

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Non-Scalpel Vasectomy Service
Commissioner Lead	Lisa Wicks, NHS Shropshire CCG
Provider Lead	
Period	1st April 2019 to 31st March 2020
Date of Review	October 2019

1. Population Needs						
<p>1.1 National/local context and evidence base</p> <p>Providers should have local strategies in place for providing information to both clients and professionals on the choices available within the service and on access to the service.</p> <p>The primary approach to be undertaken in offering this service is to be No-Scalpel Vasectomy (NSV) This differs in the fact that it obviates the need for incisions: following infiltration of local anaesthetic, a clamp is employed to secure the vas without skin penetration. A sharp-tipped dissecting forceps punctures the skin and vas sheath, to stretch a small opening in the scrotum, enabling isolation and occlusion of the vas.</p> <p>Vasectomy procedures are undertaken as a permanent form of contraception. Globally, NSV has broadened the acceptability of vasectomy as a means for sterilisation, via allaying the fear of incisions. Evidence suggests that this technique also benefits from fewer post-operative complications, without a reduction in efficacy.</p> <p>Vasectomies can be performed under local anaesthetic and take approximately 15 minutes.</p> <p>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 shows that there has been a decline in the cumulative total of vasectomies performed over the same period in both countries.</p> <p>Within the NHS, suitably trained general practitioners are able to offer NSV as a safe and reliable contraceptive procedure within the primary care setting as a minor surgery procedure.</p> <p>The failure rate of vasectomy is very low, approximately 1 in 2000. Vasectomy carries a lower failure rate in terms of post-procedure pregnancies and there is less risk related to the procedure than female sterilisation.</p> <p>In Shropshire, approximately 300 vasectomies are funded by the NHS each year.</p>						
2. Outcomes						
<p>2.1 NHS Outcomes Framework Domains & Indicators</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 15%;">Domain 1</td> <td style="width: 60%;">Preventing people from dying prematurely</td> <td style="width: 25%;"></td> </tr> <tr> <td>Domain 2</td> <td>Enhancing quality of life for people with long-term conditions</td> <td></td> </tr> </table>	Domain 1	Preventing people from dying prematurely		Domain 2	Enhancing quality of life for people with long-term conditions	
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Domain 2	Enhancing quality of life for people with long-term conditions					

Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X

2.2 Local defined outcomes

Vasectomy			
Outcome	Measure	Minimum	Target
All men are sterile after their first vasectomy.	% successful first vasectomies.	95%	100%
All men receive a timely service.	% referrals that undergo procedure within 6 weeks of referral date.	95%	100%

- Equity of care.
- Support delivery of care closer to home.
- To reduce the number of patients referred to secondary care.
- Improve patient experience.

3. Scope

3.1 Aims and objectives of service

The service will provide a quality and safe primarily no-scalpel technique vasectomy under local anaesthetic, in accordance with the Royal College of Obstetricians and Gynaecologist guidelines, (RCOG), in a primary care setting to all consenting adult males who request it, and are registered with a General Practitioner (GP) within NHS Shropshire Clinical Commissioning Group (CCG).

Clinical guidance produced with RCOG on Male sterilisation can be found here <https://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/>

The aims of the service are to:

- Provide service users with a high quality, timely vasectomy service within a Primary Care setting.
- Provide a service which is clinically effective and safe.
- Provide a service that complies with accepted best practice, relevant accreditation processes and relevant guidelines in clinical practice.
- Provide a complete holistic service user- focussed care package; including pre and post-operative care, information, advice and counselling.
- Ensure consistent and continuous care between health professionals.
- Ensure effective and efficient communication with service users and health professionals.
- Offer choice and convenience for service users.

3.2 Service description/care pathway

3.2.1 Access to the service

The Provider shall be listed on the Shropshire CCG Referral Assessment Service system. Shropshire CCG Referral Assessment Service (RAS) offers service users a choice of

provider.

The provider shall accept all clinically appropriate referrals from RAS.

The Provider shall return referrals which are not appropriate for a community service to RAS within one week in order that onward referral can be made.

The Provider shall run clinics which shall meet the needs of the Service Users; this may necessitate being outside of GP practice normal working hours.

