Local Enhanced Service Specification

Intra-Uterine Contraceptive Device Fitting for Patients Not Registered with the Service Provider 2019

1. Introduction

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services.

No part of the specification by commission, omission or implication defines or redefines essential or additional services.

2. Definition of Service

The service includes the provision, fitting, monitoring and removal of intrauterine contraceptive devices (IUDs) licensed for use in the UK to women for contraception or for the management of menorrhagia, dysmenorrhea and endometrial protection. It does not cover the service for emergency contraception. The practice will offer and provide IUDs, on behalf of practices that do not provide this service. Patients referred to this service must be registered with a GP Practice in Aneurin Bevan University Health Board. **Please see Annex 1 for patient pathway in regard to this enhanced service.**

Where the term LNG IUS is used this refers not solely to Mirena™, but to the suite of progesterone containing intrauterine devices currently available in the UK with differing amounts of progesterone and duration of use

3. Overall Aims

This Locally Enhanced Service specification for IUDs is designed to:

Ensure the availability of IUDs through primary care, as part of a range of contraceptive options offered by the practices.

Promote IUDs as an effective Long Acting Reversible Contraceptive (LARC) method of contraception.

Increase uptake and ongoing use of IUDs thereby contribute to reducing unintended pregnancies and particularly teenage pregnancies.

Increase the availability of levonorgestrel-releasing intrauterine systems LNG-IUS

in the management of menorrhagia dysmenorrhea and menopause management within primary care

Provide a LNG-IUS fitting service to medical practice registered and non – registered patients who have been appropriately investigated for the control of menorrhagia or dysfunctional bleeding.

4. Key Objectives

The objectives of this service are to:

Provide an accessible IUD insertion and removal service in general practice as part of a range of contraception choices for women.
Raise awareness of the benefits of IUDs by providing high quality advice, support and information on the full range of contraception methods to all women on or seeking contraception, and particularly to women aged under 25.
Provide accessible treatment for the management of menorrhagia, dysmenorrhea and menopause management.
To promote and offer locally based services within the primary care setting

5. Key Outcomes

It is expected that the enhanced service for contraception IUDs will contribute to:

Increased LARC uptake and continued use, particularly in under 25s.
A reduction in the number of unplanned pregnancies.
A reduction in the under 18 conception rate.
A reduction in the number of terminations of unplanned pregnancies.
Improved management of menstrual related disorders.
Reduced numbers of referrals to secondary care with community gynecology issues

6. Service Outline

Geographic coverage/boundaries
This local enhanced service (LES) is aimed at practices contracted by Aneurin Bevan University Health Board wishing to provide a service to patients who are registered with other practices within Aneurin Bevan University Health Board.

Location(s) of Service Delivery
The service will be provided from the practice premises.

Referral criteria and sources

The service will be available to women who request contraception and who choose an IUD as the most acceptable method for them.

Indications for the use of LNG-IUS for the management of menorrhagia, dysmenorrhea or menopause in primary care should be in line with NICE guideline NG88 Heavy Menstrual Bleeding (http://www.nice.org.uk/guidance/ng88)

Practitioners that provide this service to patients that are not registered must have in place auditable processes and written procedures to ensure timely and responses to referrals and effective reporting.

Exclusion criteria

Women for whom the IUD is contraindicated will be excluded from the service. Such women must be offered a choice of alternative suitable methods of contraception or management for their condition by their own GP Practice.

7. Service Delivery

This LES is supported by an Operational Policy (Annex 1). Practices participating in this service must adhere to this as a requirement.

This Locally Enhanced Service covers the following:

Referrals. Patients referred to this service should expect to be offered an appointment within 8 weeks.

Fitting, monitoring and removal of IUDs as appropriate in line with current guidelines on best practice (e.g. NICE guidance on LARCs, Faculty of Sexual and Reproductive Healthcare) and manufacturers' recommendations. All IUDs must be licensed for use in the UK.

Fitting of LNG-IUS for the management of menorrhagia in primary care as part of a care pathway agreed and developed with local gynaecology departments. To ensure these devices are used for the correct patients and approved indications and in line with NICE clinical guideline 88, Heavy Menstrual Bleeding) (http://www.nice.org.uk/guidance/ng88.

