

SCHEDULE A1

SERVICE SPECIFICATION FOR THE PROVISION OF ENHANCED CONTRACEPTIVE DEVICES IN GENERAL PRACTICE IN SOMERSET

1 National/local context and evidence base

- 1.1 Sexual health is an important area of public health. Most of the adult population of England are sexually active and access to quality sexual and reproductive health services improves the health and wellbeing of both individuals and populations. The Government has set out its ambitions for improving sexual health in its publication, *A Framework for Sexual Health Improvement in England* (Department of Health 2013).
- 1.2 Improving sexual health is a public health priority. The *Public Health Outcomes Framework for England 2016-2019* (Department of Health) set the national and local strategic direction for sexual health. There are now 5 indicators for sexual and reproductive health including reducing teenage conceptions and from 2019 a new indicator on the rate of prescribing LARC (excluding injections) in females aged 15-44. Further significant benefits to public health could be achieved by enabling women of all ages to control their fertility through access to a full range of contraceptive choices and abortion services.
- 1.3 The latest Natsal survey (*National Survey of Sexual Attitudes and Lifestyles, 2013*) showed that 10% of women aged 16-44 had been pregnant in the past year, with an estimated one in six of these pregnancies being unplanned (16.2%), 29% being ambivalent and just over half (55%) as planned pregnancies. One in 60 women (1.5%) experienced an unplanned pregnancy in a year. Unplanned pregnancies were more likely amongst the 16–19-year-old women, although most were in women aged 20-34 as this is when most women become pregnant.
- 1.4 The Public Health England Sexual and Reproductive Health Profiles show that:
- In 2020 GP prescribed LARC (excluding injections) in Somerset was 40.7 per 1000 resident female population aged 15-44 years (South West = 35.5, England = 21.1). This is a significant reduction from 2016 when the Somerset rate was 67.2, and a reduction on previous years due to the decrease in face-to-face health consultations during the Covid 19 pandemic.
 - In 2020 the total abortion rate in Somerset was 16.6 per 1000 females aged 15-44 years (South West = 15.6, England = 18.9). Abortion rates have increased nationally and in Somerset, with the biggest increase in Somerset amongst young women aged 20-24. The increase in abortion rates is being largely attributed to a declining access to LARC.

- In 2020 the under 25s repeat abortions in Somerset were 28.1% (South West = 25.1, England = 29.2%).
- In 2020, 26.4% of women in Somerset aged under 25 years who had an abortion had previously had a birth (South West = 23.3%, England 27.1%). This highlights the need for improved post-partum contraception in Somerset.
- Teenage conceptions continue to decline and in 2020 the teenage conception rate for Somerset was 11.0 per 1000 females aged 15-17 years (South West = 10.5, England = 13.0)

- 1.5 The National Institute for Health and Clinical Excellence (NICE) published clinical guidance on the effectiveness and appropriate use of long-acting reversible contraception (LARC) in October 2005 (updated July 2019) [Overview | Long-acting reversible contraception | Guidance | NICE](#). This guideline endorsed the use of LARC as the most cost-effective methods for reducing the number of unplanned pregnancies. NICE quotes five-year cumulative failure rates of <20/1000 for IUDs and <10/1000 for the IUS. A review of studies of contraceptive efficacy reported a one-year Pearl index of 0-0.6 per 100 for the progestogen contraceptive implant.
- 1.6 NICE recommended increasing uptake to reduce unintended pregnancy and calculated cost effectiveness to be greater than that for combined oral contraception at any point for an IUD and from year two for an IUS. Against this the cost per pregnancy averted in the first year was sufficiently low such as to recommend usage for any period of intended use.
- 1.7 Access to appropriate contraception enables women to avoid the potential negative health consequences of an unwanted pregnancy. NICE Clinical Guidelines (CG30) published in 2005 highlight that if 7% of women switched from their contraceptive pill to a LARC method the NHS could save around £100 million through reducing unintended pregnancies by 73,000 per annum.
- 1.8 General practices in Somerset have been providing LARC for some time, however, not all practices are able to provide the full range of LARC options, which has presented barriers to being able to offer all women timely access to the full range of contraceptive options. This service specification therefore details an adjusted way of providing LARC in general practice in Somerset going forwards.

