

## SERVICE SPECIFICATION

Service Specification No.	Lot 6
Service	Provision of Oral Emergency Contraception Services
Authority Lead	Bernie Brown, Public Health, Derby City Council
Period	1 <sup>st</sup> April 2022 – 31 <sup>st</sup> March 2027 (with optional 1+1 year extensions)
Supporting/Additional Documentation	Appendix A. Care Pathway Appendix B. Patient Record – hard copy Appendix C. Patient Group Direction (Link)

Glossary of Terms and Abbreviations	
CPPE	Centre for Pharmacy Postgraduate Education
Cu-IUD	Copper Intra-uterine Device
DCHS	Derbyshire Community Health Services – provider of the Integrated Sexual Health Service
DoC	Declaration of Competency (Assurance Framework)
IUCDs	Intra-uterine Contraceptive Device/s
ISHS	Integrated Sexual Health Service
LNG	Levonorgestrel
LPC	Local Pharmaceutical Committee
LARC	Long Acting Reversible Contraception
OEC	Oral Emergency Contraception
PGD	Patient Group Direction
PSNC	Pharmaceutical Services Negotiating Committee
STIs	Sexually Transmitted Infections
UPSI	Unprotected sexual intercourse

### 1. Purpose

#### 1.1 Aims

This Specification for the Provision of Oral Emergency Contraception (OEC) through primary care is designed to:

- (i) Enable young women aged under 25 (24 years, 364 days) to access emergency contraception
- (ii) In the first instance, ensure signposting of women aged 25 years and over to alternative providers of **FREE** OEC prior to giving the option of purchasing over the counter
- (iii) Increase the knowledge among young people of the availability of emergency contraception and contraception
- (iv) Reduce the number of unintended conceptions within Derby City
- (v) Ensure improved access to sexual health advice and OEC as Levonorgestrel (Levonelle) via appropriately trained healthcare professionals working to an agreed Patient Group Direction (PGD).
- (vi) Provide immediate advice on contraception and the higher efficacy of Ulipristal Acetate (ellaOne) and IUCD emergency contraceptive methods, and to direct the client to long term mainstream contraceptive services, particularly hard to reach groups

- (vii) Increase the knowledge of risks associated with Sexually Transmitted Infections (STIs) referring on to an appropriate service where clients may be at risk. Those aged 13-24 should be made aware of the local free condom distribution scheme (C-Card)
- (viii) Raise awareness and give assurances of the confidentiality of other locally provided services e.g. Integrated Sexual Health Service (ISHS)
- (ix) Monitor and evaluate service provision.

## 1.2 Evidence Base and General Overview

The Framework for Sexual Health Improvement in England<sup>i</sup> sets out a number of ambitions for improving sexual health, including:

- Reducing the rate of under 16's and 18's conceptions
- Greater efforts to prevent onwards transmission of HIV and STIs
- Increasing the number of people in high-risk groups being tested for HIV
- Making sure that all people have rapid and easy access to appropriate sexual health services
- Offering counselling to all women who request an abortion so they can discuss the options and choices available with a trained health professional.

Research illustrates that healthcare sources are the preferred source of access for young people<sup>ii</sup> and there is a wealth of evidence<sup>iii, iv, v, vi, vii, viii, ix</sup> that supports the aim of improving access to confidential and non-judgemental sexual health services; this shows that:

- 45% of **pregnancies** and one third of births in **England are unplanned** or associated with feelings of ambivalence
- Of all teenagers who conceive, around 50% lead to an abortion
- Abortion rates are higher amongst some ethnic minority groups which may indicate either higher rates of total unplanned pregnancies or greater proportions that culminate in abortion<sup>x</sup>.
- Women who are not reached by existing contraceptive services are ideally placed to receive opportunistic contraceptive advice, such as after taking oral emergency contraception (OEC), including the reliability of Long-Acting Reversible Contraceptive (LARC) methods, particularly to those who are not using contraception.

The Public Health Outcomes Framework incorporates a key outcome indicator to reduce the rate of under 18 conceptions, alongside increasing Chlamydia diagnosis (15-24 year olds) through screening, and a reduction in the number of people presenting with HIV at a late stage of infection. The delivery of this Service Specification is a key intervention to achieve progressing reducing teenage conceptions, and the continuing downward trend both nationally and locally is likely to be directly related to the increasing trend in LARC provision.

The Framework provides comparative data across a broad range of sexual health indicators. In general, Derby has better sexual health than the population of the country as a whole, but inequalities in sexual health outcomes persist (e.g. high teenage pregnancy rates in some areas), and rates of STIs continue to persist and increase. The provision of emergency contraception to sexually active women should be in the context of promoting good sexual health, including the prevention of sexually transmitted infections. For sexually active women under 25 years of age, any opportunistic contraceptive advice should include the routine offer and/or signposting for a Chlamydia screening test, thus supporting delivery of the Chlamydia diagnosis rate target. [Order a test online here](#)

## 1.3 Objectives

The objectives of this Service are to:

- To give patients knowledge of all the methods of emergency contraception available
- Provide an accessible and timely service for the provision of emergency oral contraception
- Provide a non-judgemental, supportive environment where women feel able to discuss their concerns and ask questions
- Ensure all women attending for OEC between 0 -120 hours of UPSI or within 5 days of expected ovulation are advised of the option for Cu-IUD and ellaOne and refer to appropriate services as necessary
- Provision of emergency oral contraception **AND** signposting to sexual health services for women at higher risk of OEC failure who would benefit from the higher efficacy of Cu-IUD or Ulipristal Acetate (UPA), and/or for their ongoing contraceptive needs
- Provide sign-posting to other sexual health services where there is a risk of STI following UPSI
- Carry out a risk assessment for possible sexual abuse or non-consensual sex and manage appropriately
- Under 25s should be encouraged, where appropriate, to be screened for chlamydia and made aware of the C-card scheme
- Provide holistic care and support individuals in addressing risk factors through signposting to appropriate service. Around 40% of the UK's disability adjusted life years lost are attributable to tobacco, hypertension, alcohol, being overweight or being physically inactive. Making changes such as stopping smoking, improving diet, increasing physical activity, losing weight, and reducing alcohol consumption can help people to reduce their risk of poor health significantly

#### **1.4 Expected Outcomes**

It is expected that the Service for oral emergency contraception will contribute to:

- A reduction in the number of unplanned pregnancies and subsequent unplanned pregnancies
- A reduction in the under 18 conception rate.
- A reduction in the number of terminations
- An increase in LARC uptake, particularly in the under 25s
- A reduction in STIs and increase in the numbers of people under 25 being screened for Chlamydia

#### **1.5 Key Beneficiaries**

Young women under the age of 25 years.