Using LNG-IUS for the management of menorrhagia and dysmenorrhea in primary care as part of a care pathway agreed and developed with local gynaecology departments. These may include other investigations and examinations such as ultrasound/biopsy/hysteroscopy. LNG-IUS should be considered where no structural or histological abnormality is present, or for fibroids less than 3 cm in diameter which are causing no distortion of the uterine cavity. The patient should be clearly informed that this is a hormonal contraception product in case

she wishes to conceive

The use of the LNG-IUS for its non-contraceptive benefits depends on then the appropriate clinical history and examination/investigations having been undertaken. Treatment is then considered as part of a care pathway as per NICE/RCOG guidelines/local Heavy Menstrual bleeding pathway Repeated later

Sexual history taking. Assessment in terms of suitability and specifically patients to be excluded from the service, to ensure that the IUD is the most appropriate method of contraception or treatment based on medical evidence, clinical guidelines (http://www.nice.org.uk/CG30), sexual history and practice.

Risk assessment. Based on sexual history to assess the need for pre insertion swabs, testing for STIs, including HIV, prior to recommending the contraceptive IUD.

Patient information. Written information e.g. NICE patient information leaflet https://www.fpa.org.uk/sites/default/files/ius-your-guide.pdf
Should be provided at the time of counselling and reinforced after fitting with information about symptoms that require urgent assessment, non-contraceptive benefits, procedures for initiation and discontinuation. Women should be given verbal and written details about the lifespan of the IUD, side-effects and effectiveness in a format appropriate to their needs. The patient's understanding of IUDs should be checked prior to fitting; considering use of interpreting service as required.

Consent. The clinician will ensure the process for obtaining valid patient consent is in line with Welsh Government Guidance and the Faculty of Sexual and Reproductive Health Service Standards document on obtaining valid consent in Sexual and Reproductive Health.

Patients referred to GP from Secondary Care.

The fitting of LNG-IUS for patients who are referred back to general practice from secondary care investigations should be undertaken in agreement with and according to consultant gynaecologist referral.

When agreeing A LNG-IUS fitting referred from a consultant gynaecologist, assurance must be made that the investigations in line with RCOG guidelines have been made and the fitting of the LNG-IUS is the appropriate treatment.

Assessment and follow up.

5-8 week post-insertion checks after IUD/IUS insertion are not a pre-requisite of, or routinely funded by the Local Enhanced Service. Where there have been difficulties with the insertion of a device then the Practitioner may determine that a post insertion check is required. The rationale for the post-insertion check should be recorded to

support Post Payment Verification. Routine annual checks are no longer recommended. Arrangements should be in place to review clients experiencing problems in a timely fashion and to provide information and treatment to manage common side effects and problems, in line with NICE guidelines and current best practice. Arrangements should be in place to ensure timely access for women requesting removal of the device for any reason including problems or at expiry of the device.

Maintenance of a Register. An up-to-date contraception register including all patients fitted with an IUD and where the practice has undertaken a 5-8 week post insertion check. This will include the type of device fitted, the batch number and expiry date and the name and designation of the person completing the procedure. This is to be used for audit purposes and to enable the Primary Care Team to target these patients for health care checks.

Additional assessment. A face to face follow-up appointment should be offered by the performing clinician, where there are perceived complications 9 weeks or more, and post insertion. A Separate claim can be made for additional assessment.

Record keeping. Production of an appropriate clinical record using appropriate read codes, adequate recording should be made, to include:

- The patient's name and NHS number
- The patient's clinical, reproductive and sexual history,
- The counselling process,
- The results of any STI testing,
- Any contraindications
- Problems with fitting/removal,
- The type and batch number of the IUD
- Reason for IUD fitting
- Expiry date of the device and follow-up arrangements
- Any adverse reactions
- Name and designation of person(s) completing the procedure
- Referring practice if applicable

Where the patient is not registered with the provider of the LES, the provider must ensure that the patient's registered practice is given all appropriate clinical details for inclusion into the patient's notes, unless the patient withholds consent to inform her GP.

Full records of all procedures should be maintained in such a way that aggregated data and details of individual patients are readily accessible if requested by ABUHB.