2 **Service outline**

- 2.1 This service provides for the fitting, monitoring and removal of specific contraceptive devices licensed for use in the UK, specifically the Intrauterine Contraceptive Device (IUCD), Levonorgestrel Intrauterine System (LNG-IUS) and sub-dermal implants. These will also be known as long-acting reversible contraception (LARC) and does not include the contraceptive injection.

- 2.2 LARC is clinically effective for contraception with lower failure rates. The LNG-IUS has additional benefits regarding the management of menorrhagia (recommended by the Royal College of Obstetricians and Gynaecologists (RCOG)).
- 2.3 Competence of the professional inserting the device is paramount to reduce failure rates and the possibility of litigation.
- 2.4 The service should be provided to afford the patient dignity and respect.
- 2.5 It is expected that the service outlined in this specification will contribute to:
- Increased LARC uptake and continued use, particularly in women aged under 25 years
 - A reduction in the number of unplanned pregnancies
 - A reduction in the under 18 conception rate
 - A reduction in the number of abortions
 - A reduction in repeat abortions
 - Improved cost effectiveness by reducing numbers of unnecessary referrals to secondary care for LARC

3 Service aims and objectives

- 3.1 This service aims to ensure that the full range of contraceptive options is provided to patients via either their registered provider, or another willing general practice provider within the Somerset Integrated Care Board (ICB) (NHS Somerset) area. This is to include the provision of high-quality advice, support and information on the full range of contraceptive methods to all women using or seeking contraception.
- 3.2 For the duration of this document, the patients registered practice, and the practice making the referral will be known as the 'registered provider' and the practice receiving the referral for a LARC fit will be known as the 'receiving provider.'
- 3.2 The specification covers the insertion, removal and management of IUS/IUD and sub-dermal implants. The service should promote LARC as an effective method of contraception.
- 3.3 Provision of accessible and timely post-coital IUCD fittings for emergency contraception.
- 3.4 To increase availability of LNG-IUS in the management of menorrhagia within primary care in line with current accepted clinical care of this condition. The commissioning of LARC for non-contraceptive purposes is the responsibility of NHS Somerset. For the purposes of this specification NHS Somerset and Somerset County Council have agreed an arrangement for this to be covered at existing activity levels for non-contraceptive purposes.

4 Service description / pathway

4.1 The Provider shall ensure that the enhanced contraceptive device service includes, but is not limited to:

- Discussing all the different methods of contraception, enabling the patient to make the choice of their preferred method
- Providing written information to patients at the time of counselling and after fitting with information on follow-up and those symptoms that require urgent assessment.¹ The information should take into consideration individual needs and include efficacy, duration of use, possible risks/side-effects, other benefits and when to seek help while using the method. The FPA recommended leaflets are recommended for use.²
- The fitting, monitoring, checking and removal of enhanced contraceptive devices as appropriate
- Provision of advice on safer sexual practices and the use of condoms and reducing the risk of acquiring sexually transmitted infections, including provision of information on C-Card condom distribution scheme where appropriate
- Utilising the special equipment that is required for LARC fitting which includes the use of an appropriate room fitted with a couch and with adequate space and equipment for resuscitation, a variety of vaginal specula and cervical dilators. An appropriately trained assistant should be present to assist the fitter and support the patient during the procedure
- Ensuring that infection control policies and procedures are in place in accordance with national guidelines with appropriate methods for decontamination and Hepatitis B conversion. Please see Section 7 for more details
- Appropriate STI screening should be done before insertion of LARC. This should be in accordance with national policy or with local policy if there is no relevant national policy. Women aged under 25 years should be encouraged to undertake screening as part of the National Chlamydia Screening Programme.
- Carrying out assessments of patients between four to six weeks after fitting the LARC where deemed necessary by the performing clinician. Routine annual checks of IUDs or IUS are no longer recommended.^{3,4,5} Women must be advised to return

¹ See reference 13.1

² See references 13.2 and 13.3.