## **2. Scope**

### **2.1 Service Description**

The Service Provider will supply Levonorgestrel Oral Emergency Contraception (OEC) when appropriate, to young women under the age of 25 years; in line with the requirements of the locally produced Patient Group Direction (PGD) (see appendix C), and provide support and advice to young

women accessing the service, including advice on the avoidance of pregnancy and STIs, through safer sex and condom use, regular contraceptive methods, and provide onward signposting to Your Sexual Health Matters (Derbyshire Integrated Sexual Health Service (ISHS) website).

Women over the age of 25 years will be appropriately signposted to alternative providers of free OEC and advised that they may purchase OEC at pharmacies over the counter at their own cost. Emergency contraception methods are not limited to OEC and include the use of Intra-uterine devices (IUDs). Though this Service only allows supply of OEC, it raises awareness of other methods of emergency contraception that are available and facilitates access to these.

The healthcare practitioner(s) delivering this Service will be required to maintain a minimum of three OEC consultations per month in order to achieve the required quality standard.

The Commissioner reserves the right to include the provision of ellaOne, within the scope of the Service delivery throughout the duration of the Contract, in order to align with population, need.

### **2.1.1 Generic Competencies**

Delivery within Pharmacy premises must make sure the General Pharmaceutical Council's (GPhC) 'standards for pharmacies' are met, including appropriate levels of professional indemnity insurance. They must ensure they meet the GPhC's 'Standards of conduct, ethics and performance'. Levonorgestrel may only be supplied by healthcare practitioners who have received the training as specified in section 3.5 (as outlined in the PGD, see appendix C) and have agreed to act in accordance with the local current PGD and the stated requirements of the Service. Healthcare practitioners must ensure that appropriate organisational records are maintained, stored securely, and archived, in line with the Department of Health's code of practice on records management.

These records should include:

- A list of named, registered health professionals authorised to practise under the PGD used within the Service
- Training records of completion and for audit purposes NB: These should be made available to the Commissioner at their request.

Superintendents must ensure all Pharmacists, including locum cover, are competent to deliver this Service at the outset, before commencement of Service delivery, and throughout the life of the Contract.

This includes the requirement to:

- Maintain clinical knowledge, appropriate to their practice, and make themselves aware of appropriate current literature and guidance
- Train their staff (where appropriate) on responding to requests for OEC when the healthcare practitioner is present and, on the procedure, to be followed to assist young women to access an alternative service is unavailable, this latter should be offered in the most sensitive and helpful way possible
- Participate in surveys/audit of activity relating to the Service
- Respond to complaints appropriately, keeping a record for monitoring purposes

### **2.2 Accessibility/acceptability**

This Service increases access to emergency contraception as a specialised service. The healthcare practitioner must ensure that the Service offered is accessible to all, sensitive and respecting relevant protected characteristics specified in the Equality Act 2010 (age, disability,

marriage and civil partnership, race, religion or belief, sexual orientation). If for any reason the service is unavailable, the Pharmacist will refer the patient to another service provider, where the patient is able to access Free OEC e.g. nearest Pharmacy, GP practice etc. Information on suppliers (local providers) of sexual health services can be found at [Your Sexual Health Matters.org.uk](http://YourSexualHealthMatters.org.uk), the NHS Choices website or by ringing 0800 3283383.

Appropriate arrangements should be made for non-English speaking Service Users and to provide the same high level of Service to those requiring interpreter services.

### **2.3 Whole System Relationships**

The Pharmacist should be aware of the importance of effective partnership working with other providers to facilitate access from and to this local specialised service. These include:

- Other pharmacies
- Derbyshire Community Health Service (DCHS) (Primary Contractor of 'Your sexual health matters / YSHM') <http://www.yoursexualhealthmatters.org.uk/> - [SH24: Online digital services](#) (STI testing and contraception services) the Integrated Sexual Health Service, Sexual Health Promotion Service and Young People's Sexual Health Services)
- School Health
- Antenatal Services
- Midwifery Services
- Abortion Services
- Sexual Assault Referral Centre (SARC)
- Child and Adolescent Mental Health Service and Adult psychiatric services
- Interpreter services
- Integrated Sexual Health Service (CASH & GUM)
- Genito-urinary Medicine (GUM)
- Social Care
- Contraception and Sexual Health Services (CASH)
- Young People's Sexual Health Services
- Youth Services
- Family Nurse Partnership
- Health Visitors
- Voluntary Services

This list is not exhaustive

The provision of this Service is underpinned by local safeguarding and vulnerable adult protection procedures.

The healthcare practitioner should support the objectives of the local sexual health network (co-ordinated by DCHS), the National Chlamydia Screening Programme, local Teenage Pregnancy Partnerships, Family Nurse Partnership and Children's Centres.

### **2.4 Interdependencies**

Key interdependencies exist with:

- Clinical appraisal processes and training providers to support development of knowledge and skills
- Declaration of Competency Assurance Framework

#### 2.4.1 Treatment Providers

The Service will be delivered from Pharmacy premises which are situated within the Derby City Council geographical boundary.

