

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Non-Contraceptive Use of Intrauterine Systems (IUSs)
Commissioner Lead	Shropshire CCG
Provider Lead	General Practices
Period	1 st April 2019 to 31 st March 2020
Date of Review	October 2019

1. Population Needs

1.1 National/local context and evidence base

This specification sets out the criteria for the use of Levonorgestrel Intrauterine Systems (LNG-IUS) for non-contraceptive purposes in Primary Care.

As well as being licensed as a contraceptive device, the Mirena® LNG-IUS is licensed for the management of idiopathic menorrhagia for a period of 5 years and protection from endometrial hyperplasia for a period of 4 years. This Locally Commissioned Service (LCS) covers the use of the device within Primary Care where clinically appropriate under these circumstances, reducing the requirement for referral into Secondary Care.

The use of any LNG-IUS purely for the purposes of contraception is commissioned by Public Health, not Shropshire CCG, and is not included within this specification.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
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	X
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

- Locally convenient service with improved access to care
- Improved quality of care
- Reduction in number of referrals to Secondary Care

3. Scope

3.1 Aims and objectives of service

This service shall allow provision of effective first-line management of menorrhagia and protection from endometrial hyperplasia using the LNG-IUS within Primary Care.

Patients requiring an IUS for contraception are excluded from this service and any related activity shall be claimed under the LARC service commissioned by Public Health.

3.2 Service description/care pathway

Fitting of LNG-IUS in primary care shall be carried out in line with NICE clinical guidelines (e.g. NG88, Heavy Menstrual Bleeding). The system must be fitted and removed by a qualified practitioner.

This service requires practices to:

- Undertake a risk assessment.
- Fit, monitor, check and remove LNG-IUS as appropriate for the management of menorrhagia and protection from endometrial hyperplasia.
- Maintain an up-to-date register of patients fitted with an LNG-IUS. This shall include the name of the fitting clinician and details of the device fitted for audit purposes.
- Provide adequate equipment. Certain special equipment is required for fitting and removal. This includes an appropriate treatment room fitted with a couch and with adequate space, emergency equipment and drugs for resuscitation. For LNG-IUS fittings, a variety of vaginal specula, (and if skills allow cervical dilators, and equipment for cervical anaesthesia also) need to be available and meet sterilisation requirements. Women shall be informed about the availability of local anaesthesia and offered where available. An appropriately trained assistant shall also be present to support the patient and assist the doctor during LNG-IUS procedures.
- Follow-up as outlined below.

A check of the device after fitting is suggested at six weeks. Routine annual reviews are not required but arrangements shall be in place to review patients experiencing problems in a timely fashion and to provide information and treatment as required.

Appropriate verbal and written information about all treatment options for the management of menorrhagia or for endometrial protection shall be provided at the time of counselling and reinforced at fitting with information on follow up, effectiveness, duration of use, side effects and those symptoms that require urgent assessment.

3.3 Population covered

All patients registered with a Shropshire CCG General Practice.

3.4 Any acceptance and exclusion criteria and thresholds

Patients requiring an IUS for the treatment of menorrhagia or protection from endometrial hyperplasia.

Patients requiring an IUS for contraception are excluded from this service and any related activity shall be claimed under the LARC service commissioned by Public Health.

3.5 Interdependence with other services/providers

The LARC service commissioned by Public Health.

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

Links to guidelines:

- NICE Guidance: <https://www.nice.org.uk/guidance/ng88>
- <https://www.medicines.org.uk/emc/medicine/1829/SPC/Mirena/>

Written information shall be provided at the time of counselling and reinforced after fitting

with information about symptoms that require urgent assessment, procedures for initiation and discontinuation. Women shall be given verbal and written details about the lifespan of the LNG-IUS, side effects and effectiveness in a format appropriate to their needs. The patient's understanding of LNG-IUS shall be checked prior to fitting; considering use of interpreting service as required.

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

None identified

4.3 Applicable local standards

Equal Opportunities

The service provider must demonstrate how they meet equal opportunity requirements in the following areas:

- They must be committed to equal opportunities and must not discriminate in performance of the service towards service users or members of staff in any way;
- The service provider must be able to provide chaperones at the patient's request;
- The service provider must also be able to provide premises, facilities and treatment rooms that are compliant with disability legislation;
- The service provider must be able to provide access to foreign language interpreter if necessary.

Clinical Qualifications

All GPs delivering this service shall be required, upon request, to provide Shropshire CCG with evidence that they have an up to date Letter of Competence (LoC) from the Faculty of Sexual and Reproductive Healthcare (FSRH). Completion of the Faculty's e-modules is also strongly recommended.

If any GPs in the practice are not in possession of a valid LoC, they shall not be able to perform the procedure. For those where the LoC is set to expire during the contract period, evidence of a valid replacement shall be required for service delivery to continue beyond the expiry date.

Current requirements set down by the Faculty of Sexual and Reproductive Health Care can be found at <https://www.fsrh.org/standards-and-guidance/>.

As with any clinical intervention, it is important that practitioners carry out sufficient volume of activity, as recommended by FSRH, to ensure they are appropriately skilled to provide high quality care and meet appropriate standards.

Clinical Governance

The service provider shall be responsible for their own system of clinical governance. This shall 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.

The service provider shall have secure IT systems in place which enable the capturing of patient information and activity reporting. They shall 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.

Activity and Audits

Adequate recording shall be made regarding the patient's clinical history, the counselling process, including documentation of verbal or written informed consent having been obtained, any problems with insertion, the type, batch number and expiry date of the device and follow-up arrangements. Any follow up consultations shall be documented.

It is a requirement of this service that the contractor supplies NHS Shropshire CCG with such information as it may reasonably request for the purposes of monitoring the contractors' performance, obligations and outcomes.

Full records of all procedures shall be maintained in such a way that aggregated data and details of individual patients are readily accessible. All contractors have a medico-legal responsibility for maintaining complete and accurate patient records. Contractors must ensure that the detail of the patient's procedure is included in the patient's lifelong record.

An annual audit of the register of patients fitted with an IUS for the treatment of menorrhagia or protection from endometrial hyperplasia during oestrogen replacement therapy including: type of device, reasons for removal; complications or significant events shall be undertaken and sent to Shropshire CCG Quality and Safety team when requested to do so.

Key Performance Indicators

Please refer to Schedule 4 Part C (Local Quality Requirements) and Schedule 6 Part A (Reporting Requirements):

- Number of patients seen per month. This shall be reported via the Monthly Data Submission made via EMIS, or by direct data submission from practices using other clinical systems.
- Practices should aim to see patients within 4 weeks of a referral being received or appointment being requested. It is recognised that some practices only have limited provision however. Practices are asked to inform the CCG of any issues that are causing significant delays for patients.
- All equipment used within this procedure shall meet the national standards for sterilisation and maintenance.
- Numbers of significant events shall be reported quarterly. This shall be reported by the Quality Reporting Template.
- Practices shall have a protocol in place detailing referral criteria, interventions and treatment pathway.

Payment

Payments shall be made quarterly in arrears and shall be calculated based on the activity included in the Monthly Data Submissions supplied by the practice via EMIS, or direct data submission from practices using other clinical systems, to NHS Shropshire CCG.

Please see Schedule 3 Part A for the Local Prices.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-C)

5.2 Applicable CQUIN goals (See Schedule 4D)

Not applicable.

6. Location of Provider Premises

The service shall be provided at the relevant General Practice premises.

7. Individual Service User Placement

Not applicable.