³ See reference 13.4.

⁴ See reference 13.5.

⁵ See reference 13.6.

at any time if they have a problem and should be provided with written information. Any problems such as abnormal bleeding or pain should be assessed urgently

- Assessing any problems such as abnormal bleeding or pain after contraceptive devices fitting urgently
- Using LNG-IUS for the management of menorrhagia 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.⁶ 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
- Anti-epileptic medication should be available at the time of IUD or IUS insertion in a patient with epilepsy⁷
- Development and maintenance of an up-to-date register of all patients that undergo the fitting or removal of a contraceptive device. This will include all patient details, the device fitted, the date of fitting, information given regarding contraceptive methods, dates for review, duration of use, reasons for removal, whether primary purpose of fitting is for non-contraceptive purposes, and complications or significant events
- Practices will need to submit Quarterly Activity Reports (appendix 1) providing information on numbers of fittings and removals. This should be submitted within 2 weeks at the end of the quarter
- Where LNG-IUS is used primarily for the management of menorrhagia this will need to be recorded and information provided to the commissioner (appendix 1). This will enable monitoring of the uptake of LARC for non-contraceptive purposes to inform future service planning. Where LARC is provided for both contraception and the management of menorrhagia this will count as contraceptive use
- Annual data detailing the number of accredited fitters within the practice and the number of fittings/removals that each accredited fitter has undertaken in the preceding twelve-month period will be submitted to commissioners. The provider will keep records of each patient treated detailing the patient's clinical history, the counselling process, the results of any chlamydia screening, the pelvic examination, problems with insertion, the type and batch number of the enhanced

⁶ See reference 13.7.

⁷ See reference 13.1.

contraceptive device, the consent form, and follow-up arrangements and outcomes

4.2 In order to provide timely access to the complete range of LARC a provider who does not offer fitting of the LARC method of choice should refer to another practice within NHS Somerset who does provide LARC (see appendix 3).

- The service will be available to any patients eligible to receive treatment, by written referral from a GP or Nurse Practitioner from a practice in the NHS Somerset area. Referrals may be made using electronic referrals when such are available
- The practice will provide waiting list management for patients referred into the service from other practices ensuring that patients are offered a choice of appointment and are seen and treated within 4 weeks of referral if clinically appropriate
- Where the receiving practice is unable to offer an appointment within 4 weeks, the patient may be returned to the registered practice, detailing this information. The registered practice will ensure that alternative contraception is provided and consider a referral to another participating practice
- In each case the patient should be fully informed of the treatment proposed
- The patient should give written consent for the procedure to be carried out
- The practice will provide a treatment letter to the patient's registered practice within 2 weeks, this report will be a copy of the detail held in records
- Included in the treatment letter, the providing practice will notify the registered practice of any necessary onward referrals and arrange for the secondary care service to report any further action to the patient's registered practice
- The practice should create an appropriate clinical record for each referred patient which provides the clinical information required for continuity at six-week check and/or future referral for LARC removal/replacement

4.3 Entry into service (referral routes)

- The service will be available to any patients eligible to receive treatment, by written referral from a GP or Nurse from another GP practice in the NHS Somerset area
- The practice will provide waiting list management for patients ensuring that patients are offered a choice of appointment and are seen and treated within 4 weeks of request, where clinically appropriate

- The practice should create an appropriate clinical record for each referred patient which provides the clinical information required for any necessary follow-up and/or future referral for LARC removal