The Provider shall offer service user a choice of appointments.

An initial appointment for counselling and pre-operative assessment shall be offered within two weeks of receipt of the referral.

The Provider shall offer an appointment for the procedure no earlier than 2 weeks and no later than 4 weeks after the counselling and pre-operative assessment to ensure a cooling off period is allowed.

Service users shall be seen within half an hour of their appointment time.

The service provider shall not cancel appointments except in exceptional circumstances. Where exceptional circumstances do occur the provider shall inform the Commissioners in writing within 7 calendar days of the event.

The Provider shall ensure that the service offered is respectful and does not discriminate on grounds of age, sexuality, ethnicity or religion (for protected characteristic groups who are most likely to experience disadvantage). Services should be sensitive to the needs of service users whose first language is not English, and those with hearing, visual or other disability.

The Provider shall offer all service users a chaperone for any examination. If the offer is declined this shall be recorded in the service user's notes. If a chaperone is present a record shall be made of the identity of the chaperone.

The Provider shall ensure protocols are in place for discharging the service users back to their own GP and transfer to secondary care if complications arise.

3.2.2 Information, Support and Assessment

The Provider shall ensure that information, including written information, about vasectomies and follow up care is given to every service user. Information shall be provided on the advantages, disadvantages and relative failure rates of each method. It shall also include a full range of information about access to other long term reversible methods of contraception. There shall be a choice of languages and formats available that are in line with the needs of service users.

Service Users shall be informed that reversal operations or intracytoplasmic sperm injections are not available on the NHS locally following sterilisation procedure unless exceptional circumstances are identified.

Every service user shall have pre-operation counselling. Counselling shall take into account cultural, religious, psychosocial, psychosexual and other psychological issues in relation to protected characteristic groups, some of which may have implications beyond fertility. The Provider shall 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.

Additional consideration shall be taken when counselling service users 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
- Not in a mutually faithful relationship or in a crisis 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

The provider shall obtain consent for the procedure to be undertaken from all service users wishing to continue with the vasectomy. Where possible agreement for the procedure to be undertaken shall be obtained from both the service user and their partner (where applicable). However, it is not a legal requirement to get a partner's permission.

In the event that a service user attends for the counselling appointment only, and fails to attend any further appointment or expresses the desire to withdraw from the procedure, the Provider shall be entitled to the pre procedure consultation tariff only.

The Provider shall ensure that the counselling, information exchange, history and examination have been completed and be satisfied that the service user does not suffer from concurrent conditions which may require an additional or alternative procedure or precaution.

3.2.3 Consent

The Provider shall ensure that all Service Users wishing to have a vasectomy have given formal consent for the vasectomy to take place.

The Provider shall ensure that in obtaining consent the Provider is complying in all respects with the requirements of any relevant guidelines.

Interpreting services shall be used where appropriate in order to obtain consent. 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). In assessing competence the Service Provider shall refer to relevant guidance.

The consent form shall include a statement of indemnity which relieves the Provider of any responsibility if a pregnancy occurs because the service user fails to comply with seminal analysis.

3.2.4 Vasectomy Procedure

All vasectomies shall be performed under local anaesthetic.

The Provider shall use single use disposable equipment wherever possible.

The clinic environment shall be suitable for delivery of an invasive procedure.

3.2.5 Post Procedure Care

The Provider shall ensure that service users are provided with information, including advice leaflets which include information on: post vasectomy care including emergency contact numbers (when and who to contact), pain relief, wound care, resuming normal activities including sexual intercourse, contraception prior to clearance and seminal analysis. There shall be a choice of languages and formats available that are in line with the needs of service users.

Service users shall be offered post procedure counselling.

The Provider shall ensure seminal analysis is carried out at the recognised laboratory as

specified by the Clinical Commissioning Group. Service Users shall be advised to continue to use effective contraception until azoospermia has been confirmed.

The Provider shall advise Service Users on how to comply with seminal analysis and supply all necessary equipment in advance of the 16 and 20 week post operation target.

The Provider shall forward seminal analysis results to the Service User and their General Practitioner.

The Provider shall maintain a register of failed vasectomies and a register of post-operative complications and report them through to the commissioner.