#### 2.5 Relevant networks and screening programmes

- National Chlamydia Screening Programme.
- DCHS – Sexual Health Network

##### 2.5.1 Service User and carer involvement

Consultation with Users of the Service regarding satisfaction should be carried out on a regular basis. A strategy for Service User involvement in monitoring and developing services will be implemented locally. Feedback from Service Users and carers will be gathered in a way that engages a wide range and diversity of Service Users and their representatives.

#### 2.6 Sub-contractors

No sub-contractors will provide any element of this Service unless agreed in writing by the Commissioner prior to the sub-contractor starting work.

The Provider will notify the Commissioner of any sub-contractor currently delivering any part of this Service on its behalf detailing the percentage of Service being delivered and its cost.

### 3. Service Delivery

#### 3.1 Service model/Care Pathways

The Service will be delivered in line with the local current PGD. This Service Specification covers the following:

This Service is designed for under 25s – as such it may be necessary to determine the age of young women requesting OEC

- If in doubt, it would be reasonable to ask for evidence of age such as a B-line Card or provisional/full driving licence; this should be done as sensitively as possible.
- Where such evidence is not available this should **NOT** preclude the young woman from receiving the service

In addition, it covers:

- Providing an area for the consultation which must ideally provide a sufficient level of privacy and safety.
- A Service that assesses the need and suitability for women to receive OEC, in line with the PGD (see appendix C). Where appropriate a supply will be made; where a supply of OEC is not appropriate, advice and referral to another source of assistance, if appropriate, will be provided.

- Ensuring that all young women accessing the service will be informed about the possibility of and higher efficacy of Cu-IUD and that they are clear about the timescales for fitting and where to access it.
- Young women who are assessed as being at higher risk of failure of OEC in line with the PGD must be informed of the higher efficacy of UPA and advised on how and where to access this.
- Provision of a Service that is following Fraser guidance<sup>1</sup> and Department of Health guidance on confidential sexual health advice and treatment for young females aged under 16<sup>2</sup>.
- Service protocols that will reflect national and local child and vulnerable adult protection guidelines<sup>3</sup>.
- The duty to ensure that all healthcare practitioners and all staff involved in the provision of the Service have relevant knowledge and are appropriately trained in the operation of the Service, including sensitive, client centred communication skills.
- The duty to ensure that all healthcare practitioners and staff involved in the provision of the Service are aware of and operate within the set protocols.
- Appropriate maintenance of records to ensure effective on-going Service delivery and audit. Records will be confidential and should be stored securely and for a length of time in line with local NHS record retention policies.
- The need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the young woman to share the information.

### 3.2 Patient Information

Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including promotion of long acting reversible contraceptive (LARC) as the most effective method, and should include advice on the use of condoms which must be given to all young women accessing this service. This should be supplemented by a referral to the Integrated Sexual Health Service that can provide treatment and further advice and care.

- Details of other sexual health services (includes location and hours of opening) which the service provider and their staff (where appropriate) can use to refer young women who require further assistance can be found at: [Clinic finder](#)
- The ongoing distribution of leaflets can be accessed online from the Family Planning Association website: <http://www.fpa.org.uk/sites/default/files/emergency-contraception-yourguide.pdf>

<sup>1</sup> Fraser Guidelines – based on a House of Lords Ruling; A health professional can give advice or treatment to a person under 16 without parental consent providing they are satisfied that.

- The young person will understand the advice;  
The young person cannot be persuaded to tell his or her parents or allow the doctor to tell them that they are seeking contraceptive advice;
- The young person is likely to begin or continue having unprotected sex with or without contraceptive treatment; and...
- The young person's physical or mental health is likely to suffer unless he or she receives contraceptive advice or treatment.

<sup>3</sup>Guidance available at [www.dh.gov.uk/sexualhealth](http://www.dh.gov.uk/sexualhealth).

<sup>4</sup> The cross government guidance on child protection, Working Together to Safeguard Children, should be referred to and is available at [www.everychildmatters.gov.uk/workingtogether](http://www.everychildmatters.gov.uk/workingtogether)

- Completion of the patient record will be made via the PharmOutcomes software platform. Data will be kept securely in line with Data Protection requirements. The data from the platform will be supplied to the Commissioner for the purposes of monitoring, audit and payment claims and will be provided to the Commissioner in a non-patient identifiable format.
- The C-Card scheme is a community-based condom distribution scheme, which provides confidential access to **free** condoms, lube, and dams, as well as sexual health advice and support to young people aged 13-24. If the pharmacy has signed up to the C-Card scheme, then all clients aged 13 - 24 should be offered this service. However, if this is not available, refer to Your Sexual Health Matters sexual health promotion services (details at [www.yoursexualhealthmatters.org.uk](http://www.yoursexualhealthmatters.org.uk) ), or call 0800 328 3383. We encourage Pharmacies to support the C-Card initiative by providing this Service however DCHS is unable to reimburse for this.

### 3.3 Eligibility to Supply Levonelle under the Patient Group Direction.

- Levonelle may only be supplied by a registered healthcare practitioner who has received the training as specified in the local PGD and has agreed to act in accordance with the PGD for Levonelle and the stated requirements of the Service.
- In addition, the supply may only be made where an appropriate current signed PGD agreement is in place
- The Pharmacist undertaking this role must have the full support of the superintendent pharmacist where appropriate.
- The Pharmacist will be required to hold a copy of a valid Disclosure and Barring Check (DBS) formerly known as a CRB check.