Provision of adequate equipment. Certain special equipment is required for IUD fitting and removal. This includes an appropriate room fitted with a couch and with adequate space and equipment for resuscitation. A variety of vaginal specula, cervical dilators, and

equipment for cervical anaesthesia also need to be available. An appropriately trained assistant also needs to be present to support the patient and assist the clinician during the procedure.

Sterilisation and infection prevention and control. Although general practitioner minor surgery has a low incidence of complications, it is important that practices providing the procedures listed in this specification operate to the highest possible standards. Practices must use disposable sterile instruments. Practices must have infection control policies that are compliant with national guidelines including the handling of used instruments, aseptic technique and the disposal of clinical waste.

Clinical skills and competencies. Practices providing services under this specification will be expected to ensure that all clinicians (partners, employees, subcontractors) carrying out the fitting and removal of IUDs are appropriately trained and qualified to do so.
All clinicians providing intrauterine contraception (doctors and nurses) should hold an in date Faculty of Sexual and Reproductive Health letter of competence in intrauterine techniques or equivalent older versions of this qualification or grandfather agreement.

Whole system relationships. The Service Provider should be aware of the importance of effective partnership working with other providers to facilitate access from and to this local enhanced service. These include:

- Other General Practices
- Antenatal services
- Midwifery services
- Sexual Assault Referral Centre (SARC)
- Child and Adolescent Mental Health Service and Adult psychiatric services
- Interpreter services
- Genito Urinary Medicine (GUM)
- Social Care
- Contraception and Sexual Health Services (CASH)
- Young People's Sexual Health Service
- Youth Services
- Health Visitors
- Voluntary Services

The service is underpinned by local safeguarding and vulnerable adult protection procedures.

Interdependencies. Key interdependencies exist with:

- Pharmacies for supply of IUDs
- Clinical appraisal processes and training providers to support development and verification of skills and competencies.

8. Client group served / Eligibility / Access criteria

The Service Provider must ensure that the service offered is accessible to all, sensitive and respecting all areas of Race, Economics, Gender, Age, Religion, Disability and Sexual Orientation. Appropriate arrangements should be made for non-English speaking women and to provide the same high level of service to those requiring interpreter services. Organisational delays should not influence or alter a woman's choice to have an IUD.

9. Quality targets and continual improvement

The practice must ensure that they contribute to the wider patient safety agenda including, but not exclusively, the control of infection agenda and the identification, reporting and investigation of incidents and complaints. Participation in clinical audit and implementation of changes arising from audits should take place. The service should be able to demonstrate learning and improvement across the quality agenda and in response to local and/or national policy guidance.

It is the responsibility of the Practice to:

Continually improve the quality of service delivery, for example, in response to audit (undertaking and completing the audit cycle), user and staff feedback (complaints, compliments, suggestions) and incidents.

Continually review and be aware of relevant new and emerging guidance and recommendations and take the appropriate steps to assess and improve services to achieve current best practice

Ensure that appropriate professional standards are maintained updated and validated through clinical supervision and provision of relevant training to support reflective practice and CPD.

During the term of this specification fully co-operate in reviewing and improving/redesigning services at the request of the ABUHB, to include improving quality and performance monitoring.

10. Details of service monitoring, evaluation and review

The practice will be required to undertake an annual audit as agreed in advance with ABUHB and provide the monitoring data to the ABUHB Primary Care Team for annual review of the LES. This information will inform service planning and allow identification and sharing good practice and/or areas for improvement where the service outline have not been met.

It is recommended that practices adopt the PCQIS Audit Toolkit to complete the annual audit. The annual audit should include:

(a) The register of patients fitted with an IUCD/IUD

(b) continuous usage rates
(c) Reasons for removal
(d) Complications

11. Accreditation, CPD and activity

Clinicians undertaking these procedures should have undertaken appropriate training and meet the standards for CPD and activity.

IUD fittings & removals: All practitioners should have undergone the appropriate training for this procedure. For IUCD/IUS fitting, each practitioner should hold a Letter of Competence (LoC) and appropriate qualifications of the DFSRH and undertake a minimum of **twelve** IUCD fittings per annum (of at least **two** different devices) along with a minimum of two hours of education in five years. Where smaller registered populations make this difficult advice and agreement from the Local Health Board should be sought in order to continue providing this service. The Health Board will exercise discretion on an individual basis in the event that practitioners are unable to evidence that they have fitted both types of device in the previous twelve months.

