Domain 5</b></td> <td><b>Treating and caring for people in safe environment and protecting them from avoidable harm</b></td> <td><b>X</b></td> </tr> </table> <p><b>2.2 Local defined outcomes</b></p> <ul style="list-style-type: none"> <li>• Increase the number of vasectomy procedures carried out in a Primary Care setting opposed to an acute-based setting.</li> <li>• To ensure care is delivered within 18 weeks and in a convenient location closer to the</li> </ul>	<b>Domain 1</b>	<b>Preventing people from dying prematurely</b>		<b>Domain 2</b>	<b>Enhancing quality of life for people with long-term conditions</b>		<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health following injury</b>		<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	<b>X</b>	<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	<b>X</b>
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patient's home

- Improved patient experience
- Reduced need for onward referral.

The Provider must take account of relevant and latest research and follow evidence-based practice when providing this service. Service provision must reflect and support current evidence-based practice including compliance with CQC regulations and NHS code of practice relating to the prevention and control of healthcare associated infections.

The provider must supply the ICB with such information as it may reasonably request for the purposes of monitoring the provider's performance of its obligations under this service level agreement. The Commissioner may also undertake unannounced inspections and audits to review compliance against best practice.

### **3. Scope**

#### **3.1 Aims and objectives of service**

The aim is to commission a community vasectomy service which is of a consistently high quality ensuring that the service is safe, clinically and cost effective, personalised, and fair, and in line with the GP with Extended Role accreditation expectations.

The service will:

- Provide a high-quality community vasectomy service for patients registered with either East Lancashire or Blackburn with Darwen GP practice
- Improve access for patients by providing alternatives to traditional hospital-based services in line with the principles of Implementing Care Closer to Home
- Contribute to broader health outcomes which include choice of a wider range of contraceptive services, community-based health services and choice in service providers
- Allow service delivery towards the 'Healthy Lives, Healthy People: Our Strategy for Public Health in England'
- Increase the number of vasectomy procedures carried out in a Primary Care setting opposed to an acute-based setting.
- Demonstrate value for money

#### **3.2 Service description/care pathway**

##### **Referrals/Booking of Appointments**

Upon receipt of the referral from the patients GP the provider will review the referral for any information that may indicate that the procedure is not appropriate either for this setting or for the patient.

The patient should be offered an appointment within 6 weeks of referral. The procedure should be carried out within an 18-week referral to treatment pathway.

##### **Assessment and Counselling**

The provider will need to assess the patient's suitability for surgery particularly:

- Any relevant medical history including current or recent medication
- History of allergy to local anaesthesia
- Active sexually transmitted infections
- Inguinal or scrotal condition
- Whether coercion is suspected
- Whether the patient has few or no children or is in an unstable relationship
- Awareness of other forms of contraception.

In addition, the counselling session should inform the patient of the purpose of the vasectomy and determine the patient understands the procedure and the decision that is being taken. It should cover:

- Irreversibility
- Details of the procedure and the arrangements that the patient should make on the day of the operation
- Details of post-operative testing and precautions that should be undertaken following the procedure until testing confirms sterilisation complete
- Failure rates
- Recanalization
- Acute and chronic complications (including infection, bleeding, and acute/chronic scrotal pain).

The provider must ensure that the patient is competent to make a choice to have this method of permanent contraception and is aware of alternative methods of contraception via the written information provided to the patient and counselling.

It is expected where clinically appropriate patients will undergo vasectomy within the community, however, if during the course of consultation or counselling that the clinical opinion is that it would be more appropriate for the patient's care to be provided in secondary care then the patient must be appropriately transferred for further management by secondary care.

Counselling should be provided by either the operating practitioner or a fully trained registered nurse within a 15-30-minute appointment, at least a week prior to the intended procedure but no earlier than 3 months in advance of the procedure. The patient's partner (where relevant) should be encouraged to attend the counselling session.

Information given to the patient should be discussed during the counselling session to ensure that the key points are understood and that the patient is ready to give informed written consent to the procedure. As a minimum the information must cover the patient's competence to make a choice and knowledge of alternative methods of contraception.

Where vasectomy is declined the provider should discuss and provide/signpost to the full range of contraceptive methods including reversible, emergency and long-acting reversible contraceptive (LARC) methods with follow-up.

## Procedure

Patients must be counselled again on the day of the procedure regarding the permanent nature of the operation and the technique to be used.

Prior to the procedure, the operating practitioner should check that the patient has received all the necessary information and has provided written consent to the procedure (especially where the counselling has not been provided by the operating practitioner). In addition, the practitioner should confirm that the patient has organised suitable transport to return home following the procedure.

A reminder should be provided to the patient of the need for continuing contraception until the final samples have been provided and the operation deemed to be successful.