### 3.4 Training

- The quality of Service provision depends on good compliance with the standards of service provision in the local PGD in providing LNG, assessing whether the woman is at increased risk of treatment failure, providing advice and checking a woman's understanding of the advice and where appropriate signposting to alternative treatment options (UPA/ IUD)
- Training and continuing professional development, in addition to audit of compliance with PGD standards are essential components of assuring the quality of OEC provision.
- All Pharmacists providing the Service will have attended appropriate training as deemed necessary by the Commissioners as outlined below:

#### 3.4.1 Initial **training – for pharmacist accreditation**, the Pharmacist is required to:

- a) Complete the Centre for Pharmacy Postgraduate Education (CPPE) Oral Emergency Contraception Open learning pack **and** Safeguarding Children open learning pack
- b) Provide proof of completion of the above modules to the Commissioner if requested
- c) Attend a 2 hour 'Basic Oral Emergency Contraception' workshop to support delivery of the local PGD

**For recognised training providers and details of local training dates please visit the Derbyshire LPC website**



In addition, the Pharmacist should also consider completing the following optional CPPE modules to support their delivery of this Service:

- Sexual health in pharmacies open learning
- Contraception open learning pack
- Sexual health: Safeguarding and Chlamydia
- Sexual Health: testing and treating workshop

**3.5 Continuing Professional Development.** To be confirmed as eligible to continue to provide the Service under the terms of this agreement, Service Providers must ensure that they undergo regular update training (e.g. CPPE courses, update sessions from the Integrated Sexual Health Service (ISH)).

To remain eligible to provide the OEC Service under the terms of this agreement, healthcare practitioners must complete a face to face Emergency Contraception CPPE update session at least once every 5 years – current certification to be supplied upon request to DCHS for verification. This timeframe may alter, depending on local LPC requirements.

### 3.6 Declaration of Competency (DoC) – Assurance Framework

- Pharmacists who deliver under this Specification will have completed all of the criteria listed for the declaration of competency (DoC) system for emergency contraception via Centre for Pharmacy Postgraduate Education (CPPE). The PSNC website ([psnc.org.uk](http://psnc.org.uk)) contains information on how to complete this process.
- Pharmacists will be responsible for reassessing their competence to deliver this Service via this framework at least once every three years and should be able to show evidence to support this.
- Pharmacists delivering under this Service will be required to enable Derby City Council access to inspect these records – to do these Pharmacists will need to check (tick) both the CPPE viewer and PharmOutcomes boxes as shown below: -

#### CPPE viewer

With our CPPE viewer facility you can allow other people to view the list of learning programmes and assessments you have accessed. This can show commissioners the learning you have completed for pharmacy services and employers can see the learning you have completed for your CPD.

☐ Tick this box to enable your CPPE viewer.

Save changes

#### PharmOutcomes

If you are completing the Declaration of Competence system in order to deliver a commissioned service which is supported by [PharmOutcomes](#) you will need to share data relating to your CPPE learning and assessment record.

☐ Tick this box to allow your data to be shared with PharmOutcomes.

Save changes

### 3.7 Applicable national standards

The Service Provider must be compliant with Standards for Better Health Core Standards (DH 2005) and 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 Service Provider 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/re-designing services at the request of the Commissioner, to include improving quality and performance monitoring.

Service Providers must ensure that they adhere to all relevant legislation and best practice / guidance including but not exclusively:

- “Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health”
- Mental Capacity Act 2005
- All current equality legislation and new equality legislation as it becomes statute and actively meets the requirements of the Equality Duties (Race, Disability and Gender) available at: <https://www.equalityhumanrights.com/en/advice-and-guidance/public-sector-equality-duty>
- Data protection act 1998, including General Data Protection Regulations (UKGDPR)
- FSRH Guideline Emergency Contraception
- NICE: Emergency contraception
- Contraceptive services for under 25s. NICE guideline PH51-  
<https://www.nice.org.uk/guidance/ph51/chapter/1-recommendations>

### **3.6 Applicable local standards**

3.6.1 Service Providers must ensure that they adhere to applicable local standards including but not exclusively:

- The Derby and Derbyshire Safeguarding Children Procedures  
<https://www.derby.gov.uk/health-and-social-care/safeguarding-children/>  
[https://derbyshirescbs.proceduresonline.com/register\\_updates.html](https://derbyshirescbs.proceduresonline.com/register_updates.html)
- Derby and Derbyshire Adults Protection Policy and Procedures  
<http://www.derby.gov.uk/health-and-social-care/safeguarding-adults-at-risk/safeguarding-vulnerable-adults>  
<https://www.derbysab.org.uk/>

<https://www.ddscp.org.uk/>

<https://www.derbysab.org.uk/media/derby-sab/content-assets/documents/Joint-Derby-and-Derbyshire-SAB-Policy--Procedures-December-2019.pdf>

- This should include understanding safeguarding referral procedures and referral pathways to social care.
- Service Providers must notify the Public Health team at Derby City Council of any breaches of Applicable National Standards.

### **3.6.2 Clinical and corporate governance**

It is a condition of delivery of this Specification that the Service Provider will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her, to the local authority clinical governance lead 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 link below:

<https://www.england.nhs.uk/patient-safety/serious-incident-framework/>

### **3.6.3 Service Quality**

#### **Clinical and Cost Effectiveness**

Service Providers will

- Pharmacies will satisfactorily comply with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance
- Demonstrate the principle of 'best value' through continuous improvement considering a combination of effectiveness (successful outcomes), efficiency (high productivity) and economy (costs).
- Ensure there are designated clinical leadership and accountability, and clear clinical protocols for effective clinical governance.

#### **Clinical audit**

Service Providers will

- Ensure the implementation of a clinical audit process to review performance and provide a framework to enable improvements to be made.
- Allow Derby City Public Health or their nominated representatives' access to their premises in order to facilitate a clinical audit or inspection of the Service being provided.

#### **Governance**

Service Provider governance arrangements will include the following –

- **Education and training**
  - Ensure staff providing the Service are suitably qualified and competent and that there are in place appropriate arrangements for maintaining and updating relevant skills and knowledge

- **Information management**

- Ensure the Service adheres to national and local rules on confidentiality and data protection.
- Ensure that Information sharing protocols are consistent with guidance from the local Caldicott guardian
- Ensure everyone in the Service understands the importance of information rights, and their own responsibility for delivering them
- Regularly review and assess your services data security arrangements

- **Staff management**

- Ensure staff and management working within the Service work as an efficient team within a well-supported environment.