Evidence of continuing professional development (CPD) and training should be maintained by the provider and may be reviewed as part of the General Practitioner (GP) appraisal process or separately to confirm accreditation for this service.

Appraisal
At appraisal clinicians are expected to demonstrate evid**e**nce of CPD and activity for IUD fitting and have log books available for review.

Practice responsibilities
Practices signing up to this LES must check and provide a single accreditation application to the ABUHB Primary Care Team for all clinicians who undertake IUD procedures. The application must demonstrate how the clinicians meet the minimum qualification, experience, CPD and activity requirements set out above.

The practice will keep an up to date register of all clinicians who de**l**iver the service, in such away as to be able to provide audit data to the ABUHB Primary Care Team on skills and competencies and to assess capacity to deliver LARC in primary care.

This should be available for review at any time and should include:

- Clinician name
- Clinical role
- Type of LARC device fitted/removed
- Relevant qualifications and experience

- Whether CPD and activity logs are maintained and meet specified requirements

12. Clinical and corporate governance

It is a condition of participation in this Locally Enhanced Service that practices will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her, to the ABUHB Primary Care Clinical Director or Deputy Medical Director of all emergency admissions or harm/potential harm to patients under this service, where such events may be due to administration/usage of the drug(s) in question or attributable to the relevant underlying medical condition using the standard Incident Reporting form.

Service Providers must ensure that they adhere to all relevant legislation and best practice.

13. Funding

Each Practice contracted to provide the enhanced service will be eligible to claim the following:

- £121.39 Assessment and fit fee. (Only payable for patients not registered).
- £30.35 following the 5-8 week check, where deemed appropriate.
- £50.58 assessment fee. (Only claimable where patient has been assessedand opted not to have procedure).
- £50.58 additional assessment fee for consultation for perceived complications, 9 or more weeks post-insertion.
- £30.00 fee for removal of the device. Practices will

be subject to post payment verification (PPV)

REFERENCES

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE). (2005) Clinical Guideline 30: Long-acting reversible contraception. Report published October 2005. Available at

www.nice.org.uk/nicemedia/pdf/cg030niceguideline.pdf

FAMILY PLANNING ASSOCIATION (FPA). (2018) Your Guide to the IUD/IUS. Leaflet published September 2017 https://www.fpa.org.uk/resources/leaflet-and-booklet-downloads

Faculty of Sexual and Reproductive Healthcare Clinical Guidance Intrauterine Contraception October 2015 https://www.fsrh.org.uk/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/ accessed 9.8.18

Faculty of Sexual and Reproductive Healthcare Clinical Guidance Contraception for women aged over 40 years November 2017 https://www.fsrh.org/standards-and-guidance/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/ accessed 9.8.18

Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility for contraceptive use UKMEC 2016 https://mag.digitalpc.co.uk/fvx/fsrh/ukmec/2016/ accessed 9.8.18

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE). (2018) Clinical Guideline 88: Heavy menstrual bleeding. Report published March 2018. Available at www.nice.org.uk/guidance/ng88

GENERAL MEDICAL COUNCIL (GMC). (2008) Consent: patients and doctors making decisions together. Report published 2008.

http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

Faculty of Sexual and Reproductive Health Training in intrauterine techniqueshttps://www.fsrh.org/education-and-training/letter-of-competence-intrauterine-techniques-lociut/

DEPARTMENT OF HEALTH (DH). (2008) The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections. Report published 11 January 2008. Available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081927

Patient pathway for post-fitting of Long Acting Reversible Contraceptive Devices

1. Patient referred by registered practice for fitting of LARC as practice not accredited to provide service themselves. Provider practice will have appropriate equipment and accredited staff able to perform procedure safely

2. Patient seen by provider practice and procedure undertaken by accredited practitioner following relevant preparation/counselling processes and using current, approved methods

3. Patient's registered practice updated by provider practice of procedure undertaken, counselling procedure, batch number of parenteral contraceptive device and any other relevant information

4. Appointment given by provider practice to patient for post procedure follow-up as necessary

5. Patient discharged from provider practice' services. Referring practice informed of discharge from services of provider practice and of any relevant further recommendations

6. Audit trail kept by both practices of all referrals and procedures undertaken and NWSSP informed of claim within 3 months of procedure date