4.4 Exit from service (discharge criteria and planning)

- Undertake the initial assessment and follow up, as necessary
- Routine annual checks are not required; however, arrangements should be in place to review clients experiencing problems in a timely fashion and the referring provider should be able to appropriately manage nuisance side-effects
- Arrangements should be in place to ensure timely access for women requesting removal of the LARC for any reason including problems or at expiry of the device
- A review should be undertaken only if there are clinical reasons for doing so
- Routine coil checks annual or otherwise are no longer necessary
- For patients referred from another practice the practice will provide a treatment letter to the patient's registered practice within 2 weeks of insertion/removal

4.5 Inclusion/exclusion criteria

4.5.1 All women of childbearing age registered with a practice in the NHS Somerset area requesting contraceptive advice will be eligible for assessment for suitability for a LARC. In addition, any woman assessed as suitable for an LNG-IUS used primarily for the management of menorrhagia will also be eligible.

4.6 Interdependencies

4.6.1 The service will work collaboratively with the local specialist sexual health service, community pharmacists offering free Emergency Hormonal Contraception and other healthcare providers to facilitate timely access to contraceptive and sexual health advice, treatment and support.

4.7 Geographic coverage of service

4.7.1 Individuals registered with practices within the NHS Somerset area.

5 **Consent and safeguarding**

5.1 In each case the patient should be fully informed of the treatment options and the treatment proposed.

- 5.2 National guidelines suggest that written consent should be obtained from patients. Somerset County Council wishes the providers to note that their interpretation of 'written consent' in this context is the recording of consent by Read Code. Where the provider Read Codes consent given, Somerset County Council will take this to mean that the patient has been fully informed of the treatment options and the treatment proposed, has been offered written information and has given consent.
- 5.3 Somerset County Council would expect that there would be exceptions to this interpretation in certain circumstances (for example if a patient was not competent or appeared uncertain or is under 16 years of age), where actual written consent would be required. It would be for the individual clinician to make the judgement as to what would be deemed necessary.
- 5.4 The General Medical Council (GMC) have also issued a document on consent.⁸ These state that the records made should include the information discussed, any specific requests by the patient, any written visual or audit information given to the patient, and details of any decisions that were made and details further guidance regarding the legal framework for capacity issues.
- 5.5 The service will be provided in compliance with Fraser guidelines and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16 years. In providing advice or treatment it is good practice to encourage the young person to talk to a parent or trusted adult.
- 5.6 All providers from whom SCC commissions services must have policies and procedures in place to meet their safeguarding duties to safeguard and promote the welfare of children and young people under section 11 of the Children's Act 2004. This includes any relevant safeguarding training being up to date. For the purpose of this policy, a child is defined as any anyone who has not attained the age of 18 years
- 5.7 When a client is under 18 years practitioners may have concerns that the young person has been the victim of sexual abuse, physical harm or has been exploited. If there is any such concern or suspicion of child abuse there is a statutory duty to safeguard and promote the welfare of children and young people (Children's Act 2004). Advice should be sought from the Designated or Named Safeguarding Professional and/or a referral made to Somerset Direct. Practitioners should consider the Somerset Child Exploitation screening tool with all under 18-year-old clients (appendix 2).
- 5.8 From 31 October 2015 a new Female Genital Mutilation (FGM) mandatory reporting duty came into effect. This duty requires regulated health and social care professionals to report visually confirmed or verbally disclosed cases of FGM in girls under 18 to the police. To make a report of FGM practitioners should call the non-emergency crime number '101' and this should be treated with the same urgency as for all other

⁸ See reference 13.8.

safeguarding cases. Advice may also be sought from the Designated or Named Safeguarding Professional.