The procedure must only be performed by local anaesthetic. Sedation is not to be used during the procedure.

The operating practitioner should remind the patient about what they can and cannot do immediately following the procedure and what to expect in relation to the wound/common problems and how to deal with them. The patient should be given advice about post-operative semen analysis. Finally, some brief advice should be given about when the patient should be able to return to work.

The patient must be provided with a contact number to access the provider should they have any questions or postoperative symptoms.

## Post-Vasectomy Semen Analysis (PVSA)

Post-vasectomy semen analysis (PVSA) is the laboratory procedure used to establish whether sperm are present in the semen following a vasectomy. As such, PVSA indicates whether surgery has been successful to achieve male sterilisation.

The 2016 Laboratory Guidelines for Postvasectomy Semen Analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons provide the following key recommendations:

- PVSA should take place a minimum of 12 weeks after surgery and after a minimum of 20 ejaculations
- Laboratories should routinely examine samples within 4 hours of production if assessing for the presence of sperm. If non-motile sperm are observed, further samples must be examined within 1 hour of production
- Assessment of a single sample is acceptable to confirm vasectomy success if all recommendations and laboratory methodology are met and no sperm are observed. Clearance can then be given.
- The level for special clearance should be <100,000/mL non-motile sperm. Special clearance cannot be provided if any motile sperm are observed and should only be given after assessment of two samples in full accordance with the methods contained within the guidelines.



2016 Laboratory  
Guidelines for Postva:

The provider must stress the importance of obtaining post vasectomy semen analysis to the patient to ensure successful completion of the procedure. The provider will inform the patient of the results of the semen samples and whether any further samples are necessary.

## **Record Keeping and Information Requirements**

The provider should maintain records of:

- All referrals received, recorded by patient name, and referring practice
- Details of any onward referrals and the reason for referring
- The patient's medical history, including consent received from the patient
- Evidence of counselling to include the explanation of risks
- Procedures completed
- Any procedure or post-operative complications
- Any adverse incidents or near misses.

The above information should be forwarded to the referring practice once the procedure is complete (after final sperm testing) so that it can be included in the patient's lifelong medical record. Should be patient chose not to provide final sperm testing the above information should be forwarded to the patients GP notifying them that final sperm testing has not been completed.

Records should be kept by the provider for a minimum of eight years.

## **Monitoring and Reporting**

The provider must supply the ICB with such information as it may reasonably request for the purposes of monitoring the provider's performance of its obligations under this service level agreement.

The provider is responsible for the development of clinical audit systems to audit the quality of care, the process of care and patient satisfaction with the service provided.

The service Provider must have an audit programme in place, which will include for example evidence of aseptic non-touch technique, hand hygiene, and infection prevention control measures relating to the environment and post procedure infection rates-the results of which will be shared with the Commissioner on request.

## **Untoward events**

All instances of serious untoward incidents must be reported, within 48 hours, to the ICB Quality Team.

## **Annual Requirements**

As a minimum, the provider will submit the following on an annual basis:

- Confirmation that the provider has undertaken a minimum of 40 vasectomy procedures within the most recent 12 months
- Confirmation that the provider provides a minimum of 1 vasectomy operating list per month
- Evidence of attendance at annual basic life support training for all GPs providing the service and any nurses assisting in providing the service
- Copy of the practice's infection prevention audit completed within the last 12 months
- Copy of an audit of complications/failure rates within the last 12 months
- Evidence of indemnity cover for the provision of vasectomy services

- Evidence of annual infection control training including hand hygiene and aseptic non-touch technique training for all GPs providing the service and any nurses assisting in providing the service.

In addition, the Commissioner will review the following the claims submitted by the provider for payment:

- Number of counselling appointments
- Number of vasectomy procedures undertaken.

### **3.3 Population covered**

The service provided shall be for eligible patients who are registered with a practice in the East Lancashire or Blackburn with Darwen geographical boundaries.

### **3.4 Any acceptance and exclusion criteria**

#### **Exclusion criteria**

- Anyone under the age of 25 years
- Anyone requesting a vasectomy reversal
- Patients are excluded from receiving this service if they are not registered within the East Lancashire or Blackburn with Darwen GP practice
- Patients with a known allergy to local anaesthetic
- Inguinal/scrotal conditions which contraindicate the procedure under local anaesthetic and or within the community
- Patients with blood disorders such as Haemophilia, Sickle Cell and Thalassaemia
- Patients with blood disorders which are anticoagulated

### **3.5 Interdependencies with other services**

- NHS Lancashire & South Cumbria Integrated Care Board
- Primary Care
- Local Acute Trusts (Secondary Care Consultants) and Pathology Laboratory
- PALS
- Independent and Voluntary Sector as appropriate