3.2.6 Confidentiality

The Service shall be, and be known to be, strictly confidential. A written Confidentiality Policy shall 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 Service Users using the service.

Confidentiality shall be maintained throughout the Service User's visit, including the minimal use of names in public areas, such as the reception or waiting areas. In order to maintain confidentiality, no information should be sent to the Service User's home address unless the Service User expressly wishes this.

Care should be taken to ensure that information is not shared with anyone else, including the Service User's General Practitioner, without consent.

The Provider shall 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.

3.2.7 Data Collection

The provider is required to:

- Produce an up-to-date register of patients receiving vasectomy services. This is to be used for audit purposes.
- Produce an appropriate GP record. Adequate recording should be made regarding the patient's clinical history, the counselling process, problems with the procedure and follow-up arrangements. If the patient is not registered with the practice providing the service, the providing practice must ensure that the patient's registered practice is given all appropriate clinical details for inclusion into the patient's notes

3.2.8 Facilities

The provider shall

- Provide adequate facilities and equipment.

3.2.9 Clinical Governance

The service provider will be responsible for their own system of clinical governance. This will include but not be limited to the following:

- An appointed Clinical Governance Lead;
- Development and implementation of Clinical Governance policies;
- Adherence to the Serious Untoward Incident reporting and investigation process;
- Compliance with Infection Control policies;
- Compliance with NHS complaints procedure and processes.

The service provider will have secure IT systems in place which enable the capturing of patient information and activity reporting. They will ensure that all information relating to patients is safeguarded and complies with the Data Protection Act (1998), the Access to Health Records Act (1990), the Freedom of Information Act (2000) and the Caldicott Principles.

3.2.10 Training

Practitioners undertaking this procedure should have undertaken the appropriate surgical skills training required to deliver this procedure and update their certification every 5 years.

Training should be based on modern, authoritative medical opinion.

3.2.11 Annual Review

All practices providing this service shall conduct an annual review to include an audit of:

- the register of patients
- complications and number of referrals to secondary care
- number of patients seen with a successful outcome

3.2.12 Tariffs and Codes

Please refer to the Read Codes included in the Supporting Documents Folder for the codes that should be used for recording patient activity for this scheme. Frequency of data extraction shall be completed on a monthly basis.

Please see Schedule 3 Part A for the Local Prices.

Please also refer to Schedule 6 Part A for the Reporting Requirements.

Practices will be requested to complete quarterly activity returns which the CCG will reconcile against activity reports run centrally from Primary Care clinical systems. Through discussion with practices differences will be identified and agreed in order to eliminate future differences. Quarterly payment adjustments will be made based on agreed actual activity levels.

In signing up to this service the practice agrees to recording patient activity using the read codes above, and agrees for the CCG to reconcile quarterly activity returns to central reports run based on these read codes, for payment and audit purposes.

3.3 Population covered

Adult men registered with a Shropshire GP.

3.4 Any acceptance and exclusion criteria and thresholds

Men under the age of 30 years shall be made aware of the implications and advised that reversal of a vasectomy is considered an excluded and restricted procedure and shall only be considered in exceptional cases.

Referrals shall be accepted from GPs.

All men registered with a Shropshire GP requesting a vasectomy shall be eligible for referral into this service. Exclusions for treatment shall be in line with relevant guidance.

3.5 Interdependence with other services/providers

Key professions that the provider shall be expected to develop effective links with include:

- Other General Practitioners
- Acute Hospital Trust
- Sexual Health Services

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

The provider shall deliver services in accordance with standards set out by relevant organisations including, but not limited to:

- NICE

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

- Faculty of Sexual and Reproductive Healthcare Guidance 2014 on Male and Female Sterilisation <https://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/>



cec-ceu-guidance-sterilisation-cpd-sep-20

4.3 Applicable local standards

None identified.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (Please refer to Schedule 4 Parts A-C)

5.2 Applicable CQUIN goals (Please refer to Schedule 4D)

Not Applicable.

6. Location of Provider Premises

The Provider's Premises are located at:

Service providers shall need to provide evidence of CQC certification and must be registered for Surgical Procedures Regulated Activity at a specified premises location.

Waiting areas should have sufficient seating to accommodate the number of service users 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.