6 Training/accreditation

- 6.1 All practitioners should have undergone accredited training for this procedure and are responsible for ensuring that their skills are updated regularly to ensure competence is maintained. The standard applied for both doctors and nurses is that of the Letter of Competence of the Faculty of Sexual and Reproductive Health (FSRH) for both IUCD/IUS and sub dermal implants in line with the Faculty of Sexual Health and Reproductive Healthcare⁹/Royal College of Nursing (RCN)¹⁰ training guidance. This qualification is accredited by the RCGP and RCN and has replaced other qualifications and should be re-certified every five years.
- 6.2 At the start of the Contract the Service Provider is required to complete a Fitters' audit form and any training needs identified will be logged by the Service Purchaser who will arrange the necessary training on LARC either through SWISH or the relevant pharmaceutical product companies.
- 6.3 Practices should model their service delivery to ensure that practitioners are able to undertake a minimum of six procedures for sub dermal procedures per annum in line with FSRH standards, of which one must be an insertion and one a removal. For LARC fitting each practitioner should undertake a minimum of twelve LARC fittings per annum (of at least two different devices). Where smaller registered populations make this difficult advice and agreement from Somerset County Council should be sought in order to continue providing this service, although inter-practice referrals should now make this unlikely.
- 6.4 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.
- 6.5 Practitioners should be competent in Basic Life Support (including anaphylaxis management) and have a responsibility for ensuring that their skills are regularly updated.
- 6.6 National guidance on premises standards must be adhered to¹¹.
- 6.7 Practitioners should be familiar with NICE guidance on LARC and should be working in compliance with this guidance.

7 Infection control

⁹ See reference 13.9.

¹⁰ See reference 13.10.

¹¹ See reference 13.11.

7.1 Providers must have infection control policies that are compliant with national guidelines¹², which include:

- disposal of clinical waste
- needle stick incidents
- environmental cleanliness
- standard precautions, including hand washing

8 Review and audit

8.1 The Provider shall carry out an annual review of the contraceptive devices service which will include an audit of:

- the register of patients fitted with the contraceptive device
- the number of patients fitted with a device where a discussion regarding choice of method and information has been provided to the patient is recorded¹³
- continuous usage rates
- failure rates
- primary purpose of fitting i.e. contraceptive or non-contraceptive
- reasons for removal, and
- complications/adverse incidents

9 Significant/adverse events

9.1 The Department of Health emphasises the importance of collected incidents nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety.

9.2 Serious incidents requiring reporting which occur in GP Practices are notifiable to NHS England. Practitioners should adhere to the NHS Somerset Serious Incident Requiring Investigation (SIRI) policy (April 2016) for incidents relating to the provision of the services in this specification. In relation to Public Health contracts this includes notification to the lead commissioner at Somerset County Council.

10 Pricing

10.1 See Schedule B: Financial Schedule

¹² See reference 13.12.

¹³ See reference 13.1.

11 Payment

- 11.1 See Schedule B: Financial Schedule

12 Patient and public involvement

- 12.1 The service will conform to professional and legal requirements especially clinical guidelines and standards of good practice issued by the National Institute for Clinical Excellence (NICE) and professional regulatory bodies, and legislation prohibiting discrimination. It is anticipated that for the majority of enhanced services translated information will be available via the Department of Health.
- 12.2 Practices should encourage, consider and report any patient feedback (positive and negative) on the service that they provide and use it to improve the care provided to patients, particularly if there are plans to alter the way a service is delivered or accessed.

13 References

- 13.1 NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE). (2005) *Clinical Guideline 30: Long-acting reversible contraception*. Report published October 2005. Last updated July 2010. Available at www.nice.org.uk/guidance/cg30
- 13.2 FPA *Your guide to the IUD*, 2021. [Resources - FPA](#)
- 13.3 FPA *Your guide to the IUS*, 2018. [Resources - FPA](#)
- 13.4 FACULTY OF FAMILY PLANNING AND REPRODUCTIVE HEALTH CARE (FFPRHC). 2004. FFPRHC Guidance: The Copper Intrauterine Device as long-term contraception. *The Journal of Family Planning and Reproductive Health Care*. **30** (1), pp29-41. Available at <http://jfprhc.bmj.com>
- 13.5 WORLD HEALTH ORGANISATION (WHO). (2004) *Selected Practice Recommendations for Contraceptive Use*. Report published 2004 (third edition 2016), Geneva. ISBN: 9789241565400. Available at: [Selected practice recommendations for contraceptive use \(who.int\)](#)
- 13.6 FACULTY OF SEXUAL AND REPRODUCTIVE HEALTHCARE (FSRH) *FSRH Guideline Intrauterine Contraception*, 2022. [FSRH Guideline Intrauterine Contraception - Faculty of Sexual and Reproductive Healthcare](#)
- 13.7 NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE). (2007) *Clinical Guideline 44: Heavy menstrual bleeding*. Report published January 2007 (updated August 2017). [Heavy menstrual bleeding: assessment and management | Guidance | NICE](#)