## **Care Environment and Amenities**

Service Providers will

- Ensure that all premises and equipment used for the provision of the Service are at all times suitable for the delivery of those Services and sufficient to meet the reasonable needs of Patients or Clients.

## **Risk Management**

Service Providers will

- Ensure there are robust processes, working practices and systematic activities that prevent or reduce the risk of harm to patients
- Ensure there are robust processes in place to support the reporting and review of all untoward incidents at the earliest opportunity. This will include the documentation, investigation and follow up with appropriate action of all untoward incidents (see 3.6.2)
- Ensure this learning is disseminated across the practice and shared with the Commissioners
- Ensure that an effective complaints procedure for patients is in place, in line with the current NHS Complaints Procedure guidance, to deal with any complaints in relation to the provision of the Service, which is available for audit
- Ensure that a process is in place for any member of the professional team to raise concerns in a confidential and structured way
- Ensure all staff and volunteers in contact with vulnerable adults and children have the appropriate Disclosure and Barring Service (DBS) clearance
- Ensure the Service has a nominated lead for safeguarding issues and adheres to the Derby and Derbyshire Safeguarding policies and procedures

## **Patient and Carer experience and involvement**

Service Providers will

- Ensure that Patients have the opportunity to make informed decisions about their treatment and care in partnership with healthcare professionals. If Patients do not have the capacity to make decisions staff should follow the DOH advice on consent and the code of practice that accompanies the Mental Capacity Act.
- Provide opportunities for Patients to give feedback to staff/service on their health care or treatment

- Ensure that treatment, care and information provided is evidence based culturally appropriate and is available in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.
- Age, religion, and culture may affect which contraceptive methods the woman considers suitable. When discussing contraception, healthcare practitioners should give information and allow the woman to choose the one that suits her best

Derby City Council reserves the right to utilise 'mystery shoppers' as part of their quality assurance framework.

## 4. Referral, Access, and Acceptance Criteria

### 4.1 Geographic coverage/boundaries

This Service will be provided from premises within the boundary of Derby City Council.

### 4.2 Location(s) of Service Delivery

The location of Services delivered from premises including branch premises (where relevant) where these are located within the Derby City boundary. All locations should seek to be as accessible as reasonably possible and be compliant with Health & Safety legislation.

### 4.3 Days/Hours of operation

The Service will be offered within the normal hours of operation of the Service

### 4.4 Referral Criteria & Route

The Service will be available to young women under the age of 25 years who request emergency contraception, provided that it is not contraindicated.

### 4.5 Inclusion/exclusion criteria

Inclusion and exclusion criteria are outlined in the PGD and will be applied during provision of the service.

**Inclusion:** Available to all women under 25. If a young person is Fraser competent and requires emergency contraception – treatment should be issued and **NOT** delayed (even if under 13 and concerned).

**Exclusion:** The Service will not be available to women who are aged 25 years and over. These women must be signposted to another provider prior to advising that they may purchase OEC from the pharmacy over the counter and at their own cost.

### 4.6 Response time & detail and prioritisation

Organisational delays should not influence or alter a woman's choice to this Service.

### 4.7 Equity issues (EIRA)

It is the responsibility of the Service Provider to comply with all current equality legislation and ensure it implements any new equality legislation as it becomes statute and actively meet the requirements of the Equality Duties (Race, Disability and Gender) these include –

- Eliminating discrimination
- Promoting equality of access to Services and of employment opportunity
- Ensuring effective data capturing and analysis of service provision
- Conducting Equality Impact Risk Assessments (EIRAs) on policies, procedures, and services
- It is recommended that Services have a clear published plan of action to achieve the equality principles in the equality duties

Equality Impact Risk Assessment (EIRA) must be undertaken and documented as part of any service review process or if any change is made to the provision of the Service which could impact on those in receipt of the Service.

All staff involved with the delivery of this Service will recognise and respect the religious, cultural, and social backgrounds of Service Users in accordance with legislation and local and national good practice.

## 5. Quality Standards

<i><b>Indicator</b></i>	<i><b>Threshold</b></i>	<i><b>Method of measurement</b></i>	<i><b>Consequence of breach</b></i>
Correctly identify the level of OEC failure risk	90%	Self-report/audit	
Give the correct latest date (to within one day) for insertion of emergency IUD	90%	Self-report/audit	
Patient Information Leaflet should be given and explained to all women requesting OEC (relevant to pharmacy provider only)	100%	Report via PharmOutcomes	
Accredited pharmacists should access the CPPE e-assessment for OEC on a 3 yearly basis	100%	Self-report/audit	
The pharmacy has available and on display, commissioner-provided service promotional material and is able to discuss the contents with the young woman	100%	Self-report/audit	
All women asking for emergency contraception are told that an intrauterine device is more effective than an oral method.	100%	Self-report/audit	
All women attending for OEC should have a discussion regarding future contraception	100%	Report via PharmOutcomes	
There must be facilities for private and confidential counselling of the young	≥95%	Self-report/audit	

women. It must meet the following three criteria: -			
<ul style="list-style-type: none"> <li>• Is a designated area where both patient and professional can sit down?</li> <li>• Talking can be carried out at normal volume, without being overheard by visitors or staff carrying out their normal activity</li> <li>• Be a designated area for confidential consultations, distinct from general public</li> </ul>			
Ensure all women attending for OEC between 0 -120 hours of UPSI or within 5 days of expected ovulation are advised of the option for Cu-IUD, which has lower documented failure rates	100%	Self-report/audit	
The pharmacy annually reviews its standard operating procedures and the referral pathways for the service.	100%	Self-report	
The pharmacist participates in a commissioner-led audit of service provision	100%		Nonparticipation will be considered as non-compliance with the Service Specification and contract may be terminated
The pharmacy operates with any agreed commissioner-led assessment of service user experience.	100%	As and when requested	
The pharmacist and their staff (where relevant) attend refresher meeting	100%	Compliance with local PGD	
The pharmacist and their staff (where relevant) will receive and agree to read any commissioner-provided refresher packs including up-dated PGD, new legislation and guidance.	100%	As and when required	
Participate in DoC Framework and ensure commissioner access to view records	100%	Via PharmOutcomes	
<b>6. Activity Indicators</b>			
Minimum number of 3 OEC consultations per month to be eligible for continued sign up to PGD		Measured by service – self report.	3 consecutive months of failure may result in termination of Service

## Activity Plan

See section 6 activity indicators

## 7. Continual Service Improvement Plan

No improvement plans are envisaged in the first 12 months other than ensuring engagement, participation, and utilisation of the scheme, however the Commissioners reserve the right to implement any improvements plans when and if required.