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g., NICE)**

The delivery of the commissioned service is underpinned by the appropriate standards, including but not limited to:

- NICE Quality Standard 49 regarding Surgical Site Infection published October 2013
- NICE Quality Standard 61, Infection Prevention and Control published April 2014 ([www.nice.org.uk/guidance/qs61/chapter/about-this-quality-standard](http://www.nice.org.uk/guidance/qs61/chapter/about-this-quality-standard))
- Faculty of Sexual and Reproductive Healthcare. Syllabus and Logbook for the Certificate in Local Anaesthetic Vasectomy
- Faculty of Sexual and Reproductive Healthcare Clinical Guidance: Male and Female

Sterilisation – September 2014

- The Health and Social Care Act 2008: Code of Practice on the Prevention and Control of Infections & Regulated Guidance (Revised 2015)  
<https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance>
- 2016 Laboratory Guidelines for Postvasectomy Semen Analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons
- Epic 3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England  
([https://improvement.nhs.uk/documents/847/epic3\\_National\\_Evidence-Based\\_Guidelines\\_for\\_Preventing\\_HCAI\\_in\\_NHSE.pdf](https://improvement.nhs.uk/documents/847/epic3_National_Evidence-Based_Guidelines_for_Preventing_HCAI_in_NHSE.pdf))

#### 4.2 Applicable standards set out in Guidance and/or issued by a competent body

##### Infection Control

The Provider must offer patients and carers clear consistent information and advice throughout all stages of their care. This should include the risks of surgical site infections. The provider should use the surgical safety check list attached when conducting all minor surgery procedures under this specification.



SSSL\_Checklist\_final  
un08.pdf

#### 4.3 Applicable local standards

As a minimum, the provider will submit the following information as an addition to the annual information in line with RCGP framework to support the governance of General Practitioners with Extended Roles. Clinicians wishing to provide this service will need to demonstrate that they fulfil the following criteria and complete the GPwER accreditation/reaccreditation template below:



GP with Extended  
roles guidance 2018.pdf



Final revised  
accreditation template.docx

- Have been accredited/reaccredited as a GP with Extended Role (GPwER) by NHS Lancashire & South Cumbria Integrated Care Board within the last 3 years, including approval of the premises, facilities, and equipment in line with CQC regulations and National Guidance
- Have current minor surgery experience
- Have specific training regarding vasectomy provision, conforming to that advocated by the Faculty of Sexual and Reproductive Healthcare (FSRH). Equivalent experience or qualifications
- Have undertaken 40 vasectomy procedures within the most recent 12 months and provided a minimum of one vasectomy operating list per month
- Attend an annual basic life support training and are competent in resuscitation

- Keep up to date with current best practice and guidance
- Compliance with the Health and Social Care Act 2012 by completing and submitting an infection prevention audit using an approved and current audit tool available from the following link:  
<http://www.ips.uk.net/professional-practice/quality-improvement-tools/quality-improvement-tools/>
- Conduct audits of own complication and failure rates
- Are registered with CQC with surgical procedures as a regulated activity.

GPs undertaking the counselling of patients regarding this service should hold the Diploma of the Faculty of Sexual & Reproductive Healthcare (DFSRH) or equivalent experience or qualifications.

Nurses undertaking counselling should hold the Advanced Certificate in Family Planning or equivalent.

Providers with no previous experience should be supervised for 40 operating sessions whilst providers with prior surgical experience should perform 8 supervised procedures. This should be within a two-year timescale and should be assessed as competent by their mentor.

All personnel providing the services should have appropriate indemnity cover with a Medical Defence organisation to meet in full claims made against them as individuals and any professional duties performed. Clinicians must inform their Medical Defence organisation that they are performing vasectomy operations.

Nurses assisting in providing this service should be trained and competent taking into consideration their professional accountability and the Nursing and Midwifery Council (NMC) guideline on the scope of professional practice, evidencing re-accreditation as required.

This will include training associated with anaphylaxis and basic life support as a minimum.

It is the provider's responsibility to monitor the on-going training and registration of nurses or any other support staff.

Staff must have access to annual infection control training including hand hygiene and aseptic non touch technique training.

The provider is required to maintain evidence of continuing professional development in relation to this service. This will need to be produced as evidence for re-accreditation. Clinical updates/training could include supervised practice, appraisal discussions, liaison/clinical audit sessions or attendance at appropriate postgraduate meetings/lectures/events etc.

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

### **5.2 Applicable CQUIN goals (See Schedule 4 Part E)**



**6. Location of Provider Premises**

The Provider's Premises are located at:

**7. Individual Service User Placement**

[Redacted]

[Redacted]

[Redacted]

- [Redacted]

- [Redacted]

- [Redacted]

- [Redacted]

[Redacted]

[Redacted]