- 13.8 GENERAL MEDICAL COUNCIL (GMC). (2008) *Consent: patients and doctors making decisions together*. Report published 2008. Available at www.gmc-uk.org/guidance/
- 13.9 FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE (FSRH). (2008) *LoC SDI and LoC IUT – Changes to training requirements and recertification*. Paper issued March 2008. www.fsrh.org
- 13.10 ROYAL COLLEGE OF NURSING (RCN). (2007) *Inserting and removing subdermal contraceptive implants: Training guidance for nurses*. Published February 2007. Updated November 2012. www.rcn.org.uk
- 13.11 NHS ESTATES. (1992) *Health building note HBN 46: General medical practice premises for the provision of primary health care services*. HMSO: London. ISBN: 9780113214037
- 13.12 DEPARTMENT OF HEALTH (DH). (2008) (UPDATED DECEMBER 2022) *The Health and Social Care Act 2008: code of practice on the prevention and control of infections and guidance*. [Health and Social Care Act 2008: code of practice on the prevention and control of infections - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/264622/Health_and_Social_Care_Act_2008_code_of_practice_on_the_prevention_and_control_of_infections.pdf)

SCHEDULE B

FINANCIAL SCHEDULE

1. Providers will receive £113.71 for IUC/D fitting and removal service (to include any required follow up as necessary). For implants, Providers will receive £45 per insertion service and £55 per removal service. The fees will only be payable where the Provider is using single use instruments. Providers using Sterile Services from an acute or Foundation trust are no longer eligible to receive payment under this enhanced service.
2. Payment will be made to the Provider on a monthly basis; the budget will be based on the previous years activity.
3. Payments will be reconciled after the end of the financial year on the basis of actual numbers of fittings / removals completed.
4. General Practices will be required to submit quarterly activity summaries to SCC detailing the number of fittings and removals for LARC and the numbers of those fitted primarily for non-contraceptive purposes.

APPENDIX 1 - QUARTERLY ACTIVITY REPORT

Home - Practice Code	Practice Name	IUCD Fittings for Contraception				Total	IUCD Fittings for Non-contraceptive purpose				Total
		Q1	Q2	Q3	Q4		Q1	Q2	Q3	Q4	
		Nexplanon - insertion and follow up				Total	Nexplanon - removal				Total
		Q1	Q2	Q3	Q4		Q1	Q2	Q3	Q4	
Inter - Practice Code (for patients referred from other GP practices)	Inter-Practice Name	IUCD Fittings for Contraception				Total	IUCD Fittings for Non-contraceptive purpose				Total
		Q1	Q2	Q3	Q4		Q1	Q2	Q3	Q4	
		Nexplanon - insertion and follow up				Total	Nexplanon - removal				Total
		Q1	Q2	Q3	Q4		Q1	Q2	Q3	Q4	

Please return to Andrew.wilson1@somerset.gov.uk or Andrew Wilson, A2, County Hall, Taunton, TA1 4DY within 2 weeks of the end of each Qtr.

APPENDIX 2

SOMERSET CHILD SEXUAL EXPLOITATION SCREENING TOOL

<https://sscb.safeguardingsomerset.org.uk/working-with-children/cse-protocols/>

Somerset Long Acting Reversible Contraception (LARC) Inter-practice referral pathway