## 8. Prices & Costs

All payments will be made on a cost per case basis. All claims for activity undertaken should be made online via the PharmOutcomes web portal. The activity claim will report non-patient identifiable data and enable the automatic processing of payments directly to Service Providers on a monthly basis. The portal can be found at: <https://pharmoutcomes.org/pharmoutcomes/>

Basis of Contract	Unit of Measurement	Price	Thresholds	Expected Annual Contract Value
Cost per case	Consultation	£11.00	n/a	£ n/a
Cost per case	Drug	£ National NHS drug tariff rate	n/a	n/a
Cost per case	Pregnancy Test (product & supply inclusive)	£7.00	n/a	n/a



<sup>1</sup>Department of Health (2012) Improving outcomes and supporting transparency. Part 1: A public health outcomes framework for England, 2013-2016

<sup>1</sup> Long-acting reversible contraception - the effective and appropriate use of long-acting reversible contraception (2005) Clinical Guideline 30 <http://www.nice.org.uk/nicemedia/pdf/CG030fullguideline.pdf>

<sup>1</sup> NICE implementation update report (2009): Long-acting reversible contraception (LARC)  
<http://www.nice.org.uk/media/386/C2/ImpUptakeReportCG30.pdf>

<sup>1</sup>Croxatto HB, Mararainen L. The pharmacodynamics and efficacy of Implanon: An overview of data. *Contraception* 1998; 58: 91s - 97s *BMJ* 1995; 311:470 (19 August)

<sup>1</sup>Harrison PF, Rosenfield A. research, introduction and use: Advancing from Norplant *Contraception* 1998; 58:323-34

<sup>1</sup>Chikamata DM, Miller S. The health services at the clinic level and implantable contraception for women. *Contraception* 2002; 65: 97-106

<sup>1</sup>Counselling key in Norplant satisfaction. *Contraceptive technology Update* 1999 Aug; 20(8): 90-1

<sup>1</sup>Churchill D et al. 2000. Consultation patterns and provision of contraception in general practice before teenage pregnancy: case-control study. *British Medical Journal* 321(7259): 486-489.

<sup>1</sup>Emergency contraception methods are not limited to OEC and include the use of Intra-uterine devices (IUDs). Though this service only allows supply of OEC, it raises awareness of other methods of emergency contraception that are available and facilitates access to these.

### Provision of Service

Provision of this service to be delivered only by practitioners who have completed the relevant training /CPD/competency requirements and who have agreed to act in accordance with the requirements of the service as stated in the relevant service Specification and contract.

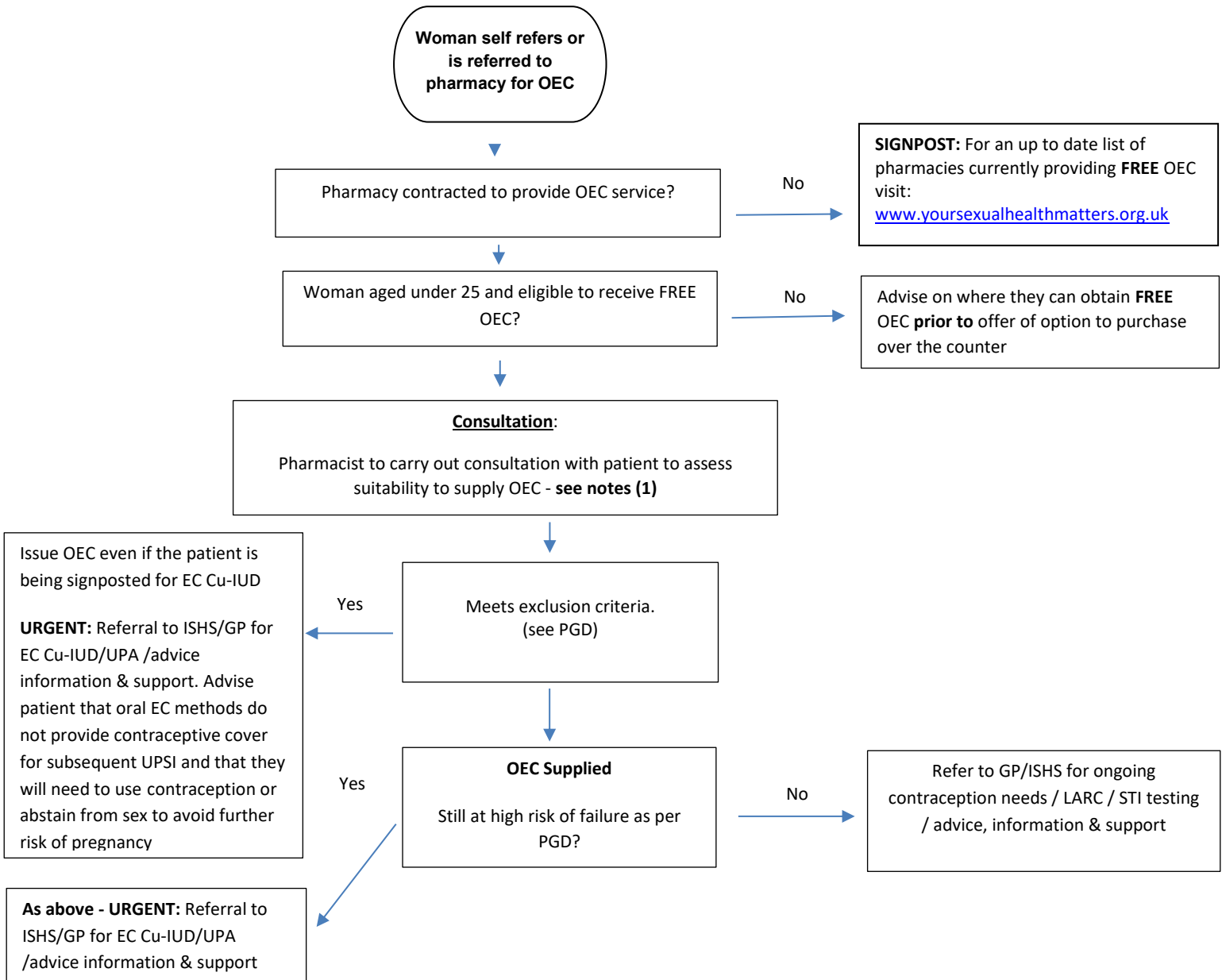
This service can only be provided by the pharmacies who have been contracted by the council to deliver this service

### Notes (1)

#### Assess need and suitability for OEC in line with PGD including:

- Assess current contraception, menstrual history
  - medical history, possibility of pregnancy
  - Under 13 - Fraser competent?
  - Method of administration
  - Side effects
  - Failure rate - including option of EC- Cu IUD. Aged ≤35 higher risk of failure of EC (ie UPSI between ovulation minus 6 days and ovulation plus 2 days **or** mid cycle and/or over 48 hours since UPSI - information must be given of higher efficacy of UPA and where to obtain it
  - Drug interactions
  - Contraception for present cycle and future use
  - Signpost to Integrated Sexual Health Service for STI testing, contraception, and support
- If <25 signpost** to C-Card via [www.yoursexualhealthmatters.org.uk](http://www.yoursexualhealthmatters.org.uk) for access to FREE condoms / chlamydia testing

Your Sexual Health Matters" (Integrated Sexual Health Service) clinic locations: Visit [www.yoursexualhealthmatters.org.uk](http://www.yoursexualhealthmatters.org.uk) or call the central booking line on 0800 328 3383



## APPENDIX B – Hard copy patient record

### Oral Emergency Contraception (OEC) Provided by Community Pharmacists

Patient Record - All sides to be completed	
<p>Place of Consultation (or Pharmacy stamp) .....</p> <p>Date: ..... Time: .....</p>	
<b>PATIENT DETAILS</b>	
<p>Name: ..... Age: ..... Postcode: .....</p> <p><i>If Patient under the age of 16 refer to Fraser Guidelines and consider 'Spotting the Signs' CRE Risk Assessment</i></p>	
<b>GP DETAILS (If given)</b>	
<p>Name: ..... Surgery: .....</p>	
<b>CURRENT CONTRACEPTION (Circle as appropriate)</b>	
<p>COC / CHC Patch / POP / Condoms / IUD / IUS / Implant / Injection / None / .....</p> <p>If recently missed Pill(s) (Details): .....</p> <p>If condom failure (Details): .....</p> <p>If recently stopped Pills – Date last Pill taken: .....</p> <p>If Implant fitted over 3 years ago – Date fitted: .....</p> <p>Is Injection overdue? <input type="checkbox"/> Yes <input type="checkbox"/> No Date of last injection: ..... weeks since last injection: ...</p> <p>Other (Specify):</p> <p>Type (Circle): Depo Provera / Sayana Press / Noristerat</p>	
<b>OTHER MEDICATIONS AND ALLERGIES</b>	
<p>.....</p> <p>.....</p> <p>.....</p> <p>..... Liver Enzyme Inducing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Allergies: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, details:</p>	

**Other Medication?**

**DETAILS OF UNPROTECTED SEXUAL INTERCOURSE (UPSI)**

Date and Time of UPSI: ..... LMP: .....

Hours since UPSI: ..... hours

Other UPSI since last menstrual period (LMP) ☐ Yes ☐ No

.....  
.....  
*If yes, give details:*

**MENSTRUAL HISTORY**

**COMPLETE EITHER (a) OR (b) AS APPROPRIATE**

**(a) For Patients not taking Oral or Patch Combined Hormonal Contraception (COC/CHC)**

Date of last menstrual period (LMP) – (First day of bleeding): .....

Current day of cycle: ..... Usual cycle length: \_\_\_\_ days

**(b) For Patients taking COC or CHC**

Date of last withdrawal bleed (WTB): ..... (first day)

Current day is: ☐ Pill/patch day or ☐ Pill/patch-free day

**COMPLETE FOR ALL PATIENTS**

LMP / WTB UNUSUAL? ☐ Yes ☐ No

PERIOD / WTB OVERDUE? ☐ Yes ☐ No

If LMP or WTB unusual or overdue - was Pregnancy Test (PT) ☐ Negative

☐ Positive ☐ Given to Patient to carry out at Home?

**PERSONAL CHARACTERISTICS, REPRODUCTIVE & MEDICAL HISTORY - LEVONORGESTREL**

1. Consent not given

☐ Yes ☐ No

2. Individuals under 16 years and assessed not competent using Fraser Guidelines	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Individuals 16 years and over and assessed as lacking capacity to consent	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. This episode of UPSI occurred more than <u>96</u> hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within <u>96</u> hours	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI)	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Less 21 days after childbirth	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Known hypersensitivity to active ingredients or to any component of the product	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Use of ulipristal acetate emergency contraception in the previous 5 days	<input type="checkbox"/> Yes <input type="checkbox"/> No

**PERSONAL CHARACTERISTICS, REPRODUCTIVE & MEDICAL HISTORY – ULIPRISTAL ACETATE**

1. Consent not given	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Individuals under 16 years and assessed not competent using Fraser Guidelines	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Individuals 16 years and over and assessed as lacking capacity to consent	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. This episode of UPSI occurred more than <u>120</u> hours ago <b>Note:</b> UPA-EC may be used again if a woman has already received UPA-EC earlier in the cycle. The GDG recommends LNG-EC should not be taken in the 5 days after UPA-EC. It is recommended that if a woman requests EC for further UPSI within 5 days of taking UPA-EC, a Cu-IUD is offered if appropriate. Alternatively, UPA-EC can be given again.	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI)	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Less 21 days after childbirth	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Breastfeeding and less than 6 weeks post-partum	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Not breastfeeding and 3-6 weeks post-partum with other risks for venous thromboembolism (VTE)	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Known hypersensitivity to the active ingredient or to any component of the product	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications).	<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Severe asthma controlled by oral glucocorticoids	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping	<input type="checkbox"/> Yes <input type="checkbox"/> No

**OEC excluded if YES to any of the above**

1. Unexplained vaginal bleeding ☐ Yes ☐ No

If YES, **OEC not excluded** - supply and advise Patient to consult GP/Sexual Health Service

2. Taking an enzyme inducer medication consider double-dose (3mg) Levonorgestrel  
3. BMI > 26kg/m<sup>2</sup> or Weight > 70kg consider double-dose (3mg) Levonorgestrel

Patient Weight: ..... kg Patient Height ..... cm Patient BMI: .....

UNDER 16 ☐ Yes ☐ No UNDER 13 ☐ Yes ☐ No  
GILLICK COMPETENT ☐ Yes ☐ No CHILD PROTECTION CONCERNS ☐ Yes ☐ No

**Contact Details if under 13 or Child Protection concerns**

Refer to social care as per safeguarding procedures - **if aged under 13 must be referred**  
(if any reservations discuss with Child Protection Unit or Community Paediatrician on call)

(Address, School and Mobile Number if possible) \_\_\_\_\_

**Referral to East Midlands Children's and Young People's Sexual Assault Service (EMCYPSAS)?** ☐ Yes ☐ No

OEC Patient Information Leaflet supplied <input type="checkbox"/> Yes <input type="checkbox"/> No	Patient Consent Obtained <input type="checkbox"/> Yes <input type="checkbox"/> No	Emergency IUD Explained <input type="checkbox"/> Yes <input type="checkbox"/> No
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Patient at Higher Risk of Failure of OEC (*ie between ovulation minus 6 and ovulation plus 2*) ☐ Yes ☐ No

OEC supply ☐ Yes ☐ No

**Licensed / Unlicensed / Not Supplied** (*circle which*)

(Refer to flow chart if necessary)

Information given about Ulipristal (EllaOne) / Levonorgestrel ☐ Yes ☐ No

☐ Last Date for IUD insertion - on or before \_\_\_\_\_, OR

☐ TOO LATE for Emergency IUD

Other concerns or any additional advice given: \_\_\_\_\_  
\_\_\_\_\_

## **RECORD OF ISSUE**

**Drug Name:** \_\_\_\_\_

**Time Taken:** OR ..... ☐ **Taken Away**

**Batch No:** ..... **Expiry Date:** \_\_\_\_\_

**Follow Up** (*if arranged*): \_\_\_\_\_

**Pharmacist** (*Please PRINT name*): \_\_\_\_\_

**Pharmacist Signature:** \_\_\_\_\_

## APPENDIX C: Patient Group Direction (PGD)

The link below is the most up to date version of the PGD at the time of writing:

[PGD Levonorgestrel 1500mcg Tablets Community Pharmacies.pdf](https://www.derbyshiremedicinesmanagement.nhs.uk/PGD_Levonorgestrel_1500mcg_Tablets_Community_Pharmacies.pdf)  
([derbyshiremedicinesmanagement.nhs.uk](https://www.derbyshiremedicinesmanagement.nhs.uk))

Future updates will be published on the Derbyshire Medicines Management Website, as and when required.

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<sup>i</sup> Department of Health and Social Care (2013) A framework for Sexual Health Improvement in England. Available at: <https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england> (accessed 23 March 2021)

<sup>ii</sup> Geary RS, Tones C, Jones KG, *et al*

Actual and preferred contraceptive sources among young people: findings from the British National Survey of Sexual Attitudes and Lifestyles

*BMJ Open* 2016;**6**:e011966. doi: 10.1136/bmjopen-2016-011966

<sup>iii</sup> Department of Health (2011) Healthy lives, healthy people, available at

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_121941](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121941) (accessed 17.12.2012)

<sup>iii</sup> Long-acting reversible contraception - the effective and appropriate use of long-acting reversible contraception (2005) Clinical Guideline 30 <http://www.nice.org.uk/nicemedia/pdf/CG030fullguideline.pdf>

<sup>iii</sup> NICE implementation update report (2009): Long-acting reversible contraception (LARC)

<http://www.nice.org.uk/media/386/C2/ImpUptakeReportCG30.pdf>

<sup>iii</sup> Harrison PF, Rosenfield A. research, introduction and use: Advancing from Norplant Contraception 1998: 58;323-34

<sup>iii</sup> Chikamata DM, Miller S. The health services at the clinic level and implantable contraception for women. *Contraception* 2002; 65: 97-106

<sup>iii</sup> Counselling key in Norplant satisfaction. *Contraceptive technology Update* 1999 Aug; 20(8): 90-1

<sup>iii</sup> Churchill D *et al.* 2000. Consultation patterns and provision of contraception in general practice before teenage pregnancy: case-control study. *British Medical Journal* 321(7259): 486-489.

<sup>iii</sup> Department of Health (2012) Improving outcomes and supporting transparency. Part 1: A public health outcomes framework for England, 2013-2016

<sup>x</sup> <https://www.gov.uk/government/publications/health-matters-reproductive-health-and-pregnancy-planning/health-matters-reproductive-health-and-pregnancy-planning#:~:text=Currently%2C%2045%25%20of%20pregnancies%20and,children%20into%20later%20in%